THIS DOCUMENT HAS BEEN PREPARED ACCORDING TO THE PROVISIONS OF ARTICLE 136(3) “TRANSITIONAL MEASURES REGARDING EXISTING SUBSTANCES” OF REACH (REGULATION (EC) 1907/2006). IT IS NOT A PROPOSAL FOR A RESTRICTION ALTHOUGH THE FORMAT IS THE SAME

TRANSITIONAL ANNEX XV DOSSIER

SUBMITTED BY: Austria
DATE: 01 December 2008

SUBSTANCE NAME: Disodium tetraborate anhydrous
IUPAC NAME: Disodium tetraborate anhydrous
EC NUMBER: 215-540-4
CAS NUMBER: 1330-43-4

Preamble

Austria volunteered as rapporteur for the substances boric acid and disodium tetraborate anhydrous on the 4th priority list, which was officially published on 26th October 2000. In 2003 a possible ”strategic partnership” between Austria and Industry (European Borates Association (EBA)) was considered as a test run for “Substance evaluation” under REACH. This approach was discussed in the Technical Committee for New and Existing Substances (TC NES III-03, September 2003) and at the CA Meeting (November 2003). Comments on this “strategic partnership” were received from TC NES and were considered in the beginning of 2004. A “declaration of intent” between Austria and EBA was signed in March 2004. The declaration specifies the duties of the partners and is attached in Annex I of the dossier.

It was decided that Industry would prepare a complete risk assessment for evaluation by the Austrian CA by the end of 2006. The first draft dossier, containing human health and environmental hazard assessments, was received on 1st June 2007 from the EBA. The draft dossier was circulated to TC NES for preliminary written procedure in June. A revised dossier was submitted by EBA to Austria in October 2007 and circulated for discussion at TC NES IV-07, December 2007. A first discussion on only the human health hazard assessment was had at TC NES IV-07. The environmental hazard assessment was submitted for written procedure. During the discussion, agreement on the critical values for the following sections was achieved: toxicokinetics, acute toxicity, skin and eye irritation, sensitization, mutagenicity, and carcinogenicity. Preliminary agreement was achieved for the endpoint for reproductive toxicity, whereas no agreement was achieved for respiratory irritation. The human health hazard assessment was not discussed a second time within the framework of TC NES and no discussions were held at TC NES meetings on the environmental hazard assessment. This was due to other risk assessment dossiers taking precedence for TC NES.

According to Article 136 (3) of (EC) 1907/2006 the rapporteur member states responsible for Risk Assessment Reports (RAR) not finalized under the Existing Substances Regulation (ESR) program are bound to submit a transitional annex XV dossier for their substances to the agency by 1st December 2008. The remaining time was used by Austria and EBA to work jointly on the transitional annex XV dossier. The following sections were carried out by Austria and reviewed by EBA: Human health hazard assessment, environmental hazard assessment with regard to the aquatic compartment and microbial activity in sewage treatment systems. The environmental hazard assessment for the terrestrial compartment as well as the first tier exposure assessments for humans and the environment were drafted by EBA and reviewed by Austria. The exposure data available at the time this dossier was compiled are insufficient for a detailed exposure assessment, and can only support a first tier approach. Additionally, the environmental hazard assessment can only be considered a first tier assessment as several data are missing. Thus, the section on risk characterization is to be regarded as preliminary and is not as elaborated as necessary for the registration dossier.

In spite of extensive discussions between Austria and Industry and engagement of internal and external experts, the results compiled in this dossier have not received comparable scrutiny as other RARs prepared under the ESR program. It should be noted that substantial amendments have been made to the dossier since November 2007 when TC NES last reviewed this dossier. Therefore, this has to be considered when using this dossier for further applications under REACH. Given the identified gaps in knowledge relating to effect data, as well as to exposure information, this risk assessment can only be seen as a first tier approach. The registrant(s) will fill these gaps for their registration dossier and areas requiring further work are summarized in annex II of this dossier. This Annex has been prepared by EBA and has been reviewed by Austria. It cannot be seen as a final list of information requirements, since during the work of Industry on the registration dossier new issues might arise.

CONTENTS

Part A Proposal

Part B

A. PROPOSAL

Section not relevant for this dossier

TABLES

FIGURES

PART B

INFORMATION ON HAZARD AND RISK

1 IDENTITY OF THE SUBSTANCE(S) AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substances

Chemical Name:	Boric acid	Disodium tetraborate anhydrous Disodium tetraborate pentahydrate Disodium tetraborate decahydrate
EC Name:	233-139-2	215-540-4[1]
CAS Number:	10043-35-3	Disodium tetraborate anhydrous: 1330-43-4 Disodium tetraborate pentahydrate: 12179-04-03 Disodium tetraborate decahydrate: 1303-96-4
IUPAC Name:	Ortho-boric acid; boric acid	Disodium tetraborate anhydrous Disodium tetraborate pentahydrate Disodium tetraborate decahydrate
Synonyms	Ortho boric acid; boracic acid; boron trihydroxide; hydrogen orthoborate	Disodium tetraborate anhydrous: Anhydrous borax; Sodium tetraborate; Boron sodium oxide ($B_4Na_2O_7$); Boric acid ($H_2B_4O_7$), disodium salt; Sodium borate, Borax, fused Disodium tetraborate pentahydrate: Borax 5-mol; Sodium borate ($Na_2B_4O_5(OH)_4$) trihydrate; Sodium tetraborate pentahydrate; Boron sodium oxide ($B_4Na_2O_7$), pentahydrate; Boric acid ($H_2B_4O_7$), Disodium salt, pentahydrate Disodium tetraborate decahydrate: Borax; Sodium tetraborate decahydrate; Borax decahydrate; Sodium biborate decahydrate; Sodium pyroborate decahydrate; Boron sodium oxide ($B_4Na_2O_7$), decahydrate; Boric acid ($H_2B_4O_7$), Disodium salt decahydrate; Tetrasodium salts, decahydrate
Trade names:	Optibor	Disodium tetraborate anhydrous: Borax glass; Dehybor; Pyrobor; Etibor 68

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[1] The hydrated forms are listed in EINECS (European Inventory of Existing Commercial Chemical Substance) under the anhydrous form of sodium tetraborate. There is an industry agreement to use the anhydrous EINECS entry.

	Disodium tetraborate pentahydrate:
	Neobor; V-bor; Etibor 48
	Disodium tetraborate decahydrate:
	Boricin; Borascu; Inkabor; Deca

The CAS numbers and EC numbers indicated in the table above are those used by the members of the European Borates Association (EBA). There is another entry on the fourth priority list2 for boric acid, CAS# 11113-50-1, EC# 234-343-4, which is described as "crude natural, containing not more than 85% of H_3BO_3, calculated on a dry weight basis". This boric acid is not supplied by the EBA members and is a Low Production Volume substance3. Therefore, this risk assessment only considers the boric acid EC# 233-139-2, CAS# 10043-35-3.

The hydrated forms of disodium tetraborate are listed under one EC number – EC#215-540-4 –which is that of the anhydrous form in the European Inventory of Existing Commercial Chemical Substances (EINECS). Some hydrated salts were listed separately within EINECS, however, there is an industry agreement to use the anhydrous EINECS entry4. Each of the hydrated states (pentahydrate and decahydrate) has a separate CAS number which provides an unique identifier for each. Disodium tetraborate pentahydrate is identified by EBA members with CAS# 12179-04-3, although this substance is also listed under CAS# 12267-73-1 and 12045-88-4. Disodium tetraborate decahydrate is identified by EBA members by 1303-96-4, although the substance is also listed under CAS# 13840-56-7.

This report covers boric acid (CAS# 10043-35-3) and disodium tetraborate anhydrous (CAS# 1330-43-4). However, since disodium tetraborate pentahydrate (CAS# 12179-04-03) and disodium tetraborate decahydrate (CAS# 1303-96-4) are hydrates of disodium tetraborate anhydrous (CAS# 1330-43-4) they are also addressed in this report. In aqueous solution the latter two substances form the same products as disodium tetraborate anhydrous (CAS# 1330-43-4) and are therefore comparable in their physical and chemical properties. Since the presented borates differ only in their amount of water of crystallisation and contain disodium tetraborate as a compound, they can equally be used for many applications.

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[2] Commission Regulation (EC) No 2364/2000 concerning the fourth list of priority substances as foreseen under Council Regulation No 793/93.

[3] ECB ESIS: European chemical Substances Information System, Version 5.00

[4] ***Extract from:*** *Manual of Decisions for Implementation of The Sixth and Seventh Amendments to Directive 67/548/EEC on Dangerous Substances (Directives 79/831/EEC And 92/32/EEC). Last modified: 23 January 2002*

2.3. Criteria for reporting Substances for EINECS

14. Hydrates of a substance or hydrated ions, formed by association of a substance with water should not be reported. The anhydrous form can be reported and will, by implication, represent all hydrated forms. The products of discrete chemical reactions in which water is a reactant, i.e. a metal hydroxide formed by the reaction of a metal oxide and water can be reported.

1.2 Composition of the substances

For each constituent/ impurity/ additive, fill in the following table (which should be repeated in case of more than one constituent). The information is particularly important for the main constituent(s) and for the constituents (or impurity) which influence the outcome of the dossier.

Chemical Name: Boric Acid

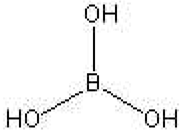
EC Number: 233-139-2

CAS Number: 10043-35-3

IUPAC Name: ortho-boric acid, boric acid

Molecular Formula: H_3BO_3
other frequently used formulas are: $B(OH)_3$ or $B_2O_3.3H_2O$

Structural Formula:



Molecular Weight: 61.8

Typical concentration (% w/w): ≥100%

Concentration range (% w/w): 99.9 – 100.34

The purity being ≥ 100% is due to the variation of crystal water in boric acid. Since boric acid consists of diboron-trioxide and water ($H_3BO_3 \leftrightarrow 1/2B_2O_3 + 3/2H_2O$), even a slight decrease in the structural water content will yield to a higher diboron-trioxide content which will increase the purity

Chemical Name: Disodium tetraborate anhydrous

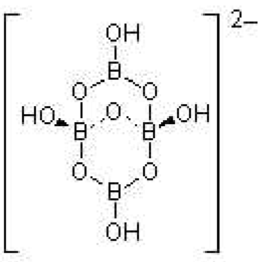
EC Number: 215-540-4

CAS Number: Disodium tetraborate anhydrous: 1330-43-4
Disodium tetraborate pentahydrate: 12179-04-03
Disodium tetraborate decahydrate: 1303-96-4

IUPAC Name: Disodium tetraborate anhydrous
Disodium tetraborate pentahydrate
Disodium tetraborate decahydrate

Molecular Formula: $Na_2B_4O_7$
$Na_2B_4O_7 \bullet 5H_2O$
$Na_2B_4O_7 \bullet 10H_2O$

Structural Formula:



$B_4O_5(OH)_4^{2-}$

Molecular Weight:
Disodium tetraborate anhydrous: 201.22
Disodium tetraborate pentahydrate: 291.35
Disodium tetraborate decahydrate: 381.37

Typical concentration (% w/w): >100% for all three hydrates

Concentration range (% w/w):
Disodium tetraborate anhydrous: 99.0 – 101.9%
Disodium tetraborate pentahydrate: 101.6 – 103.1%
Disodium tetraborate decahydrate: 101.0 – 104.6%

The purity being ≥ 100% is due to the variation of crystal water in boric acid. Since boric acid consists of diboron-trioxide and water ($H_3BO_3 \leftrightarrow 1/2B_2O_3 + 3/2H_2O$), even a slight decrease in the structural water content will yield to a higher diboron-trioxide content which will increase the purity.

1.3 Physico-chemical properties

Boric acid				
REACH ref Annex, §	**Property**	**IUCLID section**	**Value**	**Comment / Reference**
VII, 7.1	Physical state at 20°C and 101.3 kPa	4.1	White, crystalline, odourless solid	
VII, 7.2	Melting/freezing point	4.2	No melting point can be defined in the range 25-1000°C due to the decomposition of the substance.	If heated above 100°C water is lost and boric acid converts initially to metaboric acid (HBO_2) and on further heating forms boric oxide (B_2O_3). Cordia JA et al. (2003a)
VII, 7.3	Boiling point	4.3	not required	Melting point of boric oxide is >300°C.
VII, 7.4	Relative density	4.4	$D_4^{23} = 1.489 \pm 0.006$	Cordia JA et al. (2003a)
VII, 7.5	Vapour pressure	4.6	not required	Melting point of boric oxide is >300°C.
VII, 7.6	Surface tension	4.10	not applicable	Surface tension is not expected for inorganic substances.
VII, 7.7	Water solubility	4.8	49.20 ± 0.35 g/l at 20 ± 0.5°C 47.2 g/l at 20°C (literature value)	The difference between the determined water solubility (Cordia JA et al. (2003a)) and the literature value (47.2 g/l, Mellor (1980)) could be explained by the fact that the two protocol methods used in each case were different. Mellor's Comprehensive Treatise on Inorganic and Theoretical Chemistry, Volume V Boron, Part A: Boron-Oxygen Compounds, Longman London and New York, (1980), ISBN 0-582-46277-0, page 254. Cordia JA et al.(2003a)
VII, 7.8	Partition coefficient n-octanol/water (log value)	4.7	-1.09 ± 0.16 (22± 1°C)	Although not required as this is an inorganic substance, an end point has been derived in Cordia JA et al. (2003a).
VII, 7.9	Flash point	4.11	not required	Inorganic substance
VII, 7.10	Flammability	4.13	non-flammable	Rowe SM & Merritt M (2003)
VII, 7.11	Explosive properties	4.14	not explosive	Rowe SM & Merritt M (2003)
VII, 7.12	Self-ignition temperature			
VII, 7.13	Oxidising properties	4.15	No oxidising properties	
VII, 7.14	Granulometry	4.5	d_{50} = <75 – 680 µm	Boric acid is sold in both granular and powder forms. The range given here describes both granular and powder products.
IX, 7.15	Stability in organic solvents and identity of relevant	4.17	not required	Inorganic substance

Boric acid

REACH ref Annex, §	Property	IUCLID section	Value	Comment / Reference
	degradation products			
IX, 7.16	Dissociation constant	4.21	Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this purpose the formula for boric acid is best written as $B(OH)_3$. pKa = 9.0 at 25°C for boric acid in dilute solutions only ($B \leq 0.025$ M). At higher boron concentrations, polynuclear complexes are formed and several dissociation/formation constants apply.	At low boron concentrations ($B \leq 0.025$ M) the following equilibrium is found $B(OH)_3 + 2H_2O \leftrightarrow [B(OH)_4]^- + H_3O^+$ pKa = 9.0 at 25 °C Although at these concentrations, boric acid exists as undissociated boric acid $B(OH)_3$ at pH < 5, whereas at pH > 12.5 the metaborate ion -$[B(OH)_4]^-$ - becomes the main species in solution. Both species are present at pH 5-12.5 at concentrations $B \leq 0.025$ M. At higher boron concentrations ($B > 0.025$ M) an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3 \leftrightarrow$ polynuclear anions $\leftrightarrow B(OH)_4^-$. Again, pH<5, boron is mainly present at $B(OH)_3$ and in alkaline solution at pH>12.5, boron is mainly present as $B(OH)_4^-$. At in between values (pH 5-12) polynuclear anions are found as well as $B(OH)_3$ and $B(OH)_4^-$. The dissociation constant depends upon temperature, ionic strength and presence of group I metal ions (Na, K, Cs). In the presence of metal ions (e.g. Na, Mg, Ca) ion-pair complexes are formed, which further reduce the undissociated boric acid concentration: $M^{n+} + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$ These ion pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate and buffered solutions of boric acid and boric oxide (Ingri N (1963)).
XI, 7.17,	Viscosity	4.22	Not relevant	Solid substance
	Reactivity towards container material	4.18	Suitable container materials: Paper, Cardboard, Plastic (Polypropylene, High density polyethylene) Unsuitable container materials: Base metals	
	Thermal stability	4.19	Boric acid is stable up to approximately 75°C.	It dehydrates on further heating to form metaboric acid

Boric acid				
REACH ref Annex, §	**Property**	**IUCLID section**	**Value**	**Comment / Reference**
				and then boric oxide: $B(OH)_3 \rightarrow HBO_2 + H_2O$ (Temperature range 120 to 180°C) $HBO_2 \rightarrow 0.5\ B_2O_3 + H_2O$ (Temperature range 180 to ~400°C). Boric oxide and metaboric acid will convert to boric acid on contact with water or on exposure to moist air. Rapid heating to ~250°C may cause boric acid to form a highly viscous liquid whose composition lies between HBO_2 and B_2O_3. Under these conditions, a small quantity of boric acid can evaporate with the evolved water vapour. This will be visible as white fumes of condensed boric acid as the gas cools. Cordia (2003) & Kemp (1956)

Table 1.1. Physico chemical properties for Boric Acid

Disodium tetraborate anhydrous

REACH ref Annex, §	Property	IUCLID section	Value	Comment / Reference
VII, 7.1	Physical state at 20°C and 101.3 kPa	4.1	White, crystalline, odourless solid	
VII, 7.2	Melting/freezing point	4.2	737°C	Cordia JA et al.(2003b)
VII, 7.3	Boiling point	4.3	not required	Melting point is >300°C.
VII, 7.4	Relative density	4.4	$D_4^{23} = 2.354 \pm 0.007$	Spruit WET et al. (2005)
VII, 7.5	Vapour pressure	4.6	not required	Melting point is >300°C.
VII, 7.6	Surface tension	4.10	not applicable	Surface tension is not expected for inorganic substances.
VII, 7.7	Water solubility	4.8	27.0 ± 2.7 g/l at 20 ± 0.5°C Derived from studies with the pentahydrate and decahydrate	The water solubility for disodium tetraborate anhydrous as such cannot be determined because disodium tetraborate anhydrous is converted into boric acid/borate upon dissolution in water: $Na_2B_4O_7 + 7\ H_2O \rightarrow 2\ NaB(OH)_4 + 2\ B(OH)_3$. The water solubility found will be the water solubility for boric acid in the presence of sodium ions. The water solubility for disodium tetraborate anhydrous is equal to an equivalent amount of disodium tetraborate pentahydrate or disodium tetraborate decahydrate. Cordia JA et al. (2003b and c).
VII, 7.8	Partition coefficient n-octanol/water (log value)	4.7	not required	Inorganic substance
VII, 7.9	Flash point	4.11	not required	Inorganic substance
VII, 7.10	Flammability	4.13	non-flammable	
VII, 7.11	Explosive properties	4.14	not explosive	The molecular structure of disodium tetraborate anhydrous does not indicate the presence of reactive or instable groups in the molecule. The molecular structure does not indicate that disodium tetraborate anhydrous will explode under the conditions of the test as described in Test Guideline A.14 of EC Directive 92/69/EEC.
VII, 7.12	Self-ignition temperature			
VII, 7.13	Oxidising properties	4.15	No oxidising properties	
VII, 7.14	Granulometry	4.5	$d_{50} = 210 – 850 \mu m$	Disodium tetraborate anhydrous is sold in both granular and powder forms. The range given here describes both granular and powder products.
XI, 7.15	Stability in organic solvents	4.17	not required	Inorganic substance

Disodium tetraborate anhydrous

REACH ref Annex, §	Property	IUCLID section	Value	Comment / Reference
	and identity of relevant degradation products			
XI, 7.16	Dissociation constant	4.21	Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this purpose the formula for boric acid is best written as $B(OH)_3$. pKa = 9.0 at 25 °C for boric acid in dilute solutions only (B ≤ 0.025 M). At higher boron concentrations, polynuclear complexes are formed and several dissociation/formation constants apply.	The dissociation constant for disodium tetraborate anhydrous as such cannot be determined because disodium tetraborate anhydrous is converted into boric acid/borate upon dissolution in water: $Na_2B_4O_7 + 7 H_2O \rightarrow 2 NaB(OH)_4 + 2 B(OH)_3$. The dissociation constant found will be the dissociation constant for boric acid in the presence of sodium ions. At low boron concentrations (B ≤ 0.025 M) the following equilibrium is found $B(OH)_3 + 2H_2O \leftrightarrow [B(OH)_4]^- + H_3O^+$ pKa = 9.0 at 25 °C Although at these concentrations, boric acid exists as undissociated boric acid $B(OH)_3$ at pH < 5, whereas at pH > 12.5 the metaborate ion -$[B(OH)_4]^-$ - becomes the main species in solution. Both species are present at pH 5-12.5 at concentrations B ≤ 0.025 M. At higher boron concentrations (B > 0.025 M) an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3 \leftrightarrow$ polynuclear anions $\leftrightarrow B(OH)_4^-$. Again, pH<5, boron is mainly present at $B(OH)_3$ and in alkaline solution at pH>12.5, boron is mainly present as $B(OH)_4^-$. At in between values (pH 5-12) polynuclear anions are found as well as $B(OH)_3$ and $B(OH)_4^-$. The dissociation constant depends upon temperature, ionic strength and presence of group I metal ions (Na, K, Cs). In the presence of metal ions (e.g. Na, Mg, Ca) ion-pair complexes are formed, which further reduce the undissociated boric acid concentration: $M^{n+} + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$ These ion pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate and buffered solutions of boric acid and boric oxide

Disodium tetraborate anhydrous				
REACH ref Annex, §	**Property**	**IUCLID section**	**Value**	**Comment / Reference**
				(Ingri N (1963)).
XI, 7.17,	Viscosity	4.22	Not relevant	Solid substance
	Reactivity towards container material	4.18	Suitable container materials: Paper, Cardboard, Plastic (Polypropylene, High density polyethylene) Unsuitable container materials: Base metals	
	Thermal stability	4.19	Disodium tetraborate anhydrous is stable up to 524/527 °C. At this temperature a phase transition occurs. A melting point is found at 737°C.	Cordia JA et al. (2003b)

Table 1.2: Summary of physico- chemical properties for disodium tetraborate anhydrous

Disodium tetraborate pentahydrate				
REACH ref Annex, §	**Property**	**IUCLID section**	**Value**	**Comment / Reference**
VII, 7.1	Physical state at 20°C and 101.3 kPa	4.1	White, crystalline, odourless solid	
VII, 7.2	Melting/freezing point	4.2	No melting point can be defined because of decomposition of the substance.	When disodium tetraborate pentahydrate is heated, it gradually loses water of crystallisation, forming disodium tetraborate anhydrous, $Na_2B_4O_7$. An endothermal peak is observed at 131 °C, due to the loss of water. Due to a phase transition an exothermal peak is observed at 524/527°C. The crystal form of $Na_2B_4O_7$ melts at 737°C (Cordia JA et al. (2003b)).
VII, 7.3	Boiling point	4.3	not required	Melting point of disodium tetraborate anhydrous is >300°C.
VII, 7.4	Relative density	4.4	$D_4^{23} = 1.860 \pm 0.008$	Cordia JA et al. (2003b)
VII, 7.5	Vapour pressure	4.6	not required	Melting point of disodium tetraborate anhydrous is >300°C.
VII, 7.6	Surface tension	4.10	not applicable	Surface tension is not expected for inorganic substances.
VII, 7.7	Water solubility	4.8	40.06 ± 2.70 g/l at 20 ± 0.5°C 35.9 g/l at 20°C (literature value)	The difference between the determined water solubility (Cordia JA et al. (2003b)) and the literature value (35.9 g/l, Mellor (1980)) could be explained by the fact that the two protocol methods used in each case were different. Mellor's Comprehensive Treatise on Inorganic and Theoretical Chemistry, Volume V Boron, Part A: Boron-Oxygen Compounds, Longman London and New York, (1980), ISBN 0-582-46277-0, page 254.
VII, 7.8	Partition coefficient n-octanol/water (log value)	4.7	not required	Inorganic substance
VII, 7.9	Flash point	4.11	not required	Inorganic substance
VII, 7.10	Flammability	4.13	non-flammable	
VII, 7.11	Explosive properties	4.14	not explosive	The molecular structure of disodium tetraborate pentahydrate does not indicate the presence of reactive or instable groups in the molecule. The molecular structure does not indicate that disodium tetraborate pentahydrate will explode under the conditions of the test as described in Test Guideline A.14 of EC Directive 92/69/EEC.

Disodium tetraborate pentahydrate

REACH ref Annex, §	Property	IUCLID section	Value	Comment / Reference
VII, 7.12	Self-ignition temperature			
VII, 7.13	Oxidising properties	4.15	No oxidising properties	
VII, 7.14	Granulometry	4.5	d_{50} = 460 – 520 □m	
XI, 7.15	Stability in organic solvents and identity of relevant degradation products	4.17	not required	Inorganic substance
XI, 7.16	Dissociation constant	4.21	Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this purpose the formula for boric acid is best written as $B(OH)_3$. pKa = 9.0 at 25 °C for boric acid in dilute solutions only ($B \leq 0.025$ M). At higher boron concentrations, polynuclear complexes are formed and several dissociation/formation constants apply.	The dissociation constant for disodium tetraborate pentahydrate as such cannot be determined because disodium tetraborate pentahydrate is converted into boric acid/borate upon dissolution in water: $Na_2B_4O_7.5H_2O + 2\ H_2O \rightarrow 2\ NaB(OH)_4 + 2\ B(OH)_3$. The dissociation constant found will be the dissociation constant for boric acid in the presence of sodium ions. At low boron concentrations ($B \leq 0.025$ M) the following equilibrium is found $B(OH)_3 + 2H_2O \leftrightarrow [B(OH)_4]^- + H_3O^+$ pKa = 9.0 at 25 °C Although at these concentrations, boric acid exists as undissociated boric acid $B(OH)_3$ at pH < 5, whereas at pH > 12.5 the metaborate ion -$[B(OH)_4]^-$ - becomes the main species in solution. Both species are present at pH 5-12.5 at concentrations $B \leq 0.025$ M. At higher boron concentrations ($B > 0.025$ M) an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3 \leftrightarrow$ polynuclear anions $\leftrightarrow B(OH)_4^-$. Again, pH<5, boron is mainly present at $B(OH)_3$ and in alkaline solution at pH>12.5, boron is mainly present as $B(OH)_4^-$. At in between values (pH 5-12) polynuclear anions are found as well as $B(OH)_3$ and $B(OH)_4^-$. The dissociation constant depends upon temperature, ionic strength and presence of group I metal ions (Na, K, Cs). In the presence of metal ions (e.g. Na, Mg, Ca) ion-

Disodium tetraborate pentahydrate				
REACH ref Annex, §	**Property**	**IUCLID section**	**Value**	**Comment / Reference**
				pair complexes are formed, which further reduce the undissociated boric acid concentration: $M^{n+} + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$ These ion pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate and buffered solutions of boric acid and boric oxide (Ingri N (1963)).
XI, 7.17,	Viscosity	4.22	Not relevant	Solid substance
	Reactivity towards container material	4.18	Suitable container materials: Paper, Cardboard, Plastic (Polypropylene, High density polyethylene) Unsuitable container materials: Base metals	
	Thermal stability	4.19	Disodium tetraborate pentahydrate is stable up to 131°C.	At this temperature water of crystallisation is lost to form disodium tetraborate anhydrous (Cordia JA et al. (2003b)).

Table 1.3: **Summary of physico- chemical properties for disodium tetraborate pentahydrate**

Disodium tetraborate decahydrate				
REACH ref Annex, §	**Property**	**IUCLID section**	**Value**	**Comment / Reference**
VII, 7.1	Physical state at 20°C and 101.3 kPa	4.1	White, crystalline, odourless solid	
VII, 7.2	Melting/freezing point	4.2	No melting point detected below 1000°C.	Cordia JA (2003c)
VII, 7.3	Boiling point	4.3	not required	Melting point of disodium tetraborate anhydrous is >300°C.
VII, 7.4	Relative density	4.4	$D_4^{23} = 1.74 \pm 0.01$	Cordia JA (2003c)
VII, 7.5	Vapour pressure	4.6	not required	Melting point of disodium tetraborate anhydrous is >300°C.
VII, 7.6	Surface tension	4.10	not applicable	Surface tension is not expected for inorganic substances.
VII, 7.7	Water solubility	4.8	49.74 ± 3.63 g/l at 20 ± 0.5°C 47.0 g/l at 20°C (literature value)	The difference between the determined water solubility (Cordia JA (2003c)) and the literature value (47.0 g/l, Mellor (1980)) could be explained by the fact that the two protocol methods used in each case were different. Mellor's Comprehensive Treatise on Inorganic and Theoretical Chemistry, Volume V Boron, Part A: Boron-Oxygen Compounds, Longman London and New York, (1980), ISBN 0-582-46277-0, page 254.
VII, 7.8	Partition coefficient n-octanol/water (log value)	4.7	-1.53 ± 0.05 (22 ± 1°C)	Although not required as this is an inorganic substance, an end point has been derived in Cordia JA (2003c).
VII, 7.9	Flash point	4.11	not required	Inorganic substance
VII, 7.10	Flammability	4.13	non-flammable	
VII, 7.11	Explosive properties	4.14	not explosive	The molecular structure of disodium tetraborate decahydrate does not indicate the presence of reactive or instable groups in the molecule. The molecular structure does not indicate that disodium tetraborate decahydrate will explode under the conditions of the test as described in Test Guideline A.14 of EC Directive 92/69/EEC.
VII, 7.12	Self-ignition temperature			
VII, 7.13	Oxidising properties	4.15	No oxidising properties	
VII, 7.14	Granulometry	4.5	$d_{50} = 90 – 400 \mu m$	Disodium tetraborate decahydrate is sold in both granular and powder forms. The range given here describes both granular and powder products.
XI, 7.15	Stability in organic solvents	4.17	not required	Inorganic substance

Disodium tetraborate decahydrate

REACH ref Annex, §	Property	IUCLID section	Value	Comment / Reference
	and identity of relevant degradation products			
XI, 7.16	Dissociation constant	4.21	Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this purpose the formula for boric acid is best written as $B(OH)_3$. pKa = 9.0 at 25 °C for boric acid in dilute solutions only ($B \leq 0.025$ M). At higher boron concentrations, polynuclear complexes are formed and several dissociation/formation constants apply.	The dissociation constant for disodium tetraborate decahydrate as such cannot be determined because disodium tetraborate decahydrate is converted into boric acid/borate upon dissolution in water: $Na_2B_4O_7.10H_2O \rightarrow 2\ NaB(OH)_4 + 2\ B(OH)_3 + 3H_2O$. The dissociation constant found will be the dissociation constant for boric acid in the presence of sodium ions. At low boron concentrations ($B \leq 0.025$ M) the following equilibrium is found $B(OH)_3 + 2H_2O \leftrightarrow [B(OH)_4]^- + H_3O^+$ pKa = 9.0 at 25 °C Although at these concentrations, boric acid exists as undissociated boric acid $B(OH)_3$ at pH < 5, whereas at pH > 12.5 the metaborate ion -$[B(OH)_4]^-$ - becomes the main species in solution. Both species are present at pH 5-12.5 at concentrations $B \leq 0.025$ M. At higher boron concentrations ($B > 0.025$ M) an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3 \leftrightarrow$ polynuclear anions $\leftrightarrow B(OH)_4^-$. Again, pH<5, boron is mainly present at $B(OH)_3$ and in alkaline solution at pH>12.5, boron is mainly present as $B(OH)_4^-$. At in between values (pH 5-12) polynuclear anions are found as well as $B(OH)_3$ and $B(OH)_4^-$. The dissociation constant depends upon temperature, ionic strength and presence of group I metal ions (Na, K, Cs). In the presence of metal ions (e.g. Na, Mg, Ca) ion-pair complexes are formed, which further reduce the undissociated boric acid concentration: $M^{n+} + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$ These ion pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate

Disodium tetraborate decahydrate				
REACH ref Annex, §	**Property**	**IUCLID section**	**Value**	**Comment / Reference**
				and buffered solutions of boric acid and boric oxide (Ingri N (1963)).
XI, 7.17,	Viscosity	4.22	Not relevant	Solid substance
	Reactivity towards container material	4.18	Suitable container materials: Paper, Cardboard, Plastic (Polypropylene, High density polyethylene) Unsuitable container materials: Base metals	
	Thermal stability	4.19	Disodium tetraborate decahydrate is stable up to 47/48°C when water of crystallization is lost to form disodium tetraborate pentahydrate.	Cordia JA (2003c)

Table 1.4: Summary of physico- chemical properties for disodium tetraborate decahydrate

For comparative purposes, exposures to borates are often expressed in terms of boron (B) equivalents based on the fraction of boron in the source substance on a molecular weight basis. As noted previously, only boric acid and the borate anion are present at environmentally and physiologically relevant concentrations. Read-across between the different boron compounds can be done on the basis of boron (B) equivalents. (See tables 1.1 to 1.4, section on dissociation constant). Conversion factors are given in Table 1.5 below).

		Conversion factor for equivalent dose of B
Boric acid	H_3BO_3	0.1748
Disodium tetraborate anhydrous	$Na_2B_4O_7$	0.2149
Disodium tetraborate pentahydrate	$Na_2B_4O_7 \bullet 5H_2O$	0.1484
Disodium tetraborate decahydrate	$Na_2B_4O_7 \bullet 10H_2O$	0.1134

Table 1.5: Conversion factors to boron equivalents

1.4 Justification for grouping

This report covers boric acid (CAS# 10043-35-3) and disodium tetraborate anhydrous (CAS# 1330-43-4). However, since disodium tetraborate pentahydrate (CAS# 12179-04-03) and disodium tetraborate decahydrate (CAS# 1303-96-4) are hydrates of disodium tetraborate anhydrous (CAS# 1330-43-4) they are also addressed in this report. In aqueous solution the latter two substances form the same products as disodium tetraborate anhydrous (CAS# 1330-43-4) and are therefore comparable in their physical and chemical properties. Since the presented borates differ only in their amount of water of crystallisation and contain disodium tetraborate as a compound, they can equally be used for many applications.

2 MANUFACTURE AND USES

2.1 Manufacture

Borates are naturally-occurring minerals containing boron, the fifth element on the Periodic Table. Trace amounts exist in rock, soil and water. The element boron does not exist in nature by itself: boron combines with oxygen and other elements to form boric acid, or inorganic salts which are generically referred to as "borates".

The oldest form of boron known to man is the mineral salt called tincal (sodium tetraborate decahydrate, or simply sodium tetraborate). Other boron-containing minerals that occur naturally and are mined commercially include colemanite (calcium borate), hydroboracite (calcium-magnesium borate), kernite (another sodium borate), and ulexite (sodium-calcium borate). While boron is ubiquitous in the environment, substantial deposits of borates are relatively rare. The main commercially active deposits are in Turkey and the United States of America, with smaller deposits in Russia, China and South America.

The majority of boric acid is manufactured by reacting inorganic borate minerals with sulphuric acid in an aqueous solution. Sodium borate minerals are the principle source in the US and calcium borates are the principle source in Turkey. Sodium tetraborate pentahydrate and decahydrate are manufactured by dissolving the sodium borate minerals in hot liquor and recrystallising. The anhydrous form is then produced from its hydrated forms.

These manufacturing activities occur outside the EU-27 and manufactured products are imported for sale and distribution within the EU.

Manufacturing, import and distribution of boric acid and sodium tetraborates is done by three companies: Eti Mine Works, Rio Tinto Minerals and Società Chimica Larderello. These three companies are responsible for more than 95% of the EU boric acid and sodium tetraborates supply (EBA 2008a). Table 2.1 lists their locations and activities.

Table 2.1: Locations and activities by the EBA members (EBA 2008a)

Company	Location	Activities
Eti Mine Works	Antwerp, Belgium	borate packing and distribution
Borax España S.A.	Nules, Spain	borate packing and distribution
Borax Français S.A.S.	Coudekerque, France	borate refinery and distribution, manufacture of other borates, which are out of the scope of this RA
Borax Rotterdam N.V.	Rotterdam, The Netherlands	borate packing and distribution
Società Chimica Larderello	Ravenna, Italy	borate refinery and distribution, manufacture of other borates, which are out of the scope of this RA

Some further purification of boric acid and sodium tetraborates occurs in France and Italy to remove trace levels of impurities. Either the boric acid or sodium tetraborate is dissolved in hot liquor, recrystallised, dried and then packed for distribution and sale.

2.2 Uses

Boric acid and sodium tetraborates are used in several important industries in Europe, including the glass, ceramics, detergents, wood treatment and insulation fiberglass industries and are used to produce other borate compounds. Borates are particularly versatile, have a multitude of different properties and are used in a variety of different products and processes. Boric acid and sodium tetraborates are also used in a range of consumer products including cosmetic and personal care products. Moreover, borates are essential for all plants.

An anthropogenic source of boron in the environment that is not associated with any boric acid or borate product is that associated with coal combustion products, such as fly ash and bottom ash. These materials may be land-applied or land-filled and contain relatively high boron concentrations (several thousand mg/kg, Schwab et al. 1991).

2.2.1 Detergents and cleaners

Different forms of borates are used to produce laundry detergents, household or industrial cleaners and personal care products. In these applications, borates' serve to enhance stain removal and bleaching, stabilize enzymes, provide alkaline buffering, soften water and boost surfactant performance. Because borates act as a biostat, they also serve to control bacteria and fungi in personal care products.

Laundry detergents

Borates are used in a variety of household and industrial laundry detergent formulations. In powdered detergent, they can be directly incorporated to boost cleaning power or added as sodium perborate for bleaching action. They are also used in liquid detergents – enzymes for stain removal need to be stabilized in liquids, and borates have proven effective for this.

Cleaning products

Borates or perborates are used in many household and industrial products for cleaning metals, glass, sinks, bathtubs, toilets, floors and machinery. They can also be found in automatic dishwashing detergents and powdered or liquid hand soaps.

Product Uses	Boric Acid	Sodium tetraborate decahydrate (10 mol)	Sodium tetraborate pentahydrate (5 mol)	Sodium tetraborate anhydrous
Soaps		X Powder hand soap		
Liquid/Laundry Detergents		X	X Stabilizes Enzymes	
Bleach			X Sodium Perborate Precursor	
Cleaning Products			X	
Additive (e.g. hand cleaners, polishes waxes, and industrial cleaning compounds)		X	X	

2.2.2 Personal care products

Borates are used in many personal care products such as cosmetic creams, skin lotions, hair shampoos, dyes and gels, eye drops, bath salts, and denture cleaners.

Products	Boric Acid	Sodium tetraborate decahydrate (10 mol)	Sodium tetraborate pentahydrate (5 mol)	Sodium tetraborate anhydrous
Cosmetics	X	X Lotions, creams & ointments		
Toiletries	X	X		
Pharmaceuticals	X	X		

2.2.3 Glass and glass fibres

Fiberglass

Borates are an important ingredient in both insulation fiberglass - which represents the largest single use of borates worldwide - and textile fiberglass, used in everything from circuit boards to surfboards.
In both products, borates act as a powerful flux and lower glass batch melting temperatures.
They also control the relationship between temperature, viscosity and surface tension to create optimal glass fiberization. Insulation fiberglass works by trapping air within its mesh of fibers to prevent heat loss. Borates in the glass fibers also absorb more infrared radiation, adding to their insulation performance.

Glass

Borosilicate glass is used in all heat-resistant glass applications ranging from halogen lightbulbs and Pyrex® cookware to cathode-ray tubes and liquid crystal displays.
Function of borates in glass:

- to lower melt temperatures and inhibit devitrification in the glassmaking process,
- to increase the mechanical strength, as well as resistance to thermal shock, chemicals and water in the final product.

Products	Boric Acid	Sodium tetraborate decahydrate (10 mol)	Sodium tetraborate pentahydrate (5 mol)	Sodium tetraborate anhydrous
Insulation & Textile Fiber Glass	X		X	
Borosilicate Glass	X		X	X
Refractories	X	X Used as stabilizer & bonding agent that gives intermediate-temperature glassy bond. Frequently volatilizes from system.		X

2.2.4 Ceramics

Borates are used in ceramic glazes and increasingly also in ceramic tile bodies.
Glazes and enamels are the thin, glassy coatings fused onto ceramics and metals in tiles, tableware, bone china, porcelain, pots and pans, and household appliances. Borates are used to initiate glass formation and reduce glass viscosity, helping to form a smooth surface; and to reduce thermal expansion, facilitating a good

fit between the glaze or enamel and the item it covers. Borates in glazes and enamels also increase the refractive index, or lustre; enhance durability and resistance to chemicals; and help dissolve colouring agents The inclusion of borates in manufacturer's formulation allows them to use a wider range of clays, heighten productivity and decrease energy usage.

Products	Boric Acid	Sodium tetraborate decahydrate (10 mol)	Sodium tetraborate pentahydrate (5 mol)	Sodium tetraborate anhydrous
Glaze & Enamel	X		X	X
Frits	X			X

2.2.5 Metallurgy

Borates are used in the production of steel and non-ferrous metals, alloys, rare earth magnets, amorphous metals, welding fluxes and plating compounds.

In steel and non-ferrous metal production, the borate acts as a flux during the smelting operation, dissolving metallic oxide impurities that are then removed with the slag. Borates are also used as a cover flux to protect metals against air oxidation which is a key functional requirement of a brazing/welding/soldering flux. In addition the detergency properties of borates help to remove oxides, grease and other foreign matter from the metal surfaces. In electroplating nickel, boric acid is used as a pH-buffer and prevents nickel deposits cracking and pitting.

Products	Boric Acid	Sodium tetraborate decahydrate (10 mol)	Sodium tetraborate pentahydrate (5 mol)	Sodium tetraborate anhydrous
Steel & non-ferrous metal production (Flux agent)	X Prevents oxidation of metal surfaces	X	X	X
Welding, brazing & soldering fluxes	X			
Plating	X			

2.2.6 Industrial fluids

Borates are used in the manufacturing of industrial fluids such as antifreezes, lubricants, brake fluids, metalworking fluids, water treatment chemicals and fuel additives. Boric acid and sodium tetraborates are used in these applications to impart corrosion inhibition and buffering, for example in antifreeze, metalworking fluids and water treatment chemicals meaning that equipment, or the fluids themselves have a longer service life. In brake fluids the presence of a borate prevents vapour-lock by elevating the boiling point.

Products	Boric Acid	Sodium tetraborate decahydrate (10 mol)	Sodium tetraborate pentahydrate (5 mol)	Sodium tetraborate anhydrous
Metal working fluids	X		X	
Anti-freeze (engine coolant)				
Lubricants	X	X Also used in dry powdered lubricants	X Also used in dry powdered lubricants	
Brake fluids				
Water treatment chemicals	X	X	X	
Fuel additives	X			

2.2.7 Adhesives

Starch is a natural polymeric product and is found in almost every plant. Today, the principal sources of most commercial starches are maize, potato, tapioca and wheat. Borates are added to increase the viscosity, for a quicker tack and for better fluid properties.

Products	Boric Acid	Sodium tetraborate decahydrate (10 mol)	Sodium tetraborate pentahydrate (5 mol)	Sodium tetraborate anhydrous
Starch Adhesive Formulation (corrugated Paper & Paperboard)	X	X	X	
Casein and dextrin based adhesive	X	X	X	

2.2.8 Flame retardants

Boric acid and sodium tetraborates are used as flame retardants in a range of applications illustrated in the table below. Borates suppress a fire by melting and covering the flammable substrate in a layer of char, excluding oxygen from the flame.

Cellulose, the basis of wood, cotton, and most other plant-derived raw materials, is in widespread industrial use but is inherently flammable in many of its forms. The use of borates in cellulose materials imparts flame retardancy, enabling them to meet safety standards and regulations.

Products	Boric Acid	Sodium tetraborate decahydrate (10 mol)	Sodium tetraborate pentahydrate (5 mol)	Sodium tetraborate anhydrous
Wood products	X			
Cellulose Insulation	X	X	X	X
Cotton batting in mattresses/futons	X			

Fabrics	X			
Paper	X			

2.2.9 Biocides

Borate treatment for wood is used as a protection against wood destroying organisms. There are several types of borate wood preservatives used to treat solid wood, engineered wood composites and other interior building products like studs, plywood, joists and rafters.

Products	Boric Acid	Sodium tetraborate decahydrate (10 mol)	Sodium tetraborate pentahydrate (5 mol)	Sodium tetraborate anhydrous
Wood preservative	X	X	X	
Non-professional remedial products	X		X	
Professional remedial products	X	X		

2.2.10 Agriculture

Boron is an essential micronutrient for plants, vital to their growth and development. Without sufficient boron, plant fertilization, seeding and fruiting are not possible. In areas of acute deficiency, borates can increase crop yields by 30 to 40 percent. Boron applications have been documented for 132 crops in over 80 countries (Shorrocks, 1997).

Products	Boric Acid	Sodium tetraborate decahydrate (10 mol)	Sodium tetraborate pentahydrate (5 mol)	Sodium tetraborate anhydrous
Fertilizer	X	X	X	

2.2.11 Other Uses

Some of the more minor uses of boric acid and sodium tetraborates are listed in the table below.

Boric acid and sodium tetraborates are used as reagent chemicals for the manufacture of other boron substances not included in this risk assessment. These include disodium octaborate, sodium pentaborate, zinc borates, potassium borates, boron carbide, boron nitride and boron hydrides.
Boric acid is also used during the manufacturing of nylon to control the stereochemistry of the intermediates formed through the oxidation of cyclohexane.
In nuclear applications, boric acid is used to absorb neutrons in the cooling water and in the cement used for reactor containment.
Sodium tetraborate pentahydrate can be used as a cement setting agent.
The functionality as a pH buffer means that borates are used in leathering tanning (the deliming process) and in photographic chemicals.
In wallboard, the boric acid is mixed with the gypsum to prevent the gypsum being over-dried during manufacture of the board.
In abrasives sodium tetraborate anhydrous is used as an ingredient in the matrix binder of grinding wheels.
Since the terrorist attacks on 11 September 2001, boric acid has been used in paints used as thermal insulators on steel structures.

Products	Boric Acid	Sodium tetraborate decahydrate (10 mol)	Sodium tetraborate pentahydrate (5 mol)	Sodium tetraborate anhydrous
Abrasives				X
Wallboard (plasterboard)	X			
Nuclear applications	X			
Cement	X		X	
Leather tanning	X	X	X	
Nylon manufacturing, paint	X			
Photographic chemicals		X	X	
Reagent chemicals	X		X	X

2.3 Manufacturing, import and use volumes

2.3.1 All borate compounds

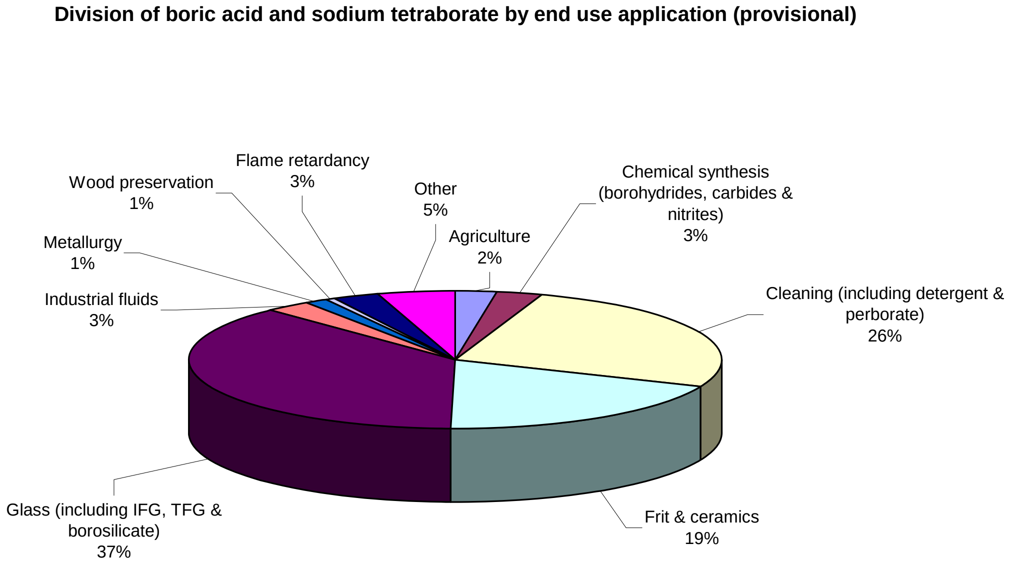

Division of boric acid and sodium tetraborate by end use application (provisional)

Fig. 2.1.: Division of boric acid and sodium tetraborates by end use application (provisional year 2005 data)

Fig 2.1 shows that the major use sectors are the glass manufacturing sector (37%) (IFG, TFG and borosilicate glass), the frits and ceramics sector (19%) and the cleaning sector (26%) (detergents and perborates). These three sectors represent 83% of the total EU use volume for borates. Other smaller uses identified are manufacturing of industrial fluids, chemical synthesis, flame retardancy, application in agriculture, wood preservation, metallurgy and other.

However, recent information on market trends in the past few years has shown that the overall demand for borates has declined in Europe over the past 5 years as a result of the demand for the largest end-use decreasing (sodium perborate, which is used as bleach in detergents). Stripping this factor out, borate demand has increased in most application areas, particularly agriculture and vitreous applications.

A revision of the use volumes for all borate substances (boric acid, disodium tetraborate decahydrate, disodium tetraborate pentahydrate and disodium tetraborate anhydrous) has been performed recently by EBA. The results are presented in Fig 2.2.

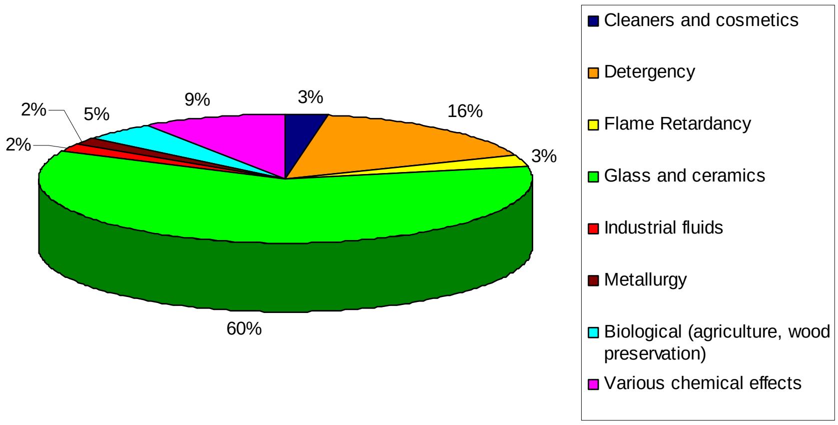


Fig. 2.2: Division of boric acid and sodium tetraborates (sodium tetraborate anhydrous, sodium tetraborate pentahydrate, sodium tetraborate decahydrate) by end use application (year 2007 data) (EBA, 2008a)

Fig 2.2 shows that the major use sectors for boric acid and sodium tetraborates are glass and ceramics (60.1%) (insulation fibreglass, ceramic applications, borosilicate glass and textile fibreglass), detergency (16.2%) (use of perborate) and 'various chemical effects' (9.5%) (miscellaneous applications mainly, not further specified). These three sectors represent nearly 86% of the total EU use volume for borates. Other sectors are biological applications (4.8%) (agricultural use (fertiliser) and wood preservation), flame retardancy (3.1%) (mainly cellulose insulation), cleaners and cosmetics (2.7%) (liquid detergents mainly), industrial fluids (1.9%) (major part metal working fluids) and metallurgy (1.7%) (metal heat treatment and miscellaneous metallurgy).

Comparing these data with the graph for the year 2005 shows that, according to the trend described above, the use of perborate in detergency is indeed reduced from 26% to 16% (19% if cleaning and cosmetics is included). The percentage for glass and ceramics of 56% for the year 2005 is slightly higher in 2007, i.e. 60%. Further, it can be noted that the agricultural use is increased from 3% to 5%. For the remaining uses, only small changes are noted in metallurgy and industrial fluids uses; the relative application in flame retardancy remained constant.

Please note that the reported uses reflect the use of boric acid and all sodium tetraborates but also perborate.

The relative part of each substance is shown in the table below (EBA, 2008a; data for year 2007). From this table, it is clear that the decahydrate form is only 4.6% of the total use volume of all sodium tetraborates. The largest part is the pentahydrate form, representing 89.6% of the total use volume. The anhydrous form represents 5.8% of the total tetraborate volume. Taking the total tonnage of all borates (boric acid and sodium tetraborates) the use volume of anhydrous and the decahydrate form is about 8% (expressed as B_2O_3). It is therefore expected that, in general, the volume of sodium tetraborate anhydrous or borax decahydrate used by a local site will be lower than that for boric acid. The pentahydrate use volume is more than twofold the boric acid use volume (as B_2O_3); hence the largest borate volumes used by a local site following the TGD (2003) default method will be for the pentahydrate form.

Table 2.2: Overview of EU use volumes for boric acid and sodium tetraborate decahydrate, sodium tetraborate pentahydrate and sodium tetraborate anhydrous (as B_2O_3) (year 2007) (EBA, 2008a)

Substance	T substance	Conversion factor from substance to B_2O_3	T (B_2O_3)	T (B_2O_3)	Relative part in total sodium tetraborates (%)	Relative part in total all borates (%)
Boric acid	119,875	0.563	67,490			29
Sodium tetraborate anhydrous	12,151	0.69	8,384	166,346	5.0%	4
Sodium tetraborate pentahydrate	305,933	0.49	149,907		90.1%	64
Sodium tetraborate decahydrate	22,069	0.365	8,055		4.9%	3
Total			**233,836**			

An overview of the distribution of the tonnage for all user sectors is presented in table 2.3. Next to the use volumes for the major sectors; the use tonnage of the main subsectors is identified.

Table 2.3: End use volumes for all borate substances (boric acid, disodium tetraborate decahydrate, disodium tetraborate pentahydrate, disodium tetraborate anhydrous) (as B_2O_3) (EBA, 2008a)

Use sector	Tonnage (2007) (T B_2O_3)	% of use
Glass and ceramics	140,600	60.1%
▪ *Borosilicate glass*		*(25% of total glass)*
▪ *Ceramic applications*		*(32% of total glass)*
▪ *IFG*		*(36% of total glass)*
▪ *TFG*		*(7% of total glass)*
Detergency	37,946	*16.2%* *(perborate)*
Cleaning and cosmetics	6,266	2.7%
▪ *Liquid detergents*		*(90% of cleaning)*
▪ *Laundry additives, swimming pool chemicals*		*(10% of cleaning)*
Flame retardancy	7,137	3.1%
▪ *Cellulose insulation*		*(79% of flame retardancy)*
▪ *Hardboard, paper, miscellaneous (flame retardancy*		*(21% of flame retardancy)*
Industrial fluids	4,492	1.9%
▪ *Metal working fluids*		*(57% of industrial fluids)*
▪ *Antifreeze, brake fluids, motor oil*		*(43% of industrial fluids)*
Metallurgy	4,004	1.7%
▪ *Metal heat treatment, miscellaneous (metallurgy)*		(73% of metallurgy)
• *Brazing fluxes, Electrolytic Capacitors, Electroplating, Ferroboron, Metal Refining (Smelting), Wire Drawing*		(27% of metallurgy)
Biological effects	11,256	4.8%
▪ *Agriculture (fertiliser)*		*(79% of biological)*
▪ *Wood preservation*		*(21% of biological)*
Various chemical effects	22,134	9.5%
▪ *Miscellaneous (various)*		*(62% of various chemical)*
▪ *Abrasives*		*(9% of various chemical)*
▪ *Wallboard*		*(5% of various chemical)*
▪ *Starch adhesives*		*(5% of various chemical)*
▪ *Nuclear applications*		*(5% of various chemical)*
▪ *Cement, leather tanning, nylon manufacturing, paint, photographic chemicals, reagent chemicals, refractories*		*(13% of various chemical)*
Total	**233,836**	

2.3.2 Boric acid, sodium tetraborate anhydrous, sodium tetraborate pentahydrate and sodium tetraborate decahydrate

The emission and exposure estimations have been made for boric acid and sodium tetraborate compounds (sodium tetraborate anhydrous, sodium tetraborate pentahydrate and sodium tetraborate decahydrate). An overview of applications for each of the substances is presented in table 2.4. End use volumes for all borate substances (as B_20_3) are reported in 2.3. These data will be used as a basis for the derivation of the environmental exposure assessment.

Table 2.4: Overview of applications for boric acid and sodium tetraborate substances

	Boric Acid	**Sodium tetraborate decahydrate (10 mol)**	**Sodium tetraborate pentahydrate (5 mol)**	**Sodium tetraborate anhydrous**
Glass and glass fibres				
Insulation & Textile Fiber Glass	X		X	
Borosilicate Glass	X		X	X
Refractories	X	X Used as stabilizer & bonding agent that gives intermediate-temperature glassy bond. Frequently volatilizes from system.		X
Ceramics				
Glaze & Enamel	X		X	X
Frits	X			X
Detergents and cleaners				
Soaps		X Powder hand soap		
Liquid/Laundry Detergents		X	X Stabilizes Enzymes	
Bleach			X Sodium Perborate Precursor	
Cleaning products			X	
Additive (e.g. hand cleaners, polishes waxes, and industrial cleaning compounds)		X	X	
Personal care products				
Cosmetics	X	X Lotions, creams & ointments		
Toiletries	X	X		
Pharmaceuticals	X	X		
Industrial fluids				
Metal working fluids	X		X	
Anti-freeze (engine coolant)				
Lubricants	X	X Also used in dry powdered lubricants	X Also used in dry powdered lubricants	
Brake fluids				
Water treatment chemicals	X	X	X	
Fuel additives	X			
Metallurgy				
Steel & non-ferrous metal production (Flux agent)	X Prevents oxidation of	X	X	X

	Boric Acid	**Sodium tetraborate decahydrate (10 mol)**	**Sodium tetraborate pentahydrate (5 mol)**	**Sodium tetraborate anhydrous**
	metal surfaces			
Welding, brazing & soldering fluxes	X			
Plating	X			
Adhesives				
Starch Adhesive Formulation (corrugated Paper & Paperboard)	X	X	X	
Casein and dextrin based adhesive	X	X	X	
Flame retardants				
Wood products	X			
Cellulose Insulation	X	X	X	X
Cotton batting in mattresses/futons	X			
Fabrics	X			
Paper	X			
Biocides				
Wood preservative	X	X	X	
Non-professional remedial products	X		X	
Professional remedial products	X	X		
Agriculture				
Fertilizer	X	X	X	
Others				
Abrasives				X
Wallboard (plasterboard)	X			
Nuclear applications	X			
Cement	X		X	
Leather tanning	X	X	X	
Nylon manufacturing, paint	X			
Photographic chemicals		X	X	
Reagent chemicals	X		X	X

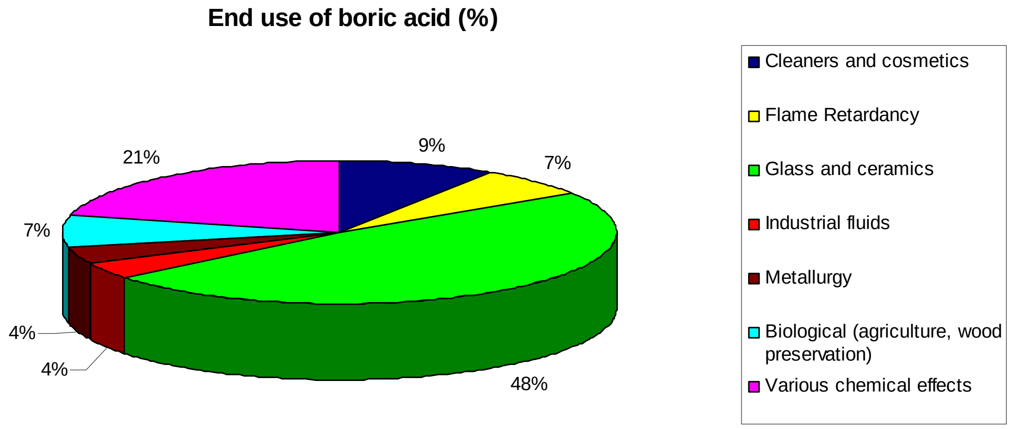


Figure 2.3: Division of boric acid by end use application (year 2007 data, confidential data) (EBA, 2008a)

Fig 2.3 shows that the major use sectors for boric acid are glass and ceramics (48%) (ceramic applications, Textile Fibre Glass, borosilicate glass) and the sector ‘various chemical effects’ (21%). Other important sectors are cleaners and cosmetics (9%) (liquid detergents mainly), flame retardancy (7%) and biological applications (7%) (agriculture (fertiliser) and wood preservation). Smaller quantities of boric acid (4% of total use each) are used in the industrial fluids and metallurgy sector.

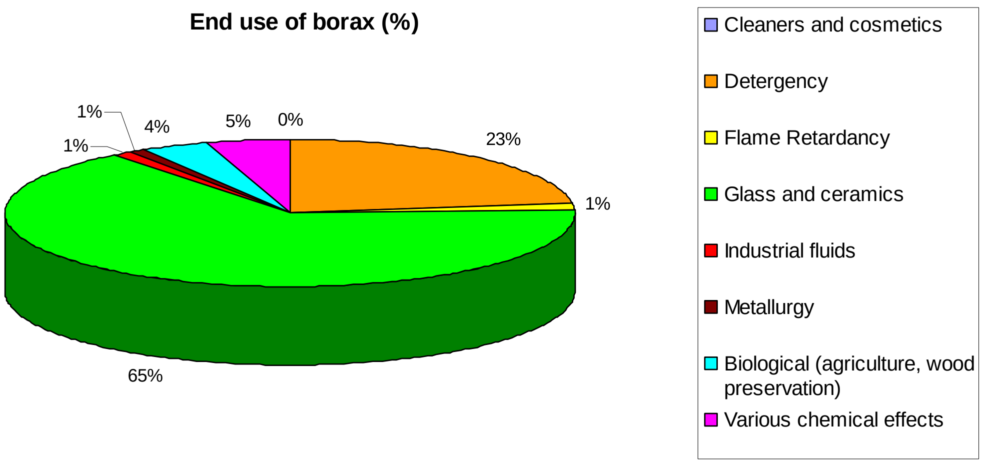


Fig. 2.4: Division of sodium tetraborates (anhydrous, pentahydrate, decahydrate) by end use application (year 2007 data, confidential data) (EBA, 2008a)

Fig 2.4 shows that the major use sectors for sodium tetraborates are glass and ceramics (65%) (Insulation FibreGlass, borosilicate glass, ceramic applications) and detergency (23%) (perborate). Sodium tetraborates are further used in the sector 'various chemical effects' (5%), biological applications (4%) (agriculture (fertiliser) and wood preservation), flame retardancy (1%), industrial fluids (1%) and metallurgy (1%).

For the purpose of exposure modelling, tonnage data as summarised in Fig 2.8 will be used. This table summarises the use volumes (expressed as B_2O_3) for different use sectors of boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate. Expressing all tonnages as B_2O_3, exposure scenarios can be developed for boric acid, sodium tetraborate compounds as well as combined uses of different compounds . This coincides with reality, since from questionnaire information it became clear that, in general, boric acid and sodium tetraborates are produced or used at the same site (Industry questionnaires; EBA, 2008b).

2.4 Uses advised against by the registrants

Section not relevant for this dossier

2.5 Description of targeting

Section not relevant for this dossier

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex I of Directive 67/548/EEC

Boric acid and the disodium tetraborates have been classified as Toxic to Reproduction, Category 2 as part of the 30th adaptation to technical progress of Directive 67/548/EEC (Commission directive 2008/58/EC, OJ L 246, 15.09.2008, p. 137).

Table 3.1: Harmonized classification according to 67/548/EEC

Index No	Chemical Name	Classification	Concentration Limits
005-007-00-2	Boric acid	Repr. Cat 2; R60-61 *	C ≥ 5.5%: T; R60-61
005-011-00-4	Disodium tetraborate anhydrous	Repr. Cat 2; R60-61 *	C ≥ 4.5%: T; R60-61
005-011-01-1	Disodium tetraborate decahydrate	Repr. Cat 2; R60-61 *	C ≥ 8.5%: T; R60-61
005-011-02-9	Disodium tetraborate pentahydrate	Repr. Cat 2; R60-61 *	C ≥ 6.5%: T; R60-61

* GHS: Category 1B, H360: May damage fertility or the unborn child

3.2 Classification in classification and labelling inventory/Industry's self classification(s) and labelling

Disodium tetraborate anhydrous, pentahydrate and decahydrate meet the criteria in Annex VI of Directive 67/548/EEC to self classify as eye irritants.

Table 3.2:Self-classification according to 67/548/EEC

Chemical Name	Classification
Disodium tetraborate anhydrous	Xi; R36
Disodium tetraborate decahydrate	Xi; R36
Disodium tetraborate pentahydrate	Xi; R36

* GHS: Category 2 Irritating to eyes, H319: Causes serious eye irritation

4 ENVIRONMENTAL FATE PROPERTIES

Boron represents an essential plant micronutrient with an average total concentration of 10 mg/kg in the earth's crust (Adriano, 2001). Dissolution of B-bearing minerals (e.g. tourmaline, muscovite), irrigation waters, fertilizers, atmospheric deposition of emitted B (e.g. coal fly ash) as well as the soils' buffer capacity, affect the B concentration in soil. The natural level of B in soils largely depends upon the soil parent material. In general, soils derived from igneous rocks and those of tropical and semitropical regions of the world are considerably lower in B content compared with soils derived from sedimentary rocks and those of arid and semiarid regions. The content of total B in the latter group may range up to 200 mg/kg, particularly in alkaline, calcareous soils, while that for the former group is usually lower than 10 mg/kg (Swaine, 1955, cited in Adriano, 2001).

It is estimated that 2 x 10^9 kg/year of boron is released into the environment through natural events such as generation of seawater aerosols, biomass burning, rock weathering, and volcanism (Park and Schlesinger, 2002). Boron mining for all uses is estimated to be about 3 to 4 x 10^8 kg/yr (Argust, 1998). The amount of boron mined (3 to 4 x 10^8 kg/yr), which amount is similar to to the amount emitted by volcanoes into the atmosphere (about 3 x 10^8 kg/yr, Argust, 1998).

Most anthropogenic boron (excluding coal-related materials) in Europe originates from mines in Turkey and California. Ratios of the boron isotopes ^{11}B and ^{10}B provide a tool to distinguish locally-derived boron from anthropogenic boron, although this has not been widely done (Vengosh et al., 1994; Chatelet and Gaillardet, 2005). ^{11}B separates preferentially into dissolved boron (i.e. boric acid), whereas ^{10}B is preferentially incorporated into solid phase (Vengosh et al., 1994). The boron-11 isotope enrichment value (identified as δ^{11}B) ranges from about 39‰in seawater, to about 0‰ in average continentual crust, to -0.9 to +10.2‰ in sodium borate minerals from Turkey and California (Vengosh et al., 1994). The ratio has been used to identify anthropogenic boron fractions in surface waters (Chatelet and Gaillardet, 2005) and groundwaters (Vengosh et al., 1994, Kloppmann et al, 2005).

4.1 Degradation

4.1.1 Stability

Borax decahydrate and inorganic borates (e.g., boric acid, sodium tetraborates) are soluble in water.. The chemical species present in solution depend on concentration and pH.

Only two soluble B species in ordinary soils can be expected (Adriano, 2001). The nonionized species, [$B(OH)_3$], is the predominant species expected in soil solution. Boric acid, [$B(OH)_3$], is a very weak, monobasic acid that acts as a Lewis acid by accepting a hydroxyl ion to form the borate anion, $[B(OH)_4]^-$. At pH greater than 9.2, $[B(OH)_4]^-$ becomes predominant.

$$B(OH)_3 + 2H_2O \leftrightarrow [B(OH)_4]^- + H_3O^+ \qquad pK_a = 9.2$$

In the pH range of 7 to 11, both species can be found.

With higher boron concentrations (B > 0.025 M) and increasing pH also polymeric B forms can precipitate, which are commonly very rare and unstable in soils. Therefore, boric acid and borate ions are the predominant B-forms in the natural soil system (Power and Woods, 1997; de Vette et al., 2001).

Boron as a natural element is not degradable. However, boron and its inorganic compounds are subject to chemical transformation processes (adsorption, complexation, precipitation,fixation) once released to the environment. One consequence of the transformation is that the mobility/bioavailability and the potential for toxicity, induced by the borate species, is changed and in many cases reduced or even removed over time. Thus, these natural processes achieve a similar result as is sought in the demonstration of biotic and abiotic degradation of synthetic organic chemicals.

Hydrolysis

Boric acid is an inorganic compound and does not have any chemical bonds prone to hydrolysis. Hydrolysis is therefore not a relevant degradation pathway under environmentally relevant conditions.

Photolysis in water

Boric acid is an inorganic compound without any light absorption characteristics in dilute solutions. It is therefore unlikely that the concentration of boric acid in water is influenced by light. Boric acid is therefore considered to be resistant to photochemical degradation.

Biodegradation

Boric acid is an inorganic substance and therefore biodegradation is not a relevant pathway. Methods used to determine persistence of organic chemicals are measures of the production of CO_2, uptake of O_2, or reduction in dissolved or total organic carbon. Such methods are clearly not applicable to inorganic substances. Persistence/degradability has therefore limited or no meaning for inorganic substances according to the Organization for Economic Cooperation and Development (OECD, 2001). Rather the substance may be transformed by normal environmental processes to either increase or decrease the availability of toxic species.

4.1.1.1 Biodegradation estimation

Not relevant

4.1.1.2 Screening tests

Not relevant

4.1.1.3 Simulation tests

Not relevant

4.1.2 Summary

Boric acid is an inorganic compound and not degradable, this is not subject to hydrolysis, photodegradation or biodegradation. Other borates yield boric acid upon dissolution in water (or borate anion in higher pH conditions). Over 200 minerals contain boron, mostly present as the sodium or calcium borate salt. Boron and its inorganic compounds are subject to chemical transformation processes (adsorption, complexation, precipitation, and fixation) once released to the environment.

Methods used to determine persistence of organic chemicals are measures of the production of CO2, uptake of O2, or reduction in dissolved or total organic carbon. Such methods are clearly not applicable to inorganic substances. Persistence/degradability has therefore limited or no meaning for inorganic substances according to the Organization for Economic Cooperation and Development (OECD, 2001). Rather the substance may be transformed by normal environmental processes to either increase or decrease the availability of toxic species.

4.2 Environmental distribution

The most important parameters determining the distribution of boric acid in the aquatic and soil compartment are its water solubility and its adsorption onto solid surfaces. Borates may enter the food-chain via plant consumption (as well as drinking water), which consequently increase B-concentrations in waste waters.

Sorption behaviour of boron in soils and sediments

Adsorption/desorption data are useful to gain information on the bioavailability, leaching potential and distribution of contaminants in soil and sediments.

The sorption and desorption behaviour of organic and inorganic pollutants in soil can be estimated by batch sorption experiments following a standard protocols (e.g. OECD guideline 106, 2000). In such experiments the solid matrix is equilibrated for 24 hours with an aqueous solution containing various concentrations of a test substance. Sorption isotherms are obtained when the sorbed amounts of the test substance are plotted against the test substance concentration in the equilibrium solutions. These sorption/desorption isotherms provide useful information about the retention capacity of a solid phase and the strength by which the sorbate is bound to this solid phase. However, no further information on sorption mechanisms (i.e. chemical bonding, physical bonding, absorption, precipitation) can be gained from such experiments.

The following plausible mechanisms are responsible for the chemical interactions of B with soil constituents: anion exchange, precipitation of insoluble borates with sesquioxides, sorption of borate ions or molecular boric acid, formation of organic complexes, and fixation B in clay lattice (e.g. Goldberg, 1997; Adriano, 2001). Major sorption sites for B in soils are: (1) Fe-, Mn-, and Al-hydroxy compounds present as coatings on or associated with clay minerals, (2) Fe-, Mn-, and Al-oxides in soils, (3) clay minerals, especially the micaceous type, (4) the edges of aluminosilicate minerals and (5) organic matter (Goldberg, 1997; Adriano, 2001).

Keren and Bingham (1985) reported that the $B(OH)_4^-$ concentration and the amount of adsorbed B increased rapidly when the pH is increased to about 9. Maximum retention was reported at alkaline pH levels of up to 9.5 when boron is mainly present as the borate ion (WHO, 1998; Blume et al., 1980).

Boron was reported to react more strongly with clay than sandy soils (Keren and Bingham, 1985). The rate of B adsorption on clay minerals is likely to consist of a continuum of fast adsorption reactions and slow fixation reactions. Short-term experiments have shown that B adsorption reaches an apparent equilibrium in less than one day (Hingston, 1964; Kerenet al., 1981). Long-term experiments showed that fixation of B continued even after six months of reaction time (Jasmund and Lindner, 1973). The magnitude of B adsorption onto clay minerals is affected by the exchangeable cation. Calcium-rich clays adsorb more B than sodium and potassium clays (Keren and Gast, 1981; Keren and O'Connor, 1982; Mattigod et al., 1985).A higher organic matter content increases the B-retention capacity of soil (Yermiyahu et al., 2001). Sorbed B amounts and B retention maxima have been significantly correlated with organic carbon content (Gupta, 1968).

Microbial action can remobilize organic-bound B (Banerji 1969, Su & Suarez 1995, Evans & Sparks 198, as reviewed by Robinson et al. 2007). Boron sorption can vary from being fully reversible to irreversible, depending on the soil type and environmental conditions (Elrashidi & O'Conner, 1982, IPCS, 1998).

Derivation of a representative partitioning coefficient is used as a screening approach to evaluate risk to soil and aquatic organisms (Guidance in IR and CSA, Chapter R.7.a). The partitioning coefficient is used with a soil or sediment concentration value to roughly estimate -the mobility of substances in soil and sediment and to evaluate the leaching potential to groundwater -the concentration of a substance in the soil solution. When the substance concentration in the soil solution exceeds toxicity criteria, some risk to the soil or sediment organisms is indicated.

Partition coefficient of B for soils

Boron adsorption on soils and soil minerals has been described by many researchers using a number of soils and models. Some studies were conducted according to the OECD guideline and are presented below. Soil descriptions and constants of the Freundlich isotherms (K_F, 1/n) are listed in table 4.1.

A study on 4 soils of different composition collected in the Netherlands was performed by DeVette et al. (2000). The selected soils were considered to reflect the variability of European soils. The highest B mobility was found in the soil with the lowest soil pH (pH=5.5), whereas no further B-sorption trend was observed within the studied soils.

Elrashidi and O'Connor (1982) studied 10 New Mexico (US) soils described as silt loam, sandy loam (3), loamy sand, sand (3), clay, and clay loam. The Freundlich constant K_F were then modelled by regression techniques with selected soil properties. Iron oxide, organic carbon and specific surface area were reported to predict 98% of the variation of the K_F values. K_F was significantly correlated with clay, organic carbon content (OC), Cation Exchange Capacity (CEC), specific surface area and conductivity of the equilibrium solution when applying simple regression. In evaluating desorption, Elrashidi and O'Conner reported that boron sorption was reversible in four soils, but not reversible in six soils.

Buchter et al. (1989) reported results for 11 soils and 15 elements. They showed that boron is relatively mobile in soil when compared to cationic metals. For instance, the sorption of Zn was two to more than 10 times greater than for boric acid in the soils of different composition.The study showed that pH is the most important soil property that affects K_F and n.The amounts of amorphous iron oxides, aluminium oxides, and amorphous material in soils influenced both cation and anion retention parameters. Singh (1971) showed that B sorption increased with increasing temperature in three Indian soils. Datta and Bhadoria (1999) investigated 25 Indian soils and identified Fe_2O_3, clay and OC-content, pH and CEC as the significant soil properties affecting boron retention.

Table 4.1: Sorption of boron to soils

Soil type[a]	pH	OC [%]	Clay [%]	CEC [mmol/kg]	Soil:solution ratio [g:mL]	Concentration range[d] [mg B/L]	K_F [L/kg]	1/n	Reference
Sandy loam	7.7	0.9	15	10.7	1 :10	1-50	0.708	0.659	deVette et al. 2000
Low humic sand	7.4	0.4	2	2.0	1 :10	1-50	3.946	0.685	
Loam	7.8	0.9	26	13.4	1 :10	1-50	1.93	0.802	
Humic sand	5.5	1.4	3	9.8	1 :10	1-50	0.749	0.542	

Soil type[a]	pH	OC [%]	Clay [%]	CEC [mmol/kg]	Soil:solution ratio [g:mL]	Concentration range[d] [mg B/L]	K_F [L/kg]	1/n	Reference
Silt loam	6.02[b]	1.00	25.0	162	1:1	0 – 100	1.93	0.644	Elrashidi and O'Connor, 1982
Sandy loam	6.02 [b]	0.45	10.0	55	1:1	0 – 100	0.409	0.666	
Loamy sand	7.03 [b]	0.17	3.4	16	1:1	0 – 100	0.087	0.935	
Sand	8.00 [b]	0.02	5.0	62	1:1	0 – 100	0.125	0.947	
Sand	7.89 [b]	0.04	7.7	81	1:1	0 – 100	0.421	1.19	
Sand	7.82 [b]	0.04	5.6	78	1:1	0 – 100	0.162	0.843	
Clay	7.57 [b]	0.97	57.0	352	1:1	0 – 100	3.99	0.572	
Clay loam	7.54 [b]	1.10	27.3	185	1:1	0 – 100	3.33	0.623	
Sandy loam	7.62 [b]	0.57	14.5	141	1:1	0 – 100	2.53	0.618	
Sandy loam	7.42 [b]	0.43	13.7	140	1:1	0 – 100	2.16	0.645	
Clay	4.8[c]	1.54	54.7	302	1:10	0.01 – 100	1.49	0.363	Buchter et al., 1989
Sandy loam	8.5[c]	0.44	10.7	147	1:10	0.01 – 100	0.851	0.787	
Loamy sand	5.9[c]	6.62	0.9	225	1:10	0.01 – 100	8.41	0.891	
Clay loam	6.0[c]	1.67	28.2	110	1:10	0.01 – 100	1.39	0.518	
Loam	7.6[c]	4.39	23.9	481	1:10	0.01 – 100	1.60	0.641	
Sandy loam[e]	7.8	1.56	14.5		1:1	5 – 200	4.21	0.735	Singh, 1971
Sandy loam[f]	7.8	1.56	14.5		1:1	5 – 200	4.80	0.731	
Loam[e]	7.8	0.195	27.6		1:1	5 – 200	1.63	0.924	
Loam[f]	7.8	0.195	27.6		1:1	5 – 200	1.85	0.955	
Loamy sand[e]	8.2	0.154	8.5		1:1	5 – 200	0.571	0.903	
Loamy sand[f]	8.2	0.154	8.5		1:1	5 – 200	1.44	0.921	
Sand	6.27	0.13	4	7.9	1:1	2 - 100	0.218	0.701	Datta and Bhadoria, 1999[g]
Sandy loam	6.04	0.21	16	18.0	1:1	2 – 100	0.229	0.756	
Loamy sand	5.90	0.17	12	36.4	1:1	2 – 100	0.212	0.760	
Clay loam	5.80	0.70	36	93.5	1:1	2 – 100	2.826	0.570	
Loam	5.14	0.73	24	63.9	1:1	2 – 100	1.538	0.594	
Loam	4.99	0.78	20	97.6	1:1	2 – 100	1.610	0.597	
Loam	6.38	0.32	20	52.7	1:1	2 – 100	1.509	0.589	
Silt loam	5.51	0.57	24	95.6	1:1	2 – 100	1.799	0.620	
Clay loam	6.26	0.37	36	32.2	1:1	2 – 100	1.359	0.579	
Loam	6.11	0.27	24	82.2	1:1	2 – 100	2.564	0.546	
Loam	6.03	0.53	20	114	1:1	2 – 100	1.359	0.653	
Sandy loam	5.50	0.28	16	42.5	1:1	2 – 100	0.460	0.657	
Sandy loam	5.68	0.43	8	32.0	1:1	2 – 100	0.780	0.613	
Sandy loam	5.54	0.22	20	37.4	1:1	2 – 100	0.400	0.726	
Sandy loam	5.63	0.32	12	34.9	1:1	2 – 100	0.686	0.588	
Sandy loam	5.42	0.30	20	50.6	1:1	2 – 100	0.576	0.658	
Sandy loam	5.13	0.30	12	93.7	1:1	2 – 100	0.439	0.734	

Soil type[a]	pH	OC [%]	Clay [%]	CEC [mmol/kg]	Soil:solution ratio [g:mL]	Concentration range[d] [mg B/L]	K_F [L/kg]	1/n	Reference
Sandy loam	6.06	0.29	20	56.4	1:1	2 – 100	1.940	0.615	
Sandy clay loam	5.97	0.53	24	107	1:1	2 – 100	1.138	0.675	
Clay loam	5.86	0.48	40	144	1:1	2 – 100	3.005	0.585	
Clay	5.80	0.49	44	199	1:1	2 – 100	2.891	0.621	
Sandy clay loam	5.30	0.53	32	87.8	1:1	2 - 100	1.581	0.620	
Clay	5.68	0.54	44	176	1:1	2 – 100	3.283	0.539	
Clay loam	5.90	0.69	40	156	1:1	2 – 100	2.810	0.602	
Clay loam	5.50	0.56	36	115	1:1	2 – 100	2.949	0.569	

a: USDA classification;
b: 1:1 soil/0.01 M $CaCl_2$;
c: 1:1 soil/water;
d: number of concentrations not reported in Elrashidi and O'Connor (1982), but > 5 according to figures; 10 concentrations used in Buchter et al. (1989), 6 in Singh (1971) and 8 in Datta and Bhadoria (1999);
e: 22 °C;
f: 45 °C;
g: article gives ranges of K_F and 1/n, raw data provided by author

Table 4.1 shows that levels of B-sorption are relatively low (K_F values ranged between below the detection limit to 8.4 L/kg) indicating a low retention capacity of soil for B. In all cases, the value of 1/n was below 1, indicating the sorption was non-linear. 1/n values revealed a strong decrease of sorbed B with increasing amounts of B added to the soils, which can be explained by the saturation of specific sorption sites for B (e.g. Fe-oxides, Al-oxides).

Correlations based on Freundlich isotherms and soil properties are empirical approaches and are applicable only for the specific conditions under which they were developed. Use of empirical models beyond these conditions could potentially lead to significant error and therefore such models must be used with appropriate caution (Goldberg et al, 2007).

A robust approach to modelling adsorption based on mechanistic considerations has been developed by Goldberg and colleagues, as she has described and tested a predictive model of boron adsorption (Goldberg, 1999, 2004, Goldberg & Glaubig 1986, Goldberg et al., 2000, 2004, 2005). The model is described as a constant capacitance model (CCM) and predicts adsorbed B from easily measured soil properties (surface area, organic carbon content (OC), inorganic carbon content (IOC), free Al oxide content). The soil parameters are used to calculate three surface complexation constants, described as the B adsorption constant, the protonation constant, and the dissociation constant. Initial studies described B adsorption on Al and Fe oxides, clay minerals and soils (Goldberg and Glaubig, 1986). The approach was evaluated with 4 California soils (Goldberg 1999) using parameters developed as an average from a previous study, thus testing its predictive ability. Subsequently, the model allowed prediction of B adsorption behavior (without re-parameterizing the model constants) for 15 soils from the western US (California) (Goldberg et al. 2000) and 22 Midwestern US soil samples (Oklahoma and Iowa; Goldberg et al., 2004).

The parameters used in the CCM (especially IOC and free aluminum oxide content) were not tested for European scenarios. Therefore, the ability to apply the CCM within the risk assessment framework is unclear so far. It can be recommended, that industry considers making use of the CCM for the REACH dossier to increase the relevance and accuracy of the environmental assessments.

Partition coefficient of B for sediments

Two recent studies reported partition coefficients for boron in the aquatic system. The reported values are representative for the marine environment, but may give a first indication on the partitioning of boron in the freshwater sediment environment. You et al. (1995) monitored the geochemical behavior of boron in sediment during early subduction zone processes and determined the K_D of exchangeable B under different temperature, pH and pressure regimes.

Under physicochemical conditions that reflect typical conditions in surface waters (i.e. pressure of 1 bar; 25°C, pH of 6.1) a K_D value of 2.9 was observed. At a pH of 7.1 the K_D increased up to 3.1. The values that are reported by You et al. (1995) are in accordance with the K_D values that were found by Palmer et al. (1987). These authors noted that the K_D increased from 2.0 to 3.1 when pH increased from 7.4 to 8.1 (temperature: 5°C; pressure: 1 bar).

These values are within the range of K_D values found in the soil compartment.

You et al. (1996) performed a similar study with suspended solids, using pore waters. Under various conditions of pH, temperature and pressure 68 K_D-values were reported. In general, K_D decreased with reaction temperature, from ≈3.5 at 25°C to essentially zero at temperature higher than 120°C. They also found that pH exerts a dominant control on B partitioning. K_D dropped significantly with pH at constant temperature, approximately 0.6 to 0.9 for every pH within the tested pH range (5.4 – 7.4). The observed effect can be attributed to the effect of pH on borate speciation and surface characteristics (Bassett, 1976; Palmer et al., 1987).

Based on their findings, You et al. (1996) derived two empirical equations for the estimation of a B-K_D:

$K_D = -3.84 - 0.020 * T + 0.88 * pH$ ($r = 0.84$) for pelagic clay rich sediments

$K_D = -1.38 - 0.008 * T + 0.59 * pH$ ($r = 0.81$) for sediments that have experienced progressive metamorphism.

Table 4.2 summarizes the different sediment and suspended solids K_D values that have been identified from open literature. No partition coefficient distribution was developed as an insufficient amount of data points were available for either the sediment phase or the suspended solid phase.

Table 4.2: Overview of sediment and suspended solids K_D values

K_D-value	pH	Reference
	Sediment compartment	
2.9 L/kg	6.1	You et al, 1995
3.1 L/kg	7.1	You et al, 1995
2.0 L/kg	7.4	Palmer et al, 1987
3.1L/kg	8.1	Palmer et al, 1987
Average value: 2.78 L/kg		
	Suspended solids	
3.5 L/kg	--	You et al, 1996

Conclusion

For the risk characterization, a mean partition coefficients for B in soil and sediments needs to be estimated. This is a simplification, as soil and sediments show a high heterogeneity, influenced by the properties of the parent material, the state of pedogenesis, the vegetation cover and human activities. In general, the B sorption capacity of soil and sediments is low and often soil sorption maxima can be found in literature. According to the studies presented in this section, 1.5 mg/kg B was retained on average by the soil matrix when the B concentration in the equilibrium was 1 mg/L. This value minor exceeds the B sorption in a soil showing frequent properties of soil in Central Europe (pH 6.0, 1.7% orgnic carbon, 28% clay, 1.3 g Fe_2O_3).

The Freundlich isotherm for this soil is decribed by a K_F value of 1.39 and a 1/n value of 0.518 (Buchter et al., 1989).

The reliability of the partitioning coefficient data values is limited dueto the limited analytical precision used in the studies. The variability in sorption behaviours (linear, non-linear) reveals different sorption capacities for soils. . To compare the soil sorption capacities, the sorbed amount of B (mg/kg) is recommended when 1 mg/L of B is in the equilibrium solution ($K_F = K_D$).

To avoid concerns about left-censored data, all values, including those less than 3 L/kg will be used to estimate a representative K_F value for soil. Using all data, the average K_F value is 1.78 L/kg. The 50th percentile value is 1.52 L/kg and this value is proposed.

The chemistry of B in soils and aquatic systems is very simple, as boron does not undergo oxidation-reduction reactions or volatilization. Redox processes can mobilize Fe and Mn-oxides, which may lead to a release of B in aquatic systems. Generally, sediments are chracterised with higher pH values than the soil matrix, which increases the B sorption capacity. Therefore the average value of 2.78 L/kg is proposed as tentative sorption value for boron in the sediment phase. The K_D value of 3.5 L/kg (You e al, 1996) is put forward as sorption value for the suspended solids phase.

The following B-sorption values (i.e. K_D or K_F) are proposed (if 1 mg/l B is in solution):
Soil: 1.5 mg/kg
Sediment: 2. 8 mg/kg
Suspended solids: 3.5 mg/kg

Recommendations for further work

For its REACH registration dossier, Industry should consider:

-validation of the CCM model developed by Goldberg and colleagues for European soil conditions. Kinetcs of sorption over time may be an additional aspect of such models and application of a validated model would increase considerably the accuracy of the risk assessment.

-development of a more reliable B-sorption value or model for sediments

-development of a more reliable B-sorption value for suspended solids

4.2.1 Volatilisation

The vapour pressure for boric acid is extremely low so volatilization is expected to be minimal. The exception is over the oceans, where evaporation of aerosols leads to small but measured quantities of boric acid vapour in the marine atmosphere (see 7.3). The solubility of such materials means that they are re-deposited into the oceans or as precipitation in coastal areas. Marine evaporation is estimated as 1.3 to 4.5 x 10^9 kg-boron per year globally (Argust, 1998, Park and Schlesinger, 2002).

4.2.2 Distribution modelling

No data available.

4.3 Bioaccumulation

The WHO (1998) review of boron noted that highly water soluble materials are unlikely to bioaccumulate to any significant degree and that borate species are all present essentially as undissociated and highly soluble boric acid at neutral pH. The available data indicate that both experimental data and field observations support the interpretation that borates are not significantly bioaccumulated

4.3.1 Aquatic bioaccumulation

4.3.1.1 Bioaccumulation estimation

For inorganic chemicals, estimates of bioaccumulation potential are not reliably predicted by octanol/water partitioning data. Although boric acid has a low measured Pow value (log Pow = -1.09, Cordia, 2003a), the result should not be considered an appropriate model system.

4.3.1.2 Measured bioaccumulation data

Laboratory data in oysters and salmon demonstrate low Bioconcentration Factors (BCF) for boron, although the tests pre-date current protocols. Thompson et al. (1976) reported BCF values of 0.7 to 1.4 L/kg for Pacific oysters (*Crassostrea gigas*) and showed that boron levels in tissue of sockeye salmon (*Oncorhynchus nerka*) were not significantly different from test water concentrations. Tissue concentrations in the oyster returned to background in 25 days. Hamilton and Wiedmeyer (1990) reported BCF < 0.1 in Chinook salmon fed boron-supplemented diets for 60 to 90 days.

Suloway et al. (1983) reported a bioconcentration factor of 0.3 L/kg for fathead minnow (*Pimephales promelas*) and green sunfish (*Lepomis cyanella*), when exposed to components of coal fly ash extract containing boron at concentrations ranging from 1.23 to 91.7 mg/L.

Saiki et al. (1993) measured boron levels in aquatic food chains in the Lower San Joaquin River (California, United States) and its tributaries. They observed the highest concentrations of boron in detritus and filamentous algae, and lower concentrations in invertebrates and fish. Saiki et al did not calculate accumulation factors and many of their analytical values were below their detection limits. Using only measurements above detection limits, the average BCF for filamentous algae was 137 L/kg (standard deviation of 224). Bioaccumulation factors (BAF) for plankton and invertebrates were less than 20 L/kg; BAF for fish were < 5 L/kg. (Since these are field data, the body concentrations reflect uptake via both food and from water; BCF values theoretically reflect uptake from water only.) If measurements below detection limits are taken to be equal to the detection limit value, the estimated values are: algae-BCF ca.190 L/kg, plankton and invertebrates-BAF <20 L/kg, and fish-BAF ca. 8 L/kg.

4.3.2 Terrestrial bioaccumulation

Regarding bioconcentration into terrestrial plants, boron is known to be a critical element for the normal growth and productivity of plants. Boron is required in plants for normal metabolic functioning with regard to: sugar transport, cell wall synthesis, lignification, carbohydrate metabolism, RNA metabolism, respiration, indole acetic acid (growth regulator) metabolism, phenol metabolism, the integrity of membranes, and the pollination process (Marschner, 1995). There is a certain minimum requirement of B for a plant. However, there are considerable interspecies differences in the levels required for optimal growth. Monocotyledons generally require less then dicotyledons (Gupta et al, 1985)

Boron uptake varies with stage of growth and the concentration varies among the plant parts (Gupta et al, 1985). Plants also are known to change soil pH locally by root exudates to enhance uptake of essential nutrients (Reimann et al. 2001, WHO 1998).

The uptake mechanism has long been debated. It was first suggested that B moves to the root surface in the soil solution by mass flow and enters the roots by passive diffusion (Bingham et al, 1970). However this concept has been challenged by Bowen (1968, 1969, 1972), Bowen and Nissen (1977), Reisenauer et al (1973). They indicated that B is actively absorbed in ionic form particularly when boron concentration in soil is low (Gupta et al, 1985). This has been confirmed by more recent studies, which provided evidence for channel- and/or transporter-mediated B transport systems (Tukano et al, 2005). The isolation of the B transporter in bor1-1 mutant plants showed elevated sensitivity to B deficiency, especially in young growing organs in shoots. BOR1 is a membrane protein that belongs to the bicarbonate transporter superfamily (Takano et al, 2002 and Frommer et al 2002).

Takano et al (2005) found that the activity of the plasma membrane transporter for B in plant -BOR1- is regulated (endocytosis and degradation) by B availability, to avoid accumulation of toxic levels of B in shoots under high-B supply, while protecting the shoot from B deficiency under B limitation.

Once in the plant, boron is passively carried in the transpiration stream to the leaves where the water evaporates and boron accumulates. This explains, why boron concentrations are generally lower in roots, stems, and fruits than in leaves (WHO 1998). Once assimilated by the plant, boron becomes one of the least mobile micronutrients (Wolg 1940, Eaton 1944, Dible and Berger, 1952). Since boron is not readily transported from old to young plant parts, the earliest deficiency symptoms are found in young parts while the earliest toxicity symptoms are found in the old plant parts (Gupta et al, 1985).

As reviewed by WHO (1998), Eaton measured leaf concentrations of 50 plant species grown in sand culture beds supplied with liquid nutrient solutions. At nutrient solutions of 5 mg B/L, Eaton (1944) found leaf concentrations ranging between 58 and 1804 mgB/kg-dw. At nutrient solutions of 25 mg B/L, Eaton found leaf concentrations from 209 to 3875 mg B/kd-dw. To express BSAF as a ratio of the plant tissue dry weight to a soil dry weight, one could hypothesize an equilibrium soil boron concentration using the Kd value of 1.63 l/kg, as estimated in Section 4.2.1. This approach would estimate BSAF values of 7.4 to 221.5 kg/kg (5 mg-B/L solution) and BSAF values of 5.2 to 44.2 kg/kg at 25 mg-B/L. However, plant roots may not behave the same in soil solution cultures as in real soils, so these BSAF estimates must be considered as highly uncertain.

Riley et al. (1994) measured boron concentrations in barley and soil, and obtained whole shoot/soil ratios of 38 to 67.5 on a dry weight basis; these ratios can be considered as estimates of BSAF values. They also found that concentration of B in the youngest emerged blades is influenced by sudden changes in the uptake of B caused by such factors as changes in soil moisture or environmental conditions affecting plant transpiration.

The phytotoxicity of boron limits the potential for excessive accumulations beyond “normal” plant tissue concentrations. Oertli and Kohl (1961) noted that necrotic or chlorotic tissues contained only a few times the boron content of green tissues, in some cases the concentration of boron in green and necrotic/chlorotic leaves were in the same range. For example, green carrot tissues contained 470 to 960 mg/kg boron, while necrotic tissue contained 2000 mg/kg – suggesting that even with excess supplies of external boron, accumulations in plant tisse would be only 2 to 5 times “normal” tissue concentrations. Healthy bean tissue contained 630 to 680 mg/kg boron, whereas necrotic tissue contained 1960-2510 mg/kg, s 3.3 to 4-fold ratio. On the other hand, green leaves of cantaloupe contained a boron concentration of 510 – 1200 mg/kg, whereas chlorotic leaves contained 600 – 930 mg/kg. They came to the conclusion that the differences in the time necessary for plants to show toxicity sympthoms are not caused by different tolerances of tissues to boron, but rather a function of the rate of accumulation of boron. If one plant species is very sensitive to boron, and another insensitive, it could be because the sensitive plant species accumulates boron very rapidly, whilst the less sensitive species accumulates it more slowly. In either leaf the cells will die at similar boron concentrations. This contrasts with bioaccumulative substances that have no apparent deletrious effects on plants so there is no self-limiting factor. It should also be noted, that due to the fact that Boron uptake strongly depends on transpiration which is influenced by climate and environment, some seasonal changes in boron tolerance were observed by Eaton (1945).

Robinson et al. (2007) found that when grown in a substrate containing 30 mg B/kg-dw , hybrid poplars (*Populus sp.*) accumulated an average of 845 mg/kg in the leaves, some 20 times more than other species grown in the same environment. Thus, they suggest growing poplars for the phytomanagement of boron contaminated sites. The substrate at this site -wood waste- contained 28 to 36 mg B/kg-dw soil (average 30 mg B/kg-dw) and the poplar leaves contained 776 to 1012 mg B/kg-dw (average 845 mg B/kg-dw). Using the ratio of tissue: soil to estimate accumulation gives BSAF values of 27.7 to 28.1. Because poplar is a hypoaccumulator, it may not be a representative species for evaluating terrestrial bioaccumulation, however.

Reimann et al (2001) reported in an investigation of 7 of the most common vascular plants (blueberry, cowberry, crowberry, birch, willow, pine and spruce), and 2 moss species of northern Europe that vascular plants clearly regulate their nutrient uptake via their roots, whilst moss receive most of their nutrients directly from the atmosphere. Almost 500 leaf samples and almost 100 soil samples were taken from 9 different catchment areas in the Baltic area. The average boron concentration in moss was 3.31 mg B/kgdw, while the average boron concentration in leaves of 7 vascular plants ranged between 14 and 32 mgB/kgdw. Soil boron concentrations were only determined -using the aqua regia extract- in the C-horizon. An average concentration of 2.5 mg B/kgdw soil was found. Assuming all roots of vascular plants would be located in the C-horizon, estimated BSAF values would range between 5.6 and 12.8 kg/kg.

Vetter (1995) found that the average boron content of 68 edible macrofungi of Hungary contained more boron (11.74 mg/kg dry mass) than the average green plant (7.4 mg/kg dry mass). The highest concentration found was 53 mg/kg dry mass in the species *Marasmius qynnei*, a non-edible species, a value 4-5 times higher than the average of edible macrofungi. This illustrates that accumulation is dependent on the species. However, no soil boron concentrations were reported, making comparison with other plant data not possible.

Mallard ducks have been studied as representative of terrestrial non-predatory organisms that consume plant food. Pendleton et al. (1995) monitored body tissue levels on diets with 1600 mg-B/kg for up to 48 days. Boron levels were higher on day 32 than on day 4 and differed among all tissues, with the highest levels in blood (average 50.2 mg/kg), followed by brain (31.4 mg/kg) and liver (24.9 mg/kg). Pendleton et al. did not report BAF values directly; however the reported data do permit calculation of the ratio of boron concentration in the tissue to boron in the diet, which represents a BAF. Pendleton et al reported that the diet contained 1600 ppm added boron. The tissue/food ratio (BAF) was thus less than 0.1. Pendleton et al. noted that boron was rapidly eliminated within 1 day on a “clean diet.”

Stanley et al. (1996) also reported boron concentrations in mallard egg and livers after feeding boron-added diets. Adult duck livers contained 4.6 mg B/kg and 8.5 mg B/kg when fed diets with 450 and 900 mg B/kg, respectively. Duck eggs contained 6.5 and 11 mg B/kg, and duckling liver contained 7.6 and 13 mg B/kg for the same diets. The tissue: food ratio (BAF) was thus less than 0.1 for all tissues.

Data also exist for herbivorous mammals that confirm rapid elimination of boron. Assuming first order kinetics for elimination, the half-life was estimated to be approximately one hour for mice and less than 12 hours for rats (Farr and Konikowski 1963; Ku et al. 1991, 1993). In rabbits, 50 to 66% of an orally administered dose of boric acid was excreted in the urine in the first 24 hours after dosing (Draize and Kelley, 1959). In cows, Owen (1944) observed essentially quantitative recoveries of boron in the urine and feces of animals fed daily rations fortified with borax

4.3.3 Summary and discussion of bioaccumulation

Boron is known to be a critical element for the normal growth and productivity of aquatic and terrestrial plants. Boron is incorporated into plant cell walls, so some accumulation vs. the environment may be anticipated, i.e., active transport. The minimum required level in plants is dependent on the plant species.

While several studies report concentrations on boron in plant tissues, only few provide both soils and tissue concentrations, data required to derive the BSAF values. Measured BSAF in barley, are provided by Riley et al. (1994) and range from 38 to 67.5 kg_{soil}/kg_{plant}. Robinson et al (2007) report boron levels in boron contaminated soils and leaves of poplar –a known hyperaccumulator of metals- from which BSAF values can be derived of 27-30. These values are well below BSAF values used to establish significant bioconcentration (BSAF 3000 to 5000).

4.4 Secondary poisoning

Secondary poisoning concerns the potential toxic impact of a substance on a predatory bird or mammal following ingestion of prey items (i.e. fish and earthworms) that contain the chemical. Accumulation of chemicals through the food chain may follow many different pathways along different trophic levels. This assessment is required for substances for which there is an indication for bioaccumulation potential. (Guidance on IR and CSA, chapter R7C p 89).

Boron accumulates in aquatic and terrestrial plants but does not magnify through the food-chain. BSAF values derived from tests performed in real soils are generally < 100. Data from both lab and field observations indicate that body burdens of boron decrease at higher trophic levels. Because boron is incorporated into plant cell walls, a diet rich in plant material is correspondingly high in boron, compared to diets rich in meat or fish. However, data from animals and humans indicates that boron is quickly removed via feces and urine, so body concentrations do not continually increase. Consequently, the potential for secondary poisoning is not significant.

5 HUMAN HEALTH HAZARD ASSESSMENT

A number of detailed hazard assessments and reviews of the toxicology of borates have been published (Culver et al, 1994a; ECETOC, 1995; EC, 1996; Murray, 1995; Hubbard, 1998; IPCS, 1998; WHO; 1998; Moore et al., 1997; US EPA, 2004; UK EVM, 2003; EFSA 2004, HERA, 2005).

Most of the simple inorganic borates exist predominantly as un-dissociated boric acid in dilute aqueous solution at physiological and environmental pH, leading to the conclusion that the main species in the plasma of mammals and in the environment is un-dissociated boric acid. Since other borates dissociate to form boric acid in aqueous solutions, they too can be considered to exist as un-dissociated boric acid under the same conditions.

The majority of toxicological studies of borates have involved either boric acid (H_3BO_3) or disodium tetraborate decahydrate (i.e., borax, or $Na_2B_4O_7.10H_2O$). Both acute and longer-term studies have been carried out on these two substances. For the other borates, boric oxide, disodium tetraborate pentahydrate, and disodium tetraborate anhydrous, only acute mammalian toxicity studies have been carried out.

For comparative purposes, dose levels of borates have been expressed in terms of boron (B) equivalents based on the fraction of boron on a molecular weight basis. Conversion factors are given in table 5.1 below. These conversion factors are important as some studies express dose in terms of B, whereas other studies express the dose in units of boric acid or disodium tetraborate decahydrate. In this report boric acid and disodium tetraborate anhydrous are being evaluated. Since the systemic effects and also some of the local effects of both substances can be traced back to boric acid, the main species present at physiological pH-values, results from one substance can be transfered to also evaluate the other substance on the basis of boron equivalents. Further, since also disodium tetraborate decahydrate and disodium tetraborate pentahydrate build boric acid in aqueous solution at physiological pH-values, results for these substances can also be used on the basis of boron equivalents.

Table 5.1: Conversion factors to Boron Equivalents

	Substance	Conversion factor for Equivalent dose of B
Boric acid	H_3BO_3	0.175
Disodium tetraborate decahydrate (Borax)	$Na_2B_4O_7 \bullet 10H_2O$	0.113
Disodium tetraborate pentahydrate	$Na_2B_4O_7 \bullet 5H_2O$	0.148
Disodium tetraborate anhydrous	$Na_2B_4O_7$	0.215

5.1 Toxicokinetics

The toxicokinetics of boric acid, boron oxide, and the sodium tetraborates (anhydrous, pentahydrate and decahydrate) are similar in rats and humans with respect to absorption, distribution, and metabolism (Dourson et al., 1998; Murray, 1998).

Absorption

Oral Absorption

Boric acid and the simple sodium borates given orally are readily and completely absorbed in humans and animals. Animals investigated include rats (Ku et al., 1991), rabbits (Draize & Kelly, 1959), sheep (Brown et al., 1989) and cattle (Owen, 1944; Weeth et al., 1981) as shown by the levels of boron in urine, blood or tissues. In rats fed ^{10}B (boron 10-isotope) at a dose of 20 µg 95% and 4% was recovered from urine and feces respectively within 24 h. Isotope ratios $^{11}B/^{10}B$ measured in the urine changed from the natural abundance of 4.11 to an enriched ratio of 0.951 during the first 3 days after the test meal was fed to rats (Vanderpool et al., 1994). In six adult human volunteers given a single oral dose of 131 mg B (as boric acid dissolved in water), 94% of the administered dose was excreted in the urine over a 96 hour period (Schou et al, 1984). Similar absorption was observed based on urinary excretion of boron in 6 volunteers drinking curative spa water with a high boron content (daily dose of 102 mg B) for two weeks (Job, 1973). In another study, greater than 90% was absorbed in human volunteers taking in 3% boric acid in an aqueous solution or as a waterless emulsifying ointment spread onto biscuits (Jansen, 1984a). In a series of human volunteer studies conducted in the early 1900s, in which large doses of boric acid were repeatedly administered orally, approximately 80% of an administered dose was recovered in the urine, while 1% was recovered in the faeces (Wiley, 1904). Reports involving accidental human ingestion, particularly in infants, where new-born infants died after accidentally ingesting boric acid, provide further evidence of oral absorption (Wong et al., 1964). After accidental boric acid uptake in 9 patients, the mean half-life of boric acid was determined to be 13.4 hours (range, 4.0 to 27.8) (Litovitz et al., 1988). For human risk assessment purposes 100% oral absorption is assumed.

Inhalation Absorption

Studies in animals

In rats, inhaled boron oxide (anhydrous boric acid) aerosol was readily absorbed, based on the increased levels of boron excreted in the urine following inhalation exposure. It is not clear if the inhaled amount of boron was absorbed entirely by the respiratory tract Swallowed particles cleared from the respiratory tract may have contributed to systemic uptake. (Wilding et al.,1959). Since boron can deposit in the upper respiratory tract, additional excretion studies by this route would be useful in determining if excretion patterns are similar across all routes of exposure.

Studies in humans

On 5 consecutive days Culver et al. (1994) measured blood and urine boron concentrations of 14 male workers exposed to dust of disodium tetraborate anhydrous, disodium tetraborate decahydrate and disodium tetraborate pentahydrate at a borax packaging and shipping facility. 4 workers were exposed to low, 5 to medium and another 5 workers to high borax dust concentrations. Exposure based on an IOM air sampler (designed to collect the inspirable particulate mass) resulted in 4.7, 16.18, and 24.77 mg B/day, respectively. Blood levels for the medium and high exposure group were significantly higher compared to the pre-shift Monday morning values (0.1 µg B/ml). The high exposure category had a calculated mean daily blood boron level of 0.26 µg boron/g blood. Within this study non-occupationally exposed values for working adults were reported (min. 0.01, max. 0.36 µg boron/ml). The pre-shift urine boron measurements had a mean of 2.75 µg boron/mg creatinine. Post-shift values averaged 10.72 µg boron/mg creatinine. These values are slightly higher than the values for non-occupationally exposed workers, which range between 0.04 - 7.8 µg boron/ml urine (assuming that 1 ml urine contains 1 mg creatinine). Culver et al. recognised species differences, between boron intake and resulting blood-boron levels, therefore he concluded that blood boron levels should be used rather than boron intake levels. However, it is not clear what amount of inhaled boron was adsorbed through the respiratory tract. Due to the large size of particles the authors suggested that most of the inhaled borax would have been deposited in the upper respiratory tract, where it could have been adsorbed directly through the mucus or could have been cleared and swallowed. An estimated adsorption (dietary, air exposure) of 0.38 mg B/kg/day was calculated were no progressive boron accumulation across the 5 days occurred.

Dermal Absorption

Dermal absorption of borates across intact skin is insignificant in all species evaluated, including human new-born infants (no rise in plasma boron levels; Friis-Hansen et al., 1982), adult humans (no increase in boron excretion in urine; Beyer et al., 1983; Hui et al, 1996; Wester et al, 1998), rabbits (Draize and Kelley, 1959), and rats (no or slight increases in urine boron concentration Nielsen, 1970). Borates have been demonstrated to penetrate damaged or abraded skin (Draize and Kelley, 1959; Nielsen, 1970, Stüttgen et al., 1982). Additionally, boric acid has been shown to be well absorbed through mucus membranes (Baselt et al, 2004). However, the use of an ointment-based vehicle may change the absorption though diseased skin compared to an aqueous jelly based vehicle (Nielsen, 1970 and Stüttgen et al, 1982), although the results by Stüttgen et al. (1982) have a number of flaws and are therefore not conclusive.

Skin absorption data was obtained in human volunteers (Hui et al., 1996; Wester et al., 1998). Volunteers (8 per group) were dosed (non-occluded) on a 900 cm^2 area (30cm x 30 cm) area of the back with ^{10}B enriched boric acid or sodium tetraborate decahydrate (5% in aqueous solution), or disodium octaborate tetrahydrate and disodium tetraborate decahydrate (10% in aqueous solution). Twenty-four hours later the residual dose was removed by washing. Boron was measured in the urine (coupled mass spectrometry). The absorption rates are given below.

Table 5.2: Dermal Absorption in Humans of boric acid and disodium tetraborate decahydrate

	Applied dose: **µg B / 900 cm**	**% Dose Absorbed ± SD**	**Rate of Absorption: Flux µg/cm^2/hr**	**Permeability Constant (Kp) (cm/hr)**
Boric Acid (5%)	2.45	0.226 ± 0.125	0.009	1.9 x 10^{-7}
Disodium tetraborate decahydrate (5%)	3.96	0.210 ± 0.194	0.00875	1.8 x 10^{-7}

SD standard deviation

The total recovery of the applied dose ranged from 48.8 - 63.6%, therefore 36.4-51.2% of the applied dose is not accounted for. The authors suggested that this may be due to loss to outside clothing and bedding. However, part of the lost dose may be located in the body or in the skin at the application site, which in that case should be considered as being absorbed. Based on other data, for instance, the low acute dermal limit studies carried out on sodium tetraborate pentahydrate and sodium tetraborate decahydrate (LD_{50} be > 2000 mg/kg bw) indicate minimal dermal absorption. In an acute dermal limit study on boric acid, the rabbit skin was abraded to increase the absorption. Even in this study limited symptoms were observed and the acute dermal LD_{50} was > 2000 mg/kg bw. This data could support minimal dermal absorption.

In vitro percutaneous absorption of ^{10}B enriched Boric Acid and Borax was tested on human skin. Absorption was determined by receptor fluid accumulation over a 24 hour dosing period and by skin content at the end of the 24 hr period. Percent doses absorbed were 1.2 for 0.05% dose, 0.28 for 0.5% dose and 0.7 for 5% dose. Skin surface soap and water washes removed 72, 86 and 81 percent doses after the 24 hr dosing interval (Wester et al., 1998).

The percutaneous absorption of disodium tetraborate decahydrate can be read across to disodium tetraborate pentahydrate and disodium tetraborate anhydrous. Disodium tetraborate pentahydrate only slightly less hydrated than the decahydrate. Anhydrous disodium tetraborate is the anhydrous salt of disodium tetraborate decahydrate and disodium tetraborate pentahydrate. For practical purposes one part of anhydrous disodium tetraborate is equivalent to 1.45 parts of disodium tetraborate pentahydrate; 1.9 parts of disodium tetraborate decahydrate; and in aqueous solution 1.23 parts of boric acid. Anhydrous disodium tetraborate is hygroscopic and takes up water to form a hydrated salt and like the other borates, in solution it will exist as undissociated boric acid. Since anhydrous disodium tetraborate and disodium tetraborate pentahydrate will form the various similar borates in the moistened form that it is applied to the skin, they are unlikely to be absorbed at any greater rate than the other borates tested.

Therefore, using the % dose absorbed plus standard deviation (SD) for boric acid, a dermal absorption for borates of 0.5% (rounded from 0,45%) can be assumed as a worse case estimate.

Distribution

There is no substantiated evidence of boron accumulation in humans or other animals although bone contains higher levels than other tissues and boron is slowly eliminated from bone (Alexander et al, 1951; Forbes et al., 1954; Forbes and Mitchell, 1957; Jansen et al, 1984b; Ward, 1987; Treinen and Chapin, 1991; Ku et al., 1991;1993; Culver et al., 1994b; Chapin et al, 1997).

Absorbed boron rapidly distributes throughout the body water in humans and animals. In a study of workers occupationally exposed to 10 mg/m^3 of airborne borax (0.22 mg B/kg/day), there was no progressive accumulation of boron in soft tissues during the working week as measured by blood and urine levels (Culver et al., 1993; 1994b). Similarly, Jansen et al. (1984a, b) concluded from pharmacokinetic studies of human volunteers that there was no tendency for boron to accumulate following a single i.v. dose of 600 mg of boric acid (approximately 105 mg B). Tissue levels of boron generally reached steady-state within three to four days among rats fed boric acid in the diet or drinking water for 28 days (Treinen and Chapin, 1991) or 3 – 4 days (Ku et al., 1991). Thus, boron does not accumulate in soft tissues with time in either humans or animals.

A poisoning case with boric acid in a pregnant woman indicated that borates can cross the placenta (Grella et al., 1976). The foetus was delivered early due to accidental poisoning of the mother with boric acid, and since no boric acid fetal blood or amniotic fluid concentrations were measured, it is not possible to conclude that boric acid passed the placenta. No information was presented on possible reproduction parameters.

In both humans and animals, boron levels in soft tissue are comparable to plasma levels, while a greater concentration of boron in bone is observed relative to other tissues. The most complete study of boron distribution conducted to date examined tissue disposition of boron in reproductive organs and other selected tissues in adult male rats fed boric acid, providing approximately 100 mg B/kg bw/day for up to seven days (Ku et al., 1991; 1993). All tissues examined, except bone and adipose tissue, appeared to reach steady state boron levels by three to four days. Bone achieved the highest concentration of boron (2 to 3 times plasma levels), and bone boron levels continued to increase throughout seven days of dietary administration (Ku et al., 1991). In contrast, adipose tissue concentration was approximately 20 % of the plasma level. No other tissues showed any appreciable accumulation of boron over plasma levels. In dogs, an accumulation in the brain, liver and fat was reported after a high single dose of 2000 mg (350 mg B)/kg bw boric acid (Pfeiffer et al., 1945). However, the accuracy of the analytical procedures in that study is questionable.

Previous studies also show a greater concentration of boron in bone relative to other tissues in humans (Alexander et al., 1951; Forbes et al., 1954;) and rats (Forbes and Mitchell, 1957). Boron levels in a number of tissues have been measured (Abou-Shakra, 1989; Ciba and Chrusciel, 1992; Ward, 1987; Sabbioni et al., 1990; Shuler et al., 1990; Minoia et al., 1990; 1994). In mice, boron distribution appeared to be homogenous in the tissues examined, except for higher levels in the kidney (bone was not analysed) (Locksley and Sweet, 1954; Laurent-Pettersson et al., 1992), but higher levels were found in bone in another study (Massie et al., 1990). In *vivo* and in *vitro* studies indicate that boric acid has a strong affinity for cis-hydroxyl groups, this effect is reversible and concentration dependent (WHO, 1998). Boric acid can form complexes with various biomolecules. It has an affinity for hydroxyl, amino, and thiol groups (IPCS, 1998). This may explain the higher concentrations of boric acid in bone, owing to the binding of to the cis -hydroxyl groups of hydroxyapetite.

Metabolism

Boric acid is not metabolised in either animals or humans, owing to the high energy level required (523kJ/mol) to break the B - O bond (Emsley, 1989). Other inorganic borates convert to boric acid at physiological pH in the aqueous layer overlying the mucosal surfaces prior to absorption. Additional support for this derives from studies in which more than 90% of administered doses of inorganic borates are excreted in the urine as boric acid. Boric acid is a very weak and exclusively monobasic acid that is believed to act, not as a proton donor, but as a Lewis acid, i.e., it accepts OH-. Because of the high pKa, regardless of the form of inorganic borate ingested (e.g., boric acid, borax or boron associated with animal or plant tissues), exists almost exclusively (>98%) as undissociated boric acid.

Elimination

In both humans and animals, boron is excreted in the urine regardless of the route of administration. It is excreted with a half-life of < 24 hours in humans and animals. Boron is slowly eliminated from bone (Chapin et al., 1997).

In humans, 99% of a single i.v. dose of boric acid was excreted in the urine; the plasma half-life was calculated to be 21 hours using a three compartment toxicokinetic model (Jansen et al., 1984b). Following oral intake of an aqueous solution of boric acid, the urinary recovery was 94 % (Jansen et al., 1984a); more than 50 % of the oral dose was eliminated in the first 24 hours, consistent with the 21 hour half-life in the i.v. study. Sutherland et al. (1998) showed in a boron balance study that only 8% of dietary boron is excreted in faeces. In a previous study, half-lives ranging from 4.0 – 27.8 hours have been reported from nine poisoning cases (Astier et al., 1988; Litovitz et al., 1988).

Elimination half-lives for animals have not been stated explicitly in the scientific literature, but they can be calculated or estimated from the data in the literature. In mice, assuming first order kinetics for elimination, the half-life was estimated to be approximately one hour, and in rat < 12 hours (Farr and Konikowski, 1963; Ku et al. 1991; 1993). In rabbits, 50 to 66% of an orally administered dose of boric acid was excreted in the urine in the first 24 hours after dosing (Draize and Kelley, 1959). A recent study indicated that the half-life may be only 3 hours in both pregnant and non-pregnant rats. The boron clearance in pregnant rats was slightly higher than in non-pregnant rats; however the difference was not statistically significant (Vaziri et al., 2001).

The major determinant of boric acid excretion is expected to be renal clearance since boric acid is excreted unchanged in the urine. Rats and mice generally have faster rates of renal clearance than humans since the glomerular filtration rate, as a function of body mass, is generally higher in rats and mice than in humans.

Clearances as a function of body surface area of 40.4 ± 3.2 ml/min/1.73m^2 for sodium tetraborate in male rats and 40 ml /min/1.73m^2 for boron in mice (Usuda et al., 1998; Farr and Konikowski, 1963) have been reported, although there are methodological and/or analytical limitations in both studies. In more recent studies boric acid clearance rates in non-pregnant rats and pregnant rats ranged from 29.0 ± 5.7 to 31.0 ± 4.5 and from 32.2 ± 5.1 to 35.6 ± 5.7 ml/min/1.73m^2, respectively (Vaziri et al., 2001).

In humans, Jansen et al (1984b) determined a clearance rate of 55 ml/min/1.73m^2 following an i.v. dose of 600 mg of boric acid (105 mg B). Farr and Konikowski (1963) also reported a similar value of 39 ml/min/1.73m2 in humans given 35 mg B/kg intravenously as sodium pentaborate, although there are methodological and analytical limitations to this 40 year old study. In a more recent study, renal clearance rates in humans were 68.30 ± 35.0ml/min/1.73m^2 for pregnant subjects and 54.31 ± 19.35 ml/min/1.73m^2 for non-pregnant subjects (Pahl et al., 2001). This indicates about 20 –25% greater clearance in pregnant humans, however, not statistically significant.

A comparison of the renal clearance between rats and humans in terms of body surface area indicated that humans clear boric acid slightly faster than rats (~1.7 - 1.9 times as fast), while a comparison by bodyweight indicates that humans may clear boric acid more slowly than rats (~ 3 - 4 times slower) (Pahl et al., 2001; Vaziri et al., 2001). The comparison by bodyweight is used for risk assessment purposes.

CONCLUSION

There is little difference between animals and humans in absorption, distribution, and metabolism. A difference in renal clearance is the major determinant in the differences between animals and humans, with the renal clearance in rats approximately 3-4 times faster than in humans.

Absorption of borates via the oral route is nearly 100%. For the inhalation route also 100% absorption is assumed as worst case scenario. Dermal absorption through intact skin is very low. For risk assessment of borates a dermal absorption of 0.5% is used as a realistic worst case approach. In the blood boric acid is the main species present. Boric acid is not further metabolised. Borates are distributed rapidly and evenly through the body, with concentrations in bone 2 - 3 higher than in other tissues. Boron is excreted rapidly, with elimination half-lives of 1h in the mouse, 3h in the rat and < 27.8 h in humans, and has low potential for accumulation. Boric acid is mainly excreted in the urine.

Table 5.3: Summary of Toxicokinetics of Inorganic Borates in rats and humans

Absorption	Readily absorbed orally and by inhalation (of respirable particles) Dermal absorption is very low (< 0.5%) except through mucus membranes and severely damaged skin
Distribution	Rapidly distributed through body water With the exception of bone - no accumulation in tissues
Metabolism	Not metabolised Exists mainly as boric acid in whole blood
Elimination	Excreted almost exclusively in the urine Half-life < 27.8 hours in humans Renal clearance is 3-4 times faster in rats than humans based on a body weight comparison

5.2 Acute toxicity

5.2.1 Acute toxicity: oral

Studies in animals

The borates are in general of low acute oral toxicity in mammals, including rats and mice. An accidental poisoning case in cows and a further study in goats do not suggest that these species are more sensitive to the effects of borates with respect to acute toxicity (Sisk et al., 1988; 1990). The rat LD50 values for the various borates are given below. No substantial differences in acute oral toxicity were seen in mice and dogs in the limited studies available. However, dogs exhibit an emetic effect in response to high doses of borates. The LD50 in dogs was determined to be > 3980 mg boric acid/kg (697 mg B) and > 6150 mg disodium tetraborate decahydrate (695 mg B) /kg (administered in a capsule). The dogs vomited shortly after treatment at all doses (158 mg boric acid (28 mg B)/kg and 246 mg disodium tetraborate decahydrate (28 mg B)/kg were the lowest doses tested) (Keller, 1962; Weir & Fisher, 1972). The main symptoms of toxicity seen in all species tested were CNS depression, ataxia and convulsions.

Two limit dose studies were conducted on disodium tetraborate anhydrous. In the first study, rats were dosed at 200 (43 mg B) and 2000 mg (430 mg B) /kg/ bw. At 2000 mg (430 mg B)/kg 2/5 male rats died. Slight body weight losses were recorded for both animals. Clinical signs indicated soft faeces, soiling of anogenital area, lethargy, hunched posture, ptosis, hypothermia and wasted appearance. In surviving males, signs of soft faeces, soiling of anogenital area and hunched posture were apparent but had resolved by day 4, but an unkempt appearance was noted between day 7 and termination (day 15). Piloerection and anogenital soiling was noted in 4 females of the same group, and these recovered by day 3. The only pathological effects observed were a distended stomach and darkened lungs in one rat that died and an enlarged liver, dark inflated lungs and red fluid in the thoracic cavity of the second rat that died. At 200 mg (43 mg B)/kg, apart from one male rat with an unkempt appearance no other clinical signs were observed. At 200 mg (43 mg B)/kg, no animals died and the only observation seen was an unkempt appearance in one male and one female at intervals during the second week. The LD_{50} was estimated to be > 200 mg (43 mg B)/kg bw in males and > 2000 mg (430 mg B)/kg in females. The second study was conducted to confirm that the LD50 is above 2000 mg (430 mg B)/kg/bw. Rats were dosed at 1600 (344 mg B) and 2500 mg (538 mg B)/kg. No deaths occurred at either dose. No effects were observed at 1600 mg (344 mg B)/kg. At 2500 mg (538 mg B)/kg, piloerection observed in one animal that recovered by day 2. No other adverse effects were observed (Denton 1995, 1996). Based on the data in the first study, it is likely that the LD50 is lower than 5000 mg (1075 mg B)/kg/bw.

Table 5.4: Acute Oral Toxicity Studies

Route	Method Guideline	Species Strain Sex no/group	Dose levels duration of exposure	Value LD_{50} /LC_{50}	Remarks	Reference
Boric Acid						
Oral	[1] No specific guidelines were available at the time of this study.	Rat: Sprague Dawley 5/group	2000; 2520; 3160; 3980;5010 and 6310 mg/kg bw	LD_{50} males + females = 3765 mg /kg bw (659 mg B/kg)	Other data supports a range of 2660 – 4100 mg/kg	Keller, 1962 Weir & Fisher, 1972; Pfeiffer et al., 1945
Disodium Tetraborate Anhydrous						
Oral	OECD 401	Rat: Crl:CD.BR 5/group	1600; 2500 mg/kg bw	> 2500 mg (538 mg B)/kg bw males		Denton. (1996).
Disodium Tetraborate Pentahydrate						
Oral	US EPA-FIFRA guidelines	Rat: Sprague Dawley 5/group	1000; 1495; 2236; 3344 5000 mg/kg bw	3305 (2403 - 4207) mg/kg (489 mg B/kg)		Reagan and Becci (1985a)
Disodium Tetraborate Decahydrate						
Oral	[1]Unknown	Rat: Sprague Dawley 5/group	4000; 4500; 5000; 5500; 6000; 6500; 7000 mg/kg bw	5560 (5150 - 6000) mg/kg (628 mg B/kg)		Meyding and Foglhian (1961),

[1] Although only old data is available for boric acid and for disodium tetraborate decahydrate, there are a number of studies in rats (and mice and dogs), which confirm the low acute oral toxicity of the borates. Further testing is therefore not justified in the interests of protecting laboratory animals.

Studies in humans

There is a large database of accidental or intentional poisoning incidents for humans. In the literature, the human oral lethal dose is regularly quoted as 2-3 g boric acid for infants, 5-6 g boric acid for children and 15-30 g boric acid for adults. This data is largely unsubstantiated. In most cases it is difficult to make a good quantitative judgment particularly since medical intervention occurred in most cases and there were often other unrelated medical conditions (Culver and Hubbard, 1996). Of 784 more recent reports of accidental ingestion, none were reported as fatal and 88.3% were asymptomatic. The estimated dose range was 10 mg to 88.8 g (Litovitz et al, 1988). However, a single intake of 30 g of boric acid was fatal in one case (Yoshitaka et el., 1993). Symptoms of acute effects may include nausea, vomiting, gastric discomfort, skin flushing, excitation, convulsions, depression and vascular collapse. Currently, sodium borate (borax) is frequently used in household cleaning products, wood preservatives and fungicides. In addition it is found as household pesticides to control ants, flies and cockroaches. One recent case of an 18-month-old child who died following the accidental ingestion of a boric acid-containing, commercially available roach pesticide (Hamilton, 2007) supports that the toddler population is currently at risk.

Two cases were chosen to demonstrate the course of acute effects on humans after ingestion of high boron concentrations.

Schillinger et al. (1982) reported the case of a 44 year old woman who had taken up half a container of boric acid powder (14g) in a suicide attempt. Within two days she developed widespread exfoliative dermatitis, which started with an erythema, first noted around the mouth. Within 24 hours it involved most parts of the body. After three days large sheets of desquamation were described. The skin lesions were accompanied by a persistent sensation of nausea with multiple episodes of vomiting. Three days after ingestion her hemoglobin value was 11.3g and her hematocrit 33.6%, seven days later these values had dropped to 6.5g and 19%, respectively. Bone marrow aspirate revealed hypercellularity, with an increase in the myeloid series, decrease in the erythroid series, adequate megakaryocytes, and iron present in the beginning. On day seven no hemolysis was observed in the peripheral blood smear and Coomb`s direct and indirect tests were negative. The bone marrow aspirate was indicative for bone marrow toxicity secondary to boric acid poisoning. The patient responded well to transfusion with three units of packed red cells. Four days after

ingestion she developed a fever of 39.0°C. On day ten she developed a patchy alopecia which progressed to alopecia totalis within a few days. Further, she showed central nervours system involvement, with loss of orientation to time and place, she had elevated liver function tests and oliguri. The patient responded well to hemaodialysis.
In another case a 62 year old received by mistake 40g boric acid instead of a glucose solution. The most important signs of poisoning were slight metabolic acidosis, total anuria for 14 hours and normochromic anaemia with a reduction of haemoglobin of 32%. All effects could be reversed by immediate dialysis, forced diuresis and gastric lavage (Stolpmann & Hopmann, 1975).

5.2.2 Acute toxicity: inhalation

Studies in animals

In an inhalation study in which rats were exposed to boric acid at actual concentrations of 2.12 mg (0.37 mg B)/L (highest attainable concentration) for 4 hours no deaths were observed. During the initial 1.5 hours of exposure to boric acid ocular and nasal discharge, hunched posture and hypoactivity were noted. Upon removal from the exposure chamber clear ocular and brown nasal discharge persisted in all animals. All rats recovered from these symptoms by day 2 and appeared active and healthy for the remainder of the study. Gross necropsy findings at terminal sacrifice were generally unremarkable (Wnorowski, 1997).

Studies in rats with disodium tetraborate pentahydrate (Wnorowski, 1994b) revealed LC50's of >2.04 mg (0.30 mg B)/L (2g/m3) respectively. All animals survived exposure to the test atmosphere. During the first hour of exposure, ocular discharge, hypoactivity and hunched posture were noted. Upon chamber removal, ocular discharge persisted in all rats and within several hours of exposure, two animals exhibited nasal discharge and all had a hunched posture. All rats recovered from the symptoms by day 6 and gained weight over a 14-day observation period. Gross necropsy findings at terminal sacrifice were generally unremarkable.

Studies in rats with disodium tetraborate decahydrate (Wnorowski, 1994a) revealed LC50's of >2.03 mg (0.23 mg B)/L. During the first hour of exposure, ocular discharge, hypoactivity and hunched posture were noted. Upon chamber removal, ocular discharge persisted in all rats and two animals had a hunched posture. All animals recovered from the above symptoms by day 7 and gained weight over the 14-day observation period. Gross necropsy findings at terminal sacrifice were generally unremarkable.

Although no test was carried out on disodium tetraborate anhydrous, it can be assumed that this substance would also have low acute inhalation toxicity.

There is no data from animal studies on boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate that indicated respiratory irritation.

Table 5.5 Acute Inhalation Toxicity Studies

Route	Method Guideline	Species Strain Sex no/group	Dose levels duration of exposure	Value LD$_{50}$ /LC$_{50}$	Remarks	Reference
Boric Acid						
Inhalation	OECD Guide-line 403 "Acute Inhalation Toxicity" (USEPA.FIFRA 40 CFR Part 160.	Rat : Sprague Dawley 5/group	Analytical concentration 2120 ±140 mg/m^3 4 hours	≥2120 mg (371 mg B)/m^3	MMAD 3.5 μm No deaths; ocular and nasal discharge, hunched posture and hypoacitivity. All rats recovered by day 2.	Wnorowski, (1997)
Disodium Tetraborate Anhydrous						
Read across from Disodium Tetraborate Pentahydrate and Disodium Tetraborate Decahydrate						
Disodium Tetraborate Pentahydrate						
Inhalation	OECD 403	Rat: Sprague Dawley	2g/m^3 nominal 4 hours	>2040 mg (302 mg B)/m^3	MMAD 3.1 μm No deaths; ocular	Wnorowski, (1994 b)

		5/group			discharge, hypoactivity and hunched posture were noted; nasal discharge in 2 rats. All rats recovered by day 6.	
Disodium Tetraborate Decahydrate						
Inhalation	OECD 403	Rat : Sprague Dawley 5/group	2g/m^3 nominal 4 hours	>2030 mg (300 mg B)/m^3	MMAD 3.6 µm No deaths; ocular discharge, hunched posture and hypoacitivity. All rats recovered by day 7.	Wnorowski, (1994 a),

MMAD … mean mass aerodynamic diameter

5.2.3 Acute toxicity: dermal

Studies in animals

The acute dermal toxicity of borates is low, being >2000 mg/kg bw for all borates tested. Although no test was carried out on disodium tetraborate anhydrous, it can be assumed that this would also have low acute dermal toxicity.

Table 5.6: Acute Dermal Toxicity Studies

Route	Method Guideline	Species Strain Sex no/group	Dose levels duration of exposure	Value LD$_{50}$ /LC$_{50}$	Remarks	Reference
Boric Acid						
Dermal	FIFRA (40 CFR 163) Acceptable protocol at the time	Rabbits; New Zealand White 5/group	Dosage to 2000 mg/kg bw: 24 hours	$\geq$ 2000 mg/kg bw (350 mg B/kg)		Weiner et al.,. 1982
Disodium Tetraborate Anhydrous						
Read across to Disodium Tetraborate Pentahydrate and Disodium Tetraborate Decahydrate						
Disodium Tetraborate Pentahydrate						
Dermal	[1]US EPA-FIFRA guidelines	Rabbits; New Zealand White 5/group	2000 mg/kg bw	>2000 mg/kg bw (296 mg B/kg)		Reagan and Becci, 1985b
Disodium Tetraborate Decahydrate						
Dermal	[1]US EPA-FIFRA guidelines	Rabbits; New Zealand White 5/group	2000 mg/kg bw	>2000 mg/kg bw (226 mg B/kg)		Reagan and Becci, 1985c

[1] This study was carried out to comply with US EPA-FIFRA guidelines at the time and carried out by the US Food and Drug Laboratories to GLP. Although it is not to modern protocols the data is consistent with other borate data and further testing is not warranted in the interests of animal welfare and protecting laboratory animals

Studies in humans

Several poisoning cases have been reported in humans. In pharmaceutical preparations boric acid has been used in the past as skin and mucosa antiseptic. Such medical uses are now obsolete because of its low efficacy and comparatively high toxicity. Also, accidental misuse in the preparation of baby formula (1 – 14 g in boric acid in the formula) and the topical use of pure boric acid powder for infants has led to poisonings in the past. This database is reviewed in several papers of data from poisoning centres as well as a detailed review of the literature cases from the mid 1800s to the 1970s by Kliegel (Kliegel, 1980; Wong et al. 1964, Litovitz et al, 1988; Goldbloom and Goldbloom, 1953; Valdes-Dapena and Arey, 1962).

5.2.4 Acute toxicity: other routes

Studies in animals

The acute intravenous LD_{50} s of a 5 % aqueous solution of boric acid were 1.78 g/kg and 1.33 g/kg in mice and rats respectively and the subcutaneous LD_{50} s were 2.07 g/kg and 1.2 g/kg for mice and guinea pigs respectively (Pfeiffer et al., 1945).

5.2.5 Acute toxicity: summary and discussion

Boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate are of low acute toxicity. Although the acute oral studies were not of modern standards and were performed prior to the introduction of GLP, they are reproducible across a number of studies and species and of acceptable quality. For acute dermal and acute inhalation some studies do meet the modern GLP standard. For all borates discussed above the acute toxicity results are: LD_{50} oral rat > 2000 mg/kg; LD_{50} dermal rat > 2000 mg/kg; LC_{50} inhalation rat > 2 mg/l.

Table 5.7: Summary of Acute Toxicity Data

Route	Value LD_{50} /LC_{50}	Reference
Boric Acid		
Oral	3765 (2660 – 4100) mg/kg	Keller (1962); Weir & Fisher, (1972); Pfeiffer et al., (1945)
Inhalation	$\geq$ 2120 mg/m³	Wnorowski, 1997
Dermal	$\geq$ 2000 mg/kg bw	Weiner et al., (1982).
Disodium Tetraborate Anhydrous		
Oral	> 2500 mg/kg bw males	Denton, (1995).
Inhalation	>2000 mg/m^3	Read across from Disodium Tetraborate Pentahydrate and Disodium Tetraborate Decahydrate
Dermal	>2000 mg/kg bw	
Disodium Tetraborate Pentahydrate		
Oral	3305 (2403 - 4207) mg/kg	Reagan and Becci (1985a)
Inhalation	>2040 mg/m3 (2g/m^3)	Wnorowski, (1994 a)
Dermal	>2000 mg/kg bw	Reagan and Becci, (1985b)
Disodium Tetraborate Decahydrate		
Oral	5560 (5150 - 6000) mg/kg	Meyding and Foglhian (1961),
Inhalation	>2.03.mg/L (2g/m^3)	Wnorowski, (1994b)
Dermal	>2000 mg/kg bw	Reagan and Becci, 1985c

5.3 Irritation

5.3.1 Skin

In a study in rabbits, boric acid did not cause skin irritation when applied to the intact or abraded skin at a dose of 0.5 g. Similarly, in studies in rabbits, sodium tetraborate decahydrate (Reagan and Becci, 1985e) and sodium tetraborate pentahydrate (Reagan and Becci, 1985d) did not cause skin irritation at doses of 0.5 g. In an earlier study in white rabbits, 5 ml of 10% boric acid (w/v) in water applied to abraded skin demonstrated very mild irritation with a primary irritation score of 2.5. In the same study, 10 ml of 5% borax (Disodium Tetraborate Decahydrate) in water (w/v) resulted in very mild irritation with a primary irritation score of 2.3. However, in the same study in Guinea pigs, neither boric acid nor borax was irritating when applied on abraded skin, with primary irritation scores less than 2 (Roudabush 1964). Although no test was carried out on disodium tetraborate anhydrous, it can be assumed that this would also not cause skin irritation.

Boric acid and disodium tetraborate decahydrate are used at concentrations of 5% in cosmetics in the US and in talc in Europe, up to 3% in other cosmetics in Europe and up to 0.5% in oral hygiene products in Europe and elsewhere (Beyer et al., 1983; EC, 2000).

Table 5.8 Skin Irritation Data

Species	Method	Average score 24, 48, 72 h		Reversibility yes/no	Result	Reference
		Erythema	Edema			
Boric Acid						
White Rabbits	21 CFR 191.11				PII 2.5 Mildly Irritating Abraded Skin	Roudabush et al. (1964)
Rabbits; New Zealand White	FIFRA (40 CFR 163) Acceptable protocol at the time	0.105	0	yes	Non irritant	Weiner et al. (1982).
Disodium Tetraborate Anhydrous						
Read across from Disodium Tetraborate Pentahydrate and Disodium Tetraborate Decahydrate – Non Irritant						
Disodium Tetraborate Pentahydrate						
Rabbit	[1]US EPA-FIFRA guidelines	0	0		Non Irritant	Reagan and Becci, (1985d)
Disodium Tetraborate Decahydrate						
White Rabbits	21 CFR 191.11				PII 2.3 Mildly Irritating Abraded Skin	Roudabush et al. (1964)
Rabbit	[1]US EPA-FIFRA guidelines	0	0		Non Irritant	Reagan and. Becci (1985e),

[1] This study was carried out to comply with US EPA-FIFRA guidelines at the time and carried out by the US Food and Drug Laboratories to GLP. Although it is not to modern protocols the data is consistent with other borate data and further testing is not warranted in the interests of animal welfare and protecting laboratory animals

5.3.2 Eye

Studies in animals

Boric Acid

Boric acid induced conjunctivae redness and chemosis and minor effects on the iris. The effects were reversible within 7 days. (Doyle, 1989a)

Table 5.9: Eye irritation Boric Acid

Species	Method	Average Score				Result	Reversibility yes/no	Reference
		Cornea	Iris	Conjunctiva				
				Redness	Chemosis			
Rabbits; New Zealand White	FIFRA (40 CFR 158, 162); TSCA (40 CFR 798).	0.00	0.11	0.94	0.56	Non irritant	Yes	Doyle, 1989a

Disodium Tetraborate Pentahydrate

A number of eye irritancy studies have been carried on disodium tetraborate pentahydrate (Reagan and Becci, 1985f, Wnorowski, 1996 and Cerven, 2000), which involved testing various batches of substance and under varying conditions, all indicating eye irritation. However the key study was carried out at the request of the US EPA to confirm that the eye irritation previously seen was caused by the glassy nature of the crystals of substance and not a chemical effect of irritation (Cerven, 2000). To confirm this, the sample was ground to a fine powder before instillation to reduce the glassy, sharp crystals in the sample (0.08 ml dosed). As a result for this study the US EPA accepted that the effects were mechanical downgraded its classification according to US FIFRA to Toxicity II (40 CFR 156) by ocular administration (Corneal involvement or irritation clearing in 8-21 days).

Disodium Tetraborate Decahydrate

Two studies have been carried out both indicating eye irritancy (Reagan and Becci, 1985g; Doyle, 1989b). In the second study, regarded as the key study the sample was ground to a fine powder to reduce the glassy, sharp crystals in the sample.

Disodium Tetraborate Anhydrous

While no data has been obtained for disodium tetraborate anhydrous, it can be assumed that it should be an eye irritant based on the data obtained with the hydrated disodium tetraborates.

Table 5.10 Eye irritation Data: Disodium Tetraborates

Species	Method	Average Score				Result	Reversibility yes/no	Reference
		Cornea	Iris	Conjunctiva				
				Redness	Chemosis			
Disodium Tetraborate Anhydrous								
Read across from Disodium Tetraborate Pentahydrate and Disodium Tetraborate Decahydrate – Irritant								
Disodium Tetraborate Pentahydrate								
Rabbit	FIFRA (40 CFR 158, 430); EPA OPPTS 870.2400	0.22	0.22	2.8	1.89	Irritant	Yes	Cerven, (2000).
Disodium Tetraborate Decahydrate								
Rabbit	FIFRA (40 CFR 158, 162); TSCA (40 CFR 798).	0.72	0.61	1.70	2.11	Irritant	Yes	Doyle, (1989b)

Studies in humans

Acute irritant effects on the eye are well documented in human workers exposed to borates (Garabrant 1984, 1985; Wegman 1991, Wegman 1994, EPA, 2004).

5.3.3 Respiratory tract

Short term effects

Studies in animals

Acute inhalation studies in rats with disodium tetraborate (pentahydrate & decahydrate) and boric acid (Wnorowski, 1994ab, 1997) revealed LC_{50}-values > 2 g/m^3. Ocular and nasal discharge, hunched posture and hypoactivity have been noticed as symptoms.

In a study by Krystofiak & Schaper (1996) metal working fluids and its single constituents, one of which is boric acid, were investigated. The test procedure followed the Alarie-method, which detects depressions of respiratory frequency in Swiss-Webster mice in response to exposure to sensory irritants. The concentration inducing a 50% decrease in respiratory frequency is termed the RD_{50}. This effect is based on stimulation of the *Nervus trigeminus* in the nasal passage. The human equivalent response is stated to be a sensation of stinging or burning, referred to as sensory irritation (Alarie, 1973). In the current experiment four mice were exposed to 300 mg/m3 boric acid (the highest achievable concentration), equivalent to 52,5 mg B/m^3, which resulted in a 20% reduction of the respiratory rate (no other dose was reported, no information on the results from individual mice or standard deviation is given). It can be concluded that boric acid acts as sensory irritant, however, the data could not be used for DNEL derivation. As stated in Chapter R.8 of the Guidance on IR and CSA, quantitative use of data generated with the Alarie-test are not generally accepted and shall only be applied when of sufficient quality.

Studies in humans

Acute irritant effects are well documented in human workers exposed to borates (e.g. Garabrant et al., 1984, 1985; Wegman et al., 1991, Woskie et al., 1998). The most relevant studies on respiratory irritation are summarized in table 5.11.

A survey of 113 workers exposed (214 unexposed) to boron oxide and boric acid in a borax mining and refining plant (Boron, California facility) was conducted by Garabrant et al. (1984). The mean total exposure was 4.1 mg/m^3 boron oxide or 4.1 mg/m^3 boric acid equivalent to 1.3 and 0.7 mg B/m^3, respectively. The dust levels had been measured by collecting total particulate in a closed face filter cassette attached to the worker's collar using a PVC filter. Smoking patterns between exposed (41% current smokers) and unexposed (43% current smokers) were similar. Significant associations were found for respiratory symptoms and eye irritation which were more frequently reported from exposed workers than from unexposed. Symptoms were eye irritation, dryness of mouth, nose or throat, sore throat, and reproductive cough. Due to several limitations of this study (Annex HH I) it cannot be used for DNEL derivations, however, the results are useful for the weight of evidence approach.

A more detailed analysis of 629 workers in the same plant was presented by Garabrant et al. (1985). This analysis was based on frequency of acute symptoms in four mean boron dust exposure categories (1.1, 4.0, 8.4, and 14.6 mg/m^3). Chronic effects investigated in this study are described in section on chronic inhalation studies. The particles were composed almost entirely of borax. Acute symptoms showing a significant linear trend in order of decreasing frequency were dryness of mouth, nose and throat, eye irritation, dry cough, nosebleeds, sore throat, productive cough, shortness of breath, and chest tightness. The frequency of these symptoms in the highest exposure category ranged from 5% to 33%. The only symptom reported by 5% or more of workers exposed to 4.0 mg/m^3 was eye irritation; no symptoms were reported by 5% or more of the workers exposed to 1.1 mg/m^3. The pulmonary function findings were not significantly affected by exposure to boron. Chest X-rays did not show abnormal regions indicative of boron exposure. Borax dust causes respiratory irritation that produces chronic bronchitis (LOAEL was considered to be 4.5 borax mg/m^3) or 0,6 mg B/m^3) with no impairment of pulmonary function. One major limitation of the study, which was also stated by the authors themselves, was that no information on minimum exposure necessary to produce irritation was given. The study is therefore not used for DNEL derivation, but can be used in a supportive way.

Wegman et al (1991, 1994) conducted a prospective cohort study to examine work-related acute irritative effects as well as chronic pulmonary function abnormalities in mining and processing plant workers exposed to boron dust (Table 5.11). The part on long term effects is described under section chronic inhalation studies. The un-published report was finalised in 1991 and the results were published later by Wegman et al. (1994).

Borax in this study refers to any one or mixtures of disodium tetraborate decahydrate, disodium tetraborate pentahydrate and disodium tetraborate anhydrous. To account for the fact that both borates and nonspecific dust may have irritant properties, exposures were presented in the basis of boron content of dust samples.

This approach was further evaluated and supported by Woskie et al. (1994). It is a good surrogate parameter for exposure to borates. A total boron level of 0.05 mg/m^3 could not be differentiated from control.

Since irritation of the eyes nose and throat may be caused by particles in the non-respirable size range, the MINIRAM real-time monitor (Miniature Real-time Aerosol Monitor) had to be calibrated to measure "total" dust, composed of inhalable, respirable (alveolar) and thoracic dust. Two types of personal exposure data were collected for each subject in this study. The first type of personal exposure was measured with the MINIRAM monitor and the second type of personal exposure was daily TWA dust and boron concentration collected by a "total" dust filter in-line with the MINIRAM sensing chamber. The MINIRAM monitor was used in conjunction with a data-logger system. This device permitted each subject to record the actual time of symptom onset by adding a mark to the exposure monitor each time they experienced an acute irritant symptom. Additionally, in hourly surveys, technicians asked whether the marker had been used, and if so, for what symptom.

The following acute respiratory symptoms were investigated to establish dose-response-relationships: nose, eye and throat irritation; sneezing; nose bleeds; coughing and breathlessness. A severity scale with 13 categories was introduced and provided reproducible and reliable results. 65% of the symptoms had a severity rank of 2 or less ("fairly little", or "less"), approximately 30% were "moderate", and approximately 5% with a ranking of 4 "pretty much" or greater. Exposed subjects experienced more frequent irritations than unexposed. Among the exposed workers, non-smokers had higher rate ratios than smokers for nasal and eye irritation, and lower ratios for throat irritations, cough, and breathlessness.

Average daily exposure (6-h time weighted average) for the exposed group was 5.72 mg/m^3 of total dust (0.44 mg/m^3 B); 79% of the group had daily exposures higher than 1.0 mg/m^3 of total dust. The majority of exposures were between 1.0 and 10.0 mg/m^3 of total dust. A total of 68% of the exposed subject-days included at least one 15-min interval in which exposure exceeded 10.0 mg/m^3 of total dust. The analyses of the incidence and severity of irritant symptoms indicate that exposure-response relationships are present for each of the specific symptoms. The exposure – response trends were statistically significant ($p < 0.05$), except for eye irritation (based on total dust). In comparison to control group exposed subjects had a rate ratio (RR) for nose irritation (RR 8.8), eye irritation (RR 5.2), throat irritation (RR 2.9), breathlessness (RR 7.1) and coughing (RR 1.7). The most striking difference was for nasal irritation where 23% of the exposed group reported at least two incident symptoms as compared to none of the unexposed.

Correlations persisted after taking account of smoking, age and the presence of common cold. Multi-responders in the study were thought to be more sensitive, but actually they were younger and had a significant higher exposure than the others. Differences in sensitivity were further investigated by Woskie et al. (1998). The exposure response analysis is based on incident, rather than on prevalent symptoms. As reported by the authors of the study the exposure measurements were underestimations of the actual boron air concentrations. A factor of ~2 between percent boron measured and theoretical boron content could be derived. Similar findings were also described by Woskie et al. (1994). As outlined by several authors the described factor varies depending on actual particle size distribution and nature of the measured dust (Woskie et al., 1994; Culver et al., 1994; Katchen et al., 1998,).

For NOEC derivation 15-minute interval exposure data were plotted against the sum of "any symptom" (nose, eye, and throat irritation, sneezing breathlessness, coughing; table 37, Wegman et al., 1991). As to exposure data the report provides no means but intervals only and therefore, the lower limits of the exposure ranges were used for non-linear regression analysis (Poisson-model). The resulting dose-response-curve including analysis of maximum likelihood estimation is shown in figure 5.1.

A background concentration of 0,02 mg B/m^3 was stated in the report (table 14, Wegman et al., 1991). Applying the equation derived from the regression analysis, gives a predicted rate for effects at background of 0,002, with lower and upper 95% CI of 0,0002 and 0,016, respectively. The upper 95% CI of this rate is considered equivalent to "no-observed-effect". The boron concentration with a lower 95% CI of the predicted rate of symptoms equal to this value (0,016) is taken as point of departure for DNEL derivation. The corresponding boron concentration equals 0,4 mg B/m^3. After correction for the methodological underestimation of exposure measurements a NOEC of 0,8 mg B/m^3 can be derived.

Despite some drawbacks of this study (Annex HH I) a clear dose response curve can be derived, the number of workers investigated and the evaluated exposure intervals was high, the exposure was representative for the workplace situation and the protocol of the observations is adequate. It is therefore used as key-study for deriving a $\mathrm{DNEL}_{\text{acute, inhalation, local}}$.

The study by Woskie et al. (1994) is a methodological work in which the methods used by Wegman et al. (1991) were evaluated. Results of real-time exposure to sodium borate dust (MINIRAM sampler in combination with a data-logger) were compared to conventional time-weighted average exposures. 17 job exposure groups were differentiated. It appeared that short-term (TWA-0,25) within-day exposures increase as TWA-6 exposures increase, suggesting that jobs with higher average exposures may have even higher and more frequent short-term exposures than predicted based on the mean daily exposure and a constant exposure. Thus, workers with high TWA exposures are at even higher risk than predicted if borate „peak" exposures are associated with an acute respiratory response.

Further, the applicability of the MINIRAM analyser for epidemiological studies was evaluated. The closed filter cassette method covers dust that might deposit in the tissues of the upper respiratory tract as well as in the respirable region („Total" dust). This method meets the ACGIH criteria for particles less than 15µm. Particles over 15µm are undersampled with this method, but in a predictable fashion.

The MINIRAM is a light-scattered photometer calibrated to estimate respirable mass concentration and is sensitive to changes in particle size distribution and composition. The calibration of the MINIRAM enables reliable monitoring of dust concentrations at the workplace. As in the study by Wegman et al. (1991) the exposures were estimated on the basis of boron content of the dust, Woskie et al. (1994) evaluated the usefulness of boron as marker for exposure to borate dust. It was found that boron should be used as the marker for sodium tetraborate, whereas the use of total dust numbers would mask the actual pattern of exposure.

The study authors concluded that the use of the MINIRAM with the data-logger in the described protocol is adequate for providing detailed information on personal exposures for use in acute health-effects epidemiology and evaluation of exposure variability. The study is supportive for the data generated by Wegman et al. (1991), but cannot be used to derive NOAEC values.

Woskie *et* al. (1998) investigated worker sensitivity and reactivity with regard to nasal irritation. Reactivity in this study was defined as how much change in response occurs with a change in exposure. In contrast, an individual's background sensitivity is defined as the degree of irritation experienced in the absence of exposure depending on an individual's background. This study examines determinants of susceptibility to the irritant effects of sodium borate in 18 responsive workers identified through self – reports of nasal irritation. The conclusion of the study was that those who may appear most susceptible to borate exposure, because of greater reactivity, were the healthy non-smoking workers not using nasal sprays/drops, not reporting allergies or colds on the test day or any history of bronchitis. To examine possible biologic mechanisms for the irritant response, a toxicokinetic dose model was used to calculate nasal osmolarity during symptom intervals. The estimated levels suggested that osmolar activation of mast cells to release histamine and other mediators is a plausible mechanism by which these workers may experience nasal irritation. The study cannot be used for DNEL derivation, but helps to interpret the data generated by Wegman et al. (1991).

Cain et al. (2004) investigated the sensory perception of dusts of sodium tetraborate pentahydrate, calcium sulphate, and calcium oxide. Twelve subjects were exposed to 5, 10, 20, 30 and 40 mg/m^3 sodium tetraborate pentahydrate dust particles for 20 min while performing moderate exercise. Exposure to CO_2 vapour was used to set a reference scale for subjects to judge the feel of the stimulus materials (reference scale: 1 = 10%, 2 = 15%, 3 = 20%, 5 = 28%, 6 = 35%; 0,4 and 5 are not indicated in the study). During exposure, subjects judged level of feel or irritation in the eye, nose, and throat (nasopharynx) at 5-min intervals. Subjects noted that feel in the nose becomes irritating about 17-18% carbon dioxide. The subjects indicated the absence of any feel or irritation by a judgement of zero. At the intervals indicated, heart rate, oxygen saturation, minute ventilation and respiration rate were recorded. During the study subjects registered time-dependent feel from exposures principally in the nose, secondarily in throat and hardly in eyes. At 10 mg/m^3 (1.5 mg B/m^3) sodium-tetraborate pentahydrate increased nasal secretion was observed, but not at 5 mg/m^3 (0.75 mg B/m^3) sodium-tetraborate pentahydrate. In general, the number of subjects who participated in this study was relatively small (n=12). The NOEC determined was 0.75 mg boron /m^3. At the LOEC 1.5 mg boron/m^3 respiratory symptoms of increased nasal secretion were observed (Cain et al., 2004).

A similar study has been carried out on boric acid by Cain et al. (2008), again twelve subjects were investigated. The feel of exposure in the nose, throat, and eye was again compared to the reference gas CO_2 (reference scale: 0 = 6%, 1 = 12.5%, 2 = 17.7%, 3 = 21.7%, 4 = 25%, 5 = 28%). Station 2 or 17.7% CO_2 is the median level subjects identified as irritating. The highest feel was reported for nose, followed by throat and eyes. A similar effect compared to sodium-tetraborate pentahydrate was obtained at 10 mg/m^3 (1.75 mg B/m^3) boric acid. In contrast to sodium-tetraborate pentahydrate, boric acid showed a flatter dose response relationship. The probability of any symptom was low and did not increase with exposure. The feel did not follow a dose response relationship e.g. the feel (nose) at a dose of 0.88 mg B/m^3 was lower than at 0.44 mg/m^3. This result was obtained three times independent of the exposure time (12.5, 22.5, and 27.5 minutes). Additionally, the MMAD used in this study might not be relevant and representative for workers exposed, as indicated by Wegman et al. (1991). Respirable dust was measured, but larger particles are more likely to deposit in the nose and upper airways. As stated by Wegman et al. (1991), the irritation in the borax facilities might be caused by the “non-respirable” size range. The reference gas CO_2 might have altered normal lung function, before subjects were being exposed to the test substrate.

The experimental design and the data of both Cain studies (2004, 2008), namely the laboratory conditions and particle size, which differs from the “real” exposure of workers, are not representative for the occupational exposure of workers. The drawbacks of both Cain studies are further outlined in Annex HH I. The studies support the DNEL derivation based on the study by Wegman et al. (1991).

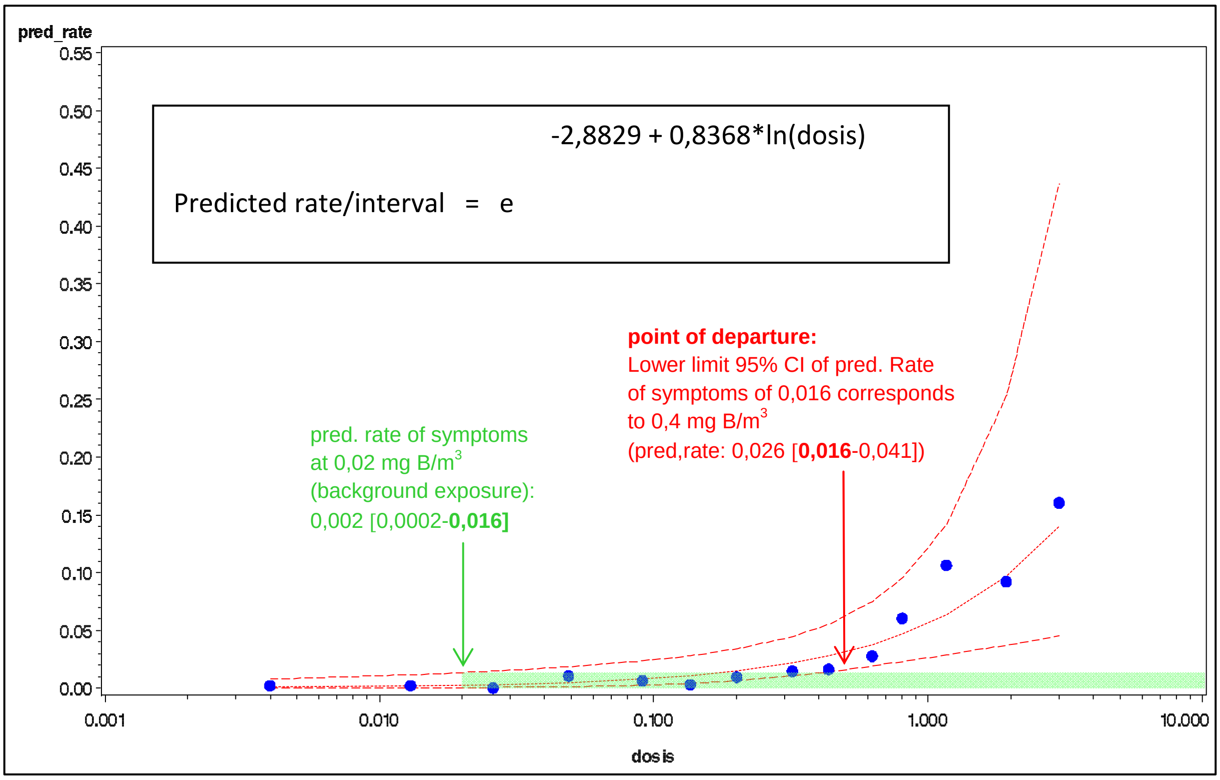
Table 5.11: Acute Inhalation Studies – Human

Route	Exposure	Sampler	NO(A)EC mg B/m^3	LO(A)EC mg B/m^3	Symptoms	Number of Volunteers	MMAD [µm] ± SD	Reference
Sodium Borates (disodium tetraborate decahydrate, disodium tetraborate pentahydrate, disodium tetraborate anhydrous)								
Inhalation	6hr / day TWA	Total dust measured with recalibrated MINIRAM onto closed face filter cassette which was gravimetrically analysed; flow 2 L/min; additionally total boron content was analysed	0.8*	> 0,8*	Nasal and throat irritation; cough and breathlessness	70 exposed and 26 unexposed	Decahydrate 14.0 ±2.4; Pentahydrate 13.4 ± 1.2; Anhydrous 16.5 ± 5.9	Wegman et al. 1991
Sodium Borates (Sodium tetraborate pentahydrate)								
Inhalation	once, 20 min, during activity (60 Watt) 5, 10, 20, 30, 40 mg/m^3 (0.75; 1.5; 3; 4.5; 6 mg boron/m^3)	MINIRAM, gravimetric sampler: 47mm Pallex filter; flow 2 L/min	0.75	**1.5**	**Increased nasal secretion**	**12 male**	**Sodium borate 7.11 ± 1.72;** **Calcium sulphate 8.24 ±1.08;** **Calcium oxide 6.53 ± 0.76**	**Cain et al. 2004**
Sodium tetraborate pentahydrate								
Inhalation	47 min, during activity 10 mg/m^3 (nominal 1.48 mg B /m^3)	MINIRAM, gravimetric sampler: 47mm Pallex filter; flow 2 L/min	not observed	1.48	Note: none of the functions reached the concentrations considered irritating, about 17-18% CO_2.	six males and six females	Sodium tetraborate pentahydrate 7 ± 1.7 µm Calcium sulphate 8 ±1.1 µm; Calcium oxide 6.5 ± 0.8 µm	Cain et al. 2008
Boric Acid								
Inhalation	47 min, during activity 2.5, 5, 10 mg/m^3 (nominal 0, 0.44, 0.88, and 1.75 mg B/m^3)	MINIRAM, gravimetric sampler: 47mm Pallex filter; flow 2 L/min	not observed	0.44	Note: none of the functions reached the concentrations considered irritating, about 17-18% CO_2.	six males and six females;	Boric acid 8 ± 3 µm (GSD of 3.6 ± 1.3 µm) Calcium sulphate	Cain et al. 2008

							8 ±1.1 µm Calcium oxide 6.5 ± 0.8 µm	

TWA time weighted average; MMAD Mass median aerodynamic diameter; GSD geometric standard deviation

* Please note that the numbers from Wegman et al. (1991) need to be multiplied by the factor of 2 to come up for underestimations of exposure measurements.



Analysis of the maximum likelihood estimation							
Parameter	DF	estimate	Standard error	Waldsch 95% CI		Wald Chi-Square	Pr > ChiSq
Intercept	1	-2,8829	0,3865	-3,6404	-2,1254	55,64	< 0,0001
Dosis	1	0,8368	0,2659	0,3156	1,3580	9,90	0,0017
Scale	0	4,0201	0,0000	4,0201	4,0201		

Fig. 5.1: Poisson regression analysis of the results from Wegman et al. (1991) Upper and lower 95% CI are indicated. Boron exposure levels are plotted on a logarithmic x-axis. The values on the x-axis represent the lower limits of the according exposure ranges. On the y-axis the predicted rate of "any symptom" is indicated. As described above the exposure measurements by Wegman et al. (1991) are underestimations and need to be corrected with a factor of 2.

Chronic inhalation studies

Studies in animals

No data from animal studies on boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate are available. In 2006, US EPA requested a rat 28-day inhalation toxicity study on boric acid to better characterize the effects of repeated inhalation exposure (US EPA, 2006). However, US EPA reconsidered the data request and decided not to require a boric acid 28-day inhalation toxicity study in the rat. Should new uses and/or other inhalation epidemiologic, experimental or incident data suggest that additional inhalation toxicity data are needed to better assess hazard from inhalation exposure, the US EPA may reconsider this study requirement (Personal communication with US EPA, email from November 2007).

Studies in humans

Garabrant *et* al. 1985 indicated that borax dust causes respiratory irritation that produces chronic bronchitis. The investigation was based on persistent symptoms (chronic effects) in three exposure categories (0.9, 4.5, and 14.6 mg/m^3 of total particulates). The pulmonary function findings were not significantly affected by exposure to boron. Chest X-rays did not show abnormal regions indicative of boron exposure. Borax dust causes respiratory irritation that produces chronic bronchitis (LOAEL was considered to be 4.5 mg/m^3) with no impairment of pulmonary function. One major limitation of the study, which was also stated by the authors themselves, was that no information on minimum exposure necessary to produce irritation could be derivedd.

The second study investigating work-related chronic abnormality in pulmonary function associated with exposure to boron dust in mining and processing operations was carried out by Wegman et al. (1991). The only parameter examined to evaluate chronic effects of sodium borate particulate exposures was pulmonary function at the beginning and end of a 7-year study period. Reduction of forced expiratory volume 1 sec (FEV1) was observed among smokers who had heavy cumulative sodium borate exposure ($\geq$80 mg/m^3-year), but not among less-exposed smokers and non-smokers. In this study approximately 50% of subjects were lost to follow up, therefore chronic respiratory effects of borate exposure could not be assessed satisfyingly.

5.3.4 Summary and discussion of irritation

Skin Irritation

Boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate are not skin irritants.

Eye Irritation

Boric acid induced conjunctivae redness and chemosis and minor effects on the iris. The effects were reversible within 7 days. Therefore, no classification is indicated.

Results from tests carried out with disodium tetraborate pentahydrate and decahydrate fulfil the criteria for classification as eye irritant R36 EU guidelines (67/548/EEC). Based on read across from disodium tetraborate pentahydrate and disodium tetraborate decahydrate, disodium tetraborate anhydrous should also be classified as eye irritant R36 EU guidelines (67/548/EEC).

Respiratory tract

Borates act as sensory irritants, indicated by the effects observed in humans (i.e. nose, eye and throat irritation; sneezing) and by the results of the Alarie-test by Krystofiak & Schaper (1996), which demonstrated a depression of the respiratory frequency in mice after exposure to boric acid. Many of the irritant symptoms (sensory irritation of the nose and throat, cough, phlegm production and broncho-constriction, as evidenced by a decrease in FEV1) are part of the respiratory defense reflex, the function of which is to protect the body from inhaled irritants. This reflex can be triggered by agents that stimulate receptors in the respiratory tract e.g. on the trigeminal nerve (Wegman et al. 1991, Nielsen et al., 2007, Krystofiak & Schaper, 1996). The actual mechanism, however, has not yet been elucidated.

Wegman et al. (1991) and Woskie et al. (1998) proposed changes of osmolarity in the lining fluid of the mucous membrane as possible cause for receptor activation. Changes in osmolarity could also act indirectly by stimulating mast cells to secrete histamine or other immune modulators. Histamine is known to be able to mediate the sensory component of irritation. The importance of osmolarity in the case of borate dusts is further substantiated by Cain et al. (2008). They also indicated that more acidic dusts, as compared to borate dusts, would lead to a change in nasal pH which might trigger the nasal receptors in a different way.

Acute irritant effects are extensively documented in human workers exposed to boric acid and borates (EPA, 2004; Wegman et al. 1991; Garabrant 1984, 1985; Woskie et al., 1994, 1998; Cain et al., 2004, 2006). The described symptoms are typical for those which would be produced in the exposed population rather than being an isolated reaction or response triggered only in individuals with hypersensitive airways. Symptoms include nasal and eye irritation, throat irritations, cough, and breathlessness. The identified dose-descriptor for acute irritant effects is the NOEC value of 0,4 mg B/m^3 based on Wegman et al. (1991). The methods used for exposure measurements in this study were underestimates and the value has to be corrected by the factor 2. This results in a final NOEC of 0,8 mg B/m^3.

5.4 Corrosivity

Boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate are not corrosive.

5.5 Sensitisation

5.5.1 Skin

Studies in animals

Boric acid, disodium tetraborate decahydrate and disodium tetraborate pentahydrate were tested in a Buehler method skin sensitisation test (Wnorowski, 1994 e, f, g). They were applied at a concentration of 95% (powder moistened with water) during both the induction and challenge phase of the test. No signs of skin sensitisation were observed.

Studies in humans

The data indicate that these borates are no sensitisers. No evidence of skin sensitisation in humans exposed occupationally to borates has been reported (Bruze et al., 1995).

Table 5.12: Sensitisation Data

Active substance	Species	Method	Number of animals sensitised/total number of animals	Result	Reference
Boric Acid	Guinea Pig	Buehler Test OECD Guide-line 406 "Skin Sensitisation"	0	Non sensitiser	Wnorowski, (1994e),
Disodium Tetraborate Anhydrous	Read across from Disodium Tetraborate Pentahydrate and Disodium Tetraborate Decahydrate – Non sensitiser				
Disodium tetraborate pentahydrate	Guinea Pig	Buehler Test OECD Guide-line 406 "Skin Sensitisation"	0	Non sensitiser	Wnorowski, (1994f),
Disodium tetraborate decahydrate	Guinea Pig	Buehler Test OECD Guide-line 406 "Skin Sensitisation"	0	Non sensitiser	Wnorowski, (1994g),

5.5.2 Respiratory system

There is no data to suggest that boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate are respiratory sensitisers.

5.5.3 Summary and discussion of senstitiation

Boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate are neither skin nor respiratory sensitisers.

5.6 Repeated dose toxicity

5.6.1 Repeated dose toxicity: oral

Studies in animals

A number of sub-chronic and chronic studies on boric acid and disodium tetraborate decahydrate were carried out in rats, mice and dogs. In some cases these studies are research studies (e.g. Dixon et al, 1979; Seal and Weeth, 1980; Lee et al., 1978; Treinen and Chapin, 1991; Ku et al., 1993), but most support that Boron can cause adverse haematological effects and that the main target organ of boron toxicity is the testis. Some of the studies are further described in section 5.9.1. The studies by Paynter, 1963a,b and Weir, 1962, 1962b, 1963, 1966a-f, 1967a,b were published in Weir & Fisher (1972). For the present dossier the original studies have been evaluated.

In a 30/60 day study in male Sprague-Dawley rats (18 per group) on disodium tetraborate decahydrate administered in drinking water (0, 500, 1000, 2000 ppm, equivalent to 0, 25, 50, 100 mg B/kg bw/day) no reduction of bodyweight or organ weights were observed, with the exception of significantly reduced epididymal weights in all dosed groups after 30 days. After 60 days the weight of testes and liver at 50 and 100 mg B/kg bw/day was also reduced. At these doses a significant loss of spermatocytes and spermatogenic cells and testicular atrophy (60 days > 30 days) concomitant with reduced enzyme activities of hyaluronidase, SDH (dehydrogenase of sorbitol) and LDH-X (lactate dehydrogenase isoenzyme X) and increased enzyme activities of G3P-DH (glyceraldehyde-3-phosphate dehydrogenase) and M-DH (malate dehydrogenase) were observed, correlating well with dose and duration of exposure. Plasma levels of FSH (follicle stimulating hormone) were increased in all treated groups, with both a dose-response and an exposure time-response apparent. LH (luteinizing hormone) and testosterone levels were not significantly altered. In this study a LOAEL of 25 mg B/kg bw/day could be identified based on reduction of epididymal weight and increased plasma FSH levels (Dixon et al., 1979). More details on fertility effects observed in this study are described in section 5.9.1.

In male Sprague-Dawley rats (18 per group) fed disodium tetraborate decahydrate for either 30 or 60 days at 60 or 125-131 mg B/kg bw/day testis weight was reduced, testicular germ cells were depleted, selected testicular enzymes were affected and fertility was reduced. Hyaluronidase, SDH, and LDH-X were significantly decreased; and G3P-DH and M-DH were significantly increased at 60 and 125-131 mg B/kg bw/day. Further, an increase in plasma FSH levels correlated well with germinal depletion and both effects were dose and time dependent. As might be expected, while recovery from inhibition of spermiation occurred at the lower doses, there was no recovery from testicular atrophy when the germ cells were lost. A NOAEL of 30 mg B/kg bw/day could be derived (Lee et al., 1978). More details on fertility effects observed in this study are described in section 5.9.1.

In another study male Long-Evans rats (15 per group) were administered disodium tetraborate decahydrate in drinking water for 70 days at levels of 0, 150 and 300 mg B/l, which is assumed to correspond to a total boron intake of 23.7 and 47.4 mg B/kg low/day, based on a bodyweight of 350 g and water intake of 49 ml/d (US EPA IRIS 2004). While reduction of haematocrit (6,8%) and impaired spermatogenesis were observed only in the high dose group, reduced body weight and reduced weight of testes and spleen were seen at both doses. A LOAEL of 23.7 mg B/kg bw/day can therefore be derived (Seal and Weeth 1980).

Although not conforming to modern protocols, data on several effects can be obtained from a 90 day study in Sprague-Dawley rats fed 0, 52.5, 175, 525, 1750, 5250 ppm boric acid equalent to 0, 2.6, 8.8, 26, 88 and 260 mg B/kg bw/day (10 males and 10 females per group). All the animals in the top dose died by week 6. Animals at the top two doses displayed rapid respiration, hunched position, bloody nasal discharge, urine stains on the abdomen, inflamed eyes, desquamation and swollen paws and tail. These animals exhibited reduced food consumption and body weight gain. At 88 mg B/kg bw/day, in females, reduced weight of livers, spleens and ovaries were observed, while for males only the kidney and adrenal weights were reduced. The adrenals in 4 males at 88 mg B/kg bw/day displayed minor increases in lipid content and size of the cells in the zona reticularis. All the male rats at 88 mg B/kg bw/day had atrophied testis, a histologically complete atrophy of the spermatogenic epithelium and a decrease in the size of the seminiferous tubules. One male at 26 mg B/kg bw/day exhibited partial testicular atrophy. Although, testicular atrophy is also occasionally seen in young and old un-treated Sprague-Dawley rats (Aleman et al., 1998), the observed effects, one third of the tubules was completely atrophic, while the rest presented an arrest of spermatogenesis usually in the spermatocyte stage, were judged adverse. The NOAEL was determined to be 8.8 mg B/kg bw/day (Weir, 1962).

In an analogous Sprague-Dawley rat 90-day study on disodium tetraborate decahydrate similar effects were observed, however, in this study the dose response relation was less clear. Partial testicular atrophy was seen in 4/10 males at 2.6 and in 10/10 males at 88 mg B/kg bw/day but not at 8.8 or 26 mg B/kg bw/day. At the latter dose, however, spermatogenic arrest was described for 1/10 males (Weir, 1962b). Due to the abnormal dose response relation observed in this study, it can be assumed that there must have been deficiencies in the way the study was conducted. Since the effects on testis observed were similar to those seen in comparable studies, it can be used to support these findings, however, it cannot be used to derive a dose-descriptor for this endpoint.

In a third Sprague-Dawley rat 90-day study on disodium tetraborate decahydrate with the same design, no adverse effects were observed at levels up to 26 mg B/kg bw/day (Weir, 1963).

In a 2 year feeding study in Sprague-Dawley rats, again on boric acid and disodium tetraborate decahydrate, testes and blood were identified as major target organs (Weir, 1966a;b). Rats were dosed with 0; 670 (117); 2000 (350); 6690 (1170) ppm boric acid (boron equivalents) equivalent to 0, 33 (5.9), 100 (17.5), 334 (58.5) mg boric acid (B)/kg bw per day and 0, 1030 (117), 3080 (350), 10300 (1170) ppm disodium tetraborate decahydrate (as boron equivalents) equivalent to 0, 52 (5.9), 155 (17.5), 516 (58.5) mg disodium tetraborate decahydrate/kg/day or 0, 5.9, 17.5 or 58.5 mg B/kg/day. The control groups comprised ,35 males and females, whereas the dosed groups consisted of 35 male and female animals, each.

Clinical signs included coarse hair coats, hunched position, and inflamed bleeding eyes, desquamation of the skin of the tail and the pads of the paws which were also swollen, marked respiratory involvement, as well as a reduction in body weight were observed in males and females of the highest dose group. Further the scrotum of all males of the high dose group was of shrunken appearance.

Decreased red cell volume and haemoglobin were observed in boric acid and disodium tetraborate decahydrate treated rats. Blood samples were taken after 1, 2, 3, 6, 12, 18 and 24 months. The observations over time were not always consistent, however, at the end of the study the values in all dosed animals were reduced compared to control, with the exception of red cell volume in the low dosed disodium tetraborate decahydrate females (see table).

Most experts do not recommend clinical pathology measurements in the long-term rat studies after one year for the evaluation of non-neoplastic findings and this recommendation has been included in the OPPTS guideline No. 870.4300 (combined chronic/cancer). The reason for this limitation to 12 months is deviations due to age dependent diseases at the end of the life cycle (Weingand et al., 1992; Long et al., 1998). Therefore, in the present studies the inconsistencies found after two years can be regarded as coincidental and do not allow a conclusive interpretation.

Significant reduction of red cell volume and haemoglobin was mainly observed after two years in high dosed males treated with boric acid (5.6% to 21.6% and 7.3% to 19,2% reduction compared to control, were observed for red blood cell volume and haemoglobin, respectively), but also in the females treated with boric acid a significant reduction of haemoglobin at all dose groups was detected at the last measurement (between 8% and 13%). In contrast in the 12 months samples only the high dosed males had significant reductions in cell volume (12.5%) and haemoglobin (10.8). There were only minor to no reductions of the measured parameters at the lower doses or in females (see table 5.13). For disodium tetraborate decahydrate blood of the high dosed animals showed reduced values for both endpoints in males and females at several time points. In the 12 months samples, however, there were no significant reductions in low and mid dosed animals. Only in mid dosed females reduction of cell volume of 10% was recorded, but with a corresponding increase of haemoglobin which indicates that this finding cannot be regarded as adverse.

Muller et al. (2006) details the many indicators of anaemia and states that these should not be considered in isolation, but should be considered in context with all the other toxicological effects of the substance. According to Muller at al. (2006) reduction of haemoglobin of 20% is a stand alone adverse effect; reductions of 10% must be supported by further effects like extramedullary haematopoiesis, haemosiderin deposition, or clinical signs such as dyspnoea, cyanosis, pallor, fatigue or jaundice. None of the clinical signs listed by Muller were reported in the animal studies. Liver and kidney, but not spleen have been examined histopathologically, thus no final conclusion about extramedullary haematopoiesis and haemosiderin can be drawn and since only 5 animals per group were sampled for blood parameters the statistical power is low.

Testicular atrophy and seminiferous tubule degeneration was observed at 6, 12 and 24 months at the highest dose level with both boric acid and disodium tetraborate decahydrate. Microscopic examination of the tissue revealed atrophied seminiferous epithelium and decreased tubular size in the testes. No effects were observed in control, low and mid dose groups.

Based on the testicular atrophy and the haematological effects observed at the highest doses tested (6690 ppm boric acid and 10300 ppm disodium tetraborate decahydrate) a NOAEL for chronic effects equal to 17.5 mg B/kg bw/day (equivalent to 100mg boric acid or 155 mg disodium tetraborate decahydrate/kg bw/day) can be derived.

Table 5.13: Haematological Parameters (Weir, 1966a,b): **% reduction compared to control**

Disodium tetraborate decahydrate	**Cell volume; males**			**Haemoglobin; males**		
Dose	**Low**	**mid**	**high**	**low**	**Mid**	**high**
12 months	3,4	1,1	12,3 *	1,6	2,6	12,6 *
24 months**	9,5 *	12,1 *	5,7	7,8	9,8 *	8,7
Disodium tetraborate decahydrate	**Cell volume; females**			**Haemoglobin; females**		
Dose	**Low**	**mid**	**high**	**low**	**Mid**	**high**
12 months	3,9	10	7,5 *	-7,8	-9	-7,9
24 months**	-4,9	4,2	10	4,7	5,4	14,8 *
Boric acid	**Cell volume; males**			**Haemoglobin; males**		
Dose	**Low**	**mid**	**high**	**low**	**Mid**	**high**
12 months	3,8	5,3	12,5 *	5,5	5,1	10,8 *
24 months**	21,6 *	5,6	10,3 *	19,2	7,3 *	13,2 *
Boric acid	**Cell volume; females**			**Haemoglobin; females**		
Dose	**Low**	**mid**	**high**	**low**	**Mid**	**high**
12 months	-2,6	2,3	5,1	-2,6	-2	2
24 months**	1,3 *	3,9	10	8,1 *	9,9 *	13,3 *

* statistically significant (Weir, 1966 a & b)

**Clinical pathology measurements are not recommended in the long-term rat studies after one year because of deviations due to age dependent diseases at the end of the life cycle (Weingand et al., 1992; Long et al., 1998).

In a mouse study carried out for 13/16 weeks, B6C3F1 mice were fed diets containing 0,1200, 2500, 5000, 10000, 20000 ppm boric acid, equivalent to 0, 194 (34), 405 (71), 811 (142), 1622 (284), 3246 (568) mg boric acid (mg B)/day in males and 0, 169 (47), 560 (98), 1120 (196), 2240 (392), 4480 (784) mg boric acid (mg B)/day in females. At the highest dose level (20000 ppm) 8/10 males and 6/10 females died and 1/10 males from the 10000 ppm group died before the end of the study. Symptoms included nervousness, haunched appearance, dehydration, foot lesions and scaly tails. A reduction in mean bodyweights was observed in the 5000, 10000 and 20000 ppm groups. Hyperkeratosis and/or acanthosis of the stomach were observed at the highest dose only, in both males and females. Further, extramedullary haematopoiesis of the spleen of minimal to mild severity was observed in all dose groups for both males and females. The numbers of animals per group which displayed this symptom is as follows: 1/10,3/10,5/10,5/10,10/10,1/10 in males and 0/10, 2/10, 4/10, 6/10, 10/10, 2/10 in females in the 0, 1200, 2500, 5000, 10000, 20000 ppm groups, respectively. Despite the fact that extramedullary haematopoiesis occurs naturally in mice, there was a dose response relationship evident. The lower incidence at the highest dose can be explained by death of the animals and their bad general condition. In the absence of any haematology data there is no direct evidence of anaemia and since nothing is reported on occurrence of haemosiderin it can be assumed that it was not present. The incidences in the low dose group of 3/10 (m) and 2/10 (f) are in the range of historical control data from 8 NTP studies: 6-28% in males and 12-52% in females (Maronpot et al.1999, Pathology of the mouse, Reference Atlas, Cache River Press). This dose could therefore be seen as the NOAEL in this study. However, since there is no direct evidence of anaemia the effects on testes seen at doses > 5000 ppm are the first adverse effects observed and support a NOAEL of 142 mg B/kg bw/day (NTP 1987).

Testicular atrophy with some interstitial cell hyperplasia was observed in the top dose in a US National Toxicology Program (NTP) bioassay in B6C3F1 mice fed 0, 2500, 5000 ppm in food for 2 years equivalent to 0, 446 and 1150 mg boric acid/kg bw/day, equivalent to 78.1 and 201.3 mg B/kg bw/day. Splenic extramedullary haematopoiesis occurs naturally in mice. An incidence was reported in males as 3/48, 11/49, 10/48, and in females as 10/49, 11/34, 7/50 in the control, low- and high-dose groups, respectively. There is no other mention or discussion about extramedullary haematopoiesis in the rest of the report, so it was not regarded as an important finding. Based on the observed testicular effects a NOAEL of 78.1 mgB/kg bw/day can be derived (NTP, 1987).

The 90 day dog studies on boric acid and disodium tetraborate decahydrate (Paynter, 1963a,b) are of limited value and considered inadequate for risk assessment although they support qualitatively that Boron can cause adverse haematological effects and that the main target organ of boron toxicity is the testis (see Annex HH II A).

5 female and male dogs per group were dosed with dietary levels of 0, 0.01, 0.1, 1.0 % boric acid equivalent to 0, 0.4, 4.4, and 33 mg B/kg/day and 0, 0.0154, 0.154, 1.54 % disodium tetraborate decahydrate equivalent to 0, 0.4, 4.1, and 38 mg B/kg/day, based on the actual body weight and food consumption data in the study. At the mid-dose testes of all males showed an ‘artifactual distortion’ of the outer third of the glands which might be a substance related effect, since it was observed in all males of this dose, but not in males from control and low dose groups. The spermatogenic epithelium was intact at this dose. In the high dose animals severe atrophy of the testes was observed.

A slight degree of extramedullary haematopoiesis was present in the spleen of the test animals somewhat more consistently than in the control animals. At the highest dose haemosiderin was also present in reticular cells of the liver and spleen and the proximal tubule of the kidney, indicating increased red blood cell destruction. Additionally a decrease in haematocrit and haemoglobin values (min 9% and max 28%) was seen in this group for males and females treated with boric acid or disodium tetraborate decahydrate. A combination of these effects is a clear indication for increased red blood cell destruction even though all the clinical laboratory findings from blood and urine samples were within normal limits and comparable to controls. However, the blood effects observed (HB, HCT, extramedullary haematopoiesis, hemosiderin) are slight and not consistently dose dependent.

Furthermore it is not possible to separate potentially treatment-related effects from the generally bad health status of the animals, which is shown in the clinical pathology parameters (inflammation in intestines). There is the possibility that the treatment with the vermifuge was not sufficient, since many individuals showed increased relative eosinophil counts (up to 33%), normal range :< 10% (Bush 1991) during the study. A very common helminth in the dog is Ancylostoma caninum, which causes haemorrhages in the intestine. The inflammation in the mucosa of the small intestine may be due to these parasites.

Apart from the death of one dog in the high dose group of the disodium tetraborate decahydrate study, which may not be attributable to the substance, no further clinical signs were observed.

In 2 year oral toxicity studies in dogs for both boric acid and disodium tetraborate decahydrate the testes were identified as a main target organ. These studies had major deficiencies and are inadequate for risk assessment, but do confirm the effects seen in other species. Dogs were fed 0, 0.033, 0.067, 0.20, 0.67% boric acid equivalent to 0, 1.7, 3.8, 10.9, and 41 mg B/kg/day and 0, 0.051, 0.103, 0.309, 1.03% disodium tetraborate decahydrate equivalent to 0, 1.9, 3.6, 9.6, and 38 mg B/kg/day, based on the actual body weight and food consumption data in the study. No significant clinical findings were observed (Weir, 1966 e,f; 1967 a,b). Each dose group comprised 4 males and females, however, in some cases the animals of one group were not sacrificed at the same time point. These studies are further discussed in section 5.9.1.

Table 5.14: Key Repeated dose toxicity studies

Route	duration of study	Species Strain Sex no/group	dose levels	Results	LO(A)EL	NO(A)EL	Reference
Boric Acid							
Oral in diet	13 weeks for control and top dose group, 16 weeks for other dose groups	Mouse, B6C3F1 10/sex/ Group	0, 1200, 2500, 5000, 10000, 20000 ppm of boric acid. Equivalent to 0, 194, 405, 811, 1622, 3246 mg boric acid/kg bw/day in males & 0, 169, 560, 1120, 2240, 4480 mg boric acid/kg bw per day in females Equivalent to 0, 34, 71, 142, 284, 568 mg B/kg bw/day in males & 0, 47, 98, 196, 392, 784 mg B/kg bw per day in females.	At ≥ 142 mg B/kg bw/day: degeneration and atrophy of the seminiferous tubules was observed. At all dose levels extra medullary haematopoiesis of the spleen	≥ 142mg B/kg bw/day in males 196 mg B/kg bw/day in females	71 mg B/kg bw/day in males 98 mg B/kg bw/day	National Toxicology Program (NTP) Technical Report Series No. 324, 1987
Oral in diet	90 days	Rat Sprague Dawley Treatment: 10/sex/group	0, 52.5, 175, 525, 1750, 5250 ppm Equivalent to 2.6, 8.8, 26, 88 and 260 mg B/kg bw/d.	At ≥ 88 mg B/kg bw/day: Reduction bodyweight; clinical signs of toxicity; testicular atrophy At 26 mg B/kg bw/day on male exhibited partial testicular atrophy	26 mg B/kg bw/day	8.8 mg B/kg bw/day	Weir, 1962
Oral in diet	2 year, interim kills at 6 and 12 months	Rat Sprague Dawley controls: 70/sex Treatment: 35/sex/group Interim kills with 5/sex/group	0, 670, 2000, 6690 ppm Equivalent to 0, 33, 100, 334 mg boric acid/kg bw/day Equivalent to 5.9, 17.5, 58.5 B/kg bw/day	58.5 mg B/kg bw/day: Reduction bodyweight; clinical signs of toxicity; testicular atrophy, reductions in red cell volume and Hb	58.5 mg B/kg bw/day	17.5 B/kg bw/day	Weir, 1966a

Disodium tetraborate decahydrate							
Oral in drinking water	30 and 60 days	Rat, Sprague Dawley male 18/group	0, 500, 1000, 2000 ppm Equivalent to 25, 50, 100 mg B/kg bw/day	Significant reduction in epididymal weight in all dose groups after 30 days In all dosed groups increase of plasma FSH levels and decrease of diameter of the seminiferous tubules. 60 days: reductions in testes and liver weights ≥ 50 mg B/kg bw/day; 60 days > 30 days: significant loss of germinal elements and testicular atrophy ≥ 50 mg B/kg bw/day Changes of testicular enzyme activities ≥ 50 mg B/kg bw/day	25 mg B/kg bw/day	-	Dixon et al. (1979)
Oral in diet	2 years	Rat, Sprague Dawley male and female 70/sex/ group in controls; 35/sex/group treated	0, 1030, 3080, 10300 ppm, Equivalent to 0, 5.9, 17.5 or 58.5 mg B/kg/day	58.5 mg B/kg bw/day: reduced bodyweight; clinical signs of toxicity; reduction in red cell volume and haemoglobin; testicular atrophy	58.5 mg B/kg bw/day	17.5 mg B/kg bw/day	Weir, 1966 b.

5.6.2 Repeated dose toxicity: inhalation

No studies available

5.6.3 Repeated dose toxicity: dermal

No studies available

Studies in humans

The use of case histories is problematic when evaluating toxicological endpoints in a risk assessment and should be evaluated with caution when interpreting cause and effect relationships for the following reasons: Case histories using overt poisoning cases cannot be used to make inferences about chronic endpoints, no information on the haematological parameters is available in these cases prior to intake of boric acid or borax, haematological parameters and electrolytes will be affected in cases that involve severe vomiting and diarrhoea, no nutritional history is provided for these cases that would affect haematological endpoints in particular, no information is available of other concurrent medical conditions or medications used in these cases, poisoning cases are a biased sample since only cases with symptoms are reported, case histories do not provide any dose response information, the purity or concentration of the product is often unknown, and doses are difficult to verify and frequently cannot be defined.

Generally, it can be stated that chronic boron intoxication may have a mode of presentation quite different from that of the acute form (Gordon et al, 1973) and single large doses (~250-300 mg B/adult) are often less dangerous than repeated smaller doses (Jordon & Crissey, 1957). Since the drug is principally eliminated by the kidney, impaired renal function may account for the high blood levels observed in some patients (Jordon & Crissey, 1956) and this might also be an explanation for differences in human responses.

Oral

In humans multiple exposures to boric acid and borax result in various symptoms which may appear singly or together and include dermatitis, desquamation of the skin, alopecia, loss of appetite, nausea, vomiting, diarrhea, menstruation disorders, anemia and focal or generalized central nervous system irritation or convulsions. Much data comes from the mid 1800s to around 1940, when boric acid and disodium tetraborate decahydrate were used systematically for a variety of medical conditions including amenorrhea, malaria, epilepsy, urinary tract infection and exudative pleuritis (Kliegel, 1980). No consistent data are available on the lethal dose of boric acid and borax in man (ECETOC, 1995).

Symptoms varied widely, with no clear dose dependence. While ingestion of 88.4 mg B (505mg boric acid)/kg bw/day for 3-5 days led to the death of 5 of 11 poisoned newborns after a survival period of 2-3 days (Wong et al., 1964) no symptoms were seen in an infant who had ingested 32.2 mg B (184mg boric acid)/kg bw /day during the same period. Ingestion of much lower doses over a few weeks (~45 – 170 mg B/day, equivalent to 266 – 1504 mg borax), affected not only the skin but also central nervous functions of two young patients (4.5 and 9 months respectively). The infants fell into seizures which were accompanied by EEG abnormalities. In one of these cases (~170 mg B (1504 mg borax)/day) a severe anaemia was documented, which reversed after termination of borax up-take (Gordon et al., 1973).

Daily oral doses of boric acid and borax in adults ranged from 70 mg B/day to 1.600 mg B/day (equivalent to 400 – 9143 mg boric acid or 620 – 14159 mg borax). Repeated doses in the 600 mg to 1.400 mg B/day range (equivalent to 3429 – 8000 mg boric acid or 5310 – 12389 mg borax) were given for as long as several weeks to months (Kliegel, 1980).

Herren & Wyss (1964) described the probably longest treatment with a boron compound. A 48 year old man was treated for epilepsy for 20 years with approximately 25 g boric tartrate, sodium salt per day which is equivalent to 0.8g B/day. The patient showed dermatitis, apathy, anorexia, alopecia, seborrheic eczema, gingivitis, nausea, emesis, diarrhea, hypoplastic anaemia and a gastric ulcer, though, any side effects from large chronic ingestion from tartrate cannot be excluded. All symptoms reversed when the treatment was stopped and returned after re-uptake of the treatment.

Also Wiley (1904) described a tendency to diminished percentage of hemoglobin in a group of 12 volunteers who were administered borax in food. Not all individuals displayed this effect, however, it was stated that the blood examinations were not consistently performed.

The most frequently reported symptoms in poisoning cases between 113 mg – 500 mg B/day (equivalent to 646 – 1857 mg boric acid or 1000 – 4425 mg borax) are nausea, emesis, diarrhea, skin rash, erythema, desquamation and alopecia, but it is important to note that in about half of these cases no vomiting was induced. One of the highest doses observed which did not induce vomiting was described for a male person with epilepsy who was treated with 570 mg B (5044 mg borax)/day for 2 years (Kliegel, 1980). In cases where withdrawal of treatment was reported, recovery occurred with no lasting effects (Kliegel, 1980).

Dermal

Several poisoning cases after treatment of burned or abraded skin have been described. Exact doses are difficult to derive for dermal application, but the described effects are the same as for oral exposure, namely nausea, emesis, diarrhoea, erythema, exfoliation of the skin, convulsions. In many cases of diaper dermatitis and severe burns treatment with boric acid and borax resulted in respiratory depression, cyanosis and death of the patients (Kliegel, 1980).

Inhalation

One poisoning case via the inhalation route was described in a 50 year old man who was exposed to borax dust occupationally. The induced effects were alopecia, insomnia, headache, erythema and desquamation with verification of boron in the urine (Tan, 1970). The sole long-term (7-year) follow-up study failed to identify any long-term health effects, although a healthy worker effect cannot be entirely ruled out, given the rate of attrition (47%) (Wegman et al., 1994). Two descriptive studies have been carried out to assess reproductive toxicity in relation to dust exposure (Sayli, 1998, 2001). For a detailed description of Wegman et al. (1994) see section 5.3.3., the studies by Sayli (1998, 2001) and Whorton et al, (1994) are further delineated in section 5.9.

5.6.4 Summary and discussion of repeated dose toxicity:

A number of studies on boric acid or disodium tetraborate decahydrate in diet or via drinking water for periods of 30 days to two years in rats, mice and dogs are available, however, the majority of these studies do not comply with current test guidelines, and they lack essential information regarding e.g. histological descriptions and statistical evaluations of the results. Most studies support that boron can cause adverse haematological effects and that the main target organ of boron toxicity is the testis. Other effects observed at high doses include rapid respiration, hunched position, bloody nasal discharge; urine stains on the abdomen, inflamed bleeding eyes, desquamation and swollen paws and tail, reduced food consumption and body weight gain. Treatment with boric acid and disodium tetraborate decahydrate disrupted spermiation, induced degeneration of testicular tubules and caused testicular atrophy. For effects on the blood system extramedullary haematopoiesis, reduced red cell volume and haemoglobin values and deposition of haemosiderin in spleen, liver and proximal tubules of the kidney were described. Several cases of anaemia have been observed in human poisoning cases. However, although doses in these poisoning cases are difficult to define, the effects occurred generally at relatively high concentrations.

Boric acid, the main species present under physiological conditions, acts as a Lewis acid and as such owns the ability to complex with hydroxyl, amino and thiol groups from diverse biomolecules, like e.g. carbohydrates and proteins (BfR, 2006). Such a mechanism could be involved in effects of boron on different enzyme activities (Huel et al., 2004). For instance the inhibiting effect on δ-Aminolevulinic Acid Dehydratase (ALA-D) in a newborn population described by Huel et al. (2004) could be caused by such interactions. ALA-D plays an important and well-known role in haematopoiesis (Suzen et al., 2003; reviewed in Huel et al., 2004), one possible explanation for the observed reductions in red blood cell and blood heamatrocrit in animals (Weir, 1966a,b). Moreover, elevation of ALA as a consequence of reduced enzyme activity was discussed as major neurotoxic mechanism. Elevation of ALA results in overproduction of ROS (Bechara et al., 1993; Hermes-Lima et al., 1991; reviewed in Huel et al., 2004), inhibition of Na^+K^+ -ATPase (Russell, 1983; reviewed in Huel et al., 2004), action potential deficiency and intramitochondrial Ca liberation (Hermes-Lima et al., 1991; reviewed in Huel et al., 2004). This might explain the CNS effects observed in animals and humans in response to boron exposure. ALA elevation was also described to perturbate the GABAergic system (Minnema & Michaelson, 1986; reviewed in Huel et al., 2004) and influence the adrenergic system (Cuter et al., 1985; reviewed in Huel et al., 2004).

Though a non-mammal species, effects on enzyme activities were also reported in mallard ducks (*Anas platyrhynchos*). Boron affected serum chemistries, causing decreased haemoglobin and increased calcium and triglyceride concentrations in plasma. In addition, brain acetylcholine esterase activity was increased in both sexes, and ATPase activity was increased in males only (Hoffman et al., 1990). The results obtained in these animals support the observed effects in mammals, however, they are only considered in a qualitative fashion.

A NOAEL for effects on testes and the blood system of 17.5 mg B/kg bw/day can be derived (with a LOAEL of 58.5 mg B/kg bwday) from two 2-year studies in rats on boric acid and disodium tetraborate decahydrate (Weir, 1966a,b).

5.7 Mutagenicity

5.7.1 In-vitro data

A number of *in vitro* mutagenicity studies, including bacterial mutation assays in *Salmonella typhimurium* and *Escherichia coli*, gene mutation in mammalian cells (L5178Y mouse lymphoma, V79 Chinese hamster cells, C3H/10T1/2 cells), bacterial DNA-damage assay, unscheduled DNA synthesis (hepatocytes), chromosomal aberration and sister chromatid exchange in mammalian cells (Chinese hamster ovary, CHO cells) have been carried out on boric acid and one study on disodium tetraborate decahydrate. No evidence of mutagenic activity was observed (NTP, 1987; Haworth et al., 1983; Landolph, 1985; Bakke, 1991; Stewart, 1991).

Table 5.15 Key In Vitro Mutagenicity data with boric acid

Test system Method Guideline	organism/ strain(s)	concentrations tested (give range)	Result		Remark give information on cytotoxicity and other	Reference
			+ S9	- S9		
US EPA 40 CRF Part 158; FIFRA, Section 158.340, Guideline 84-2. Comparable to OECD 471	S. typhimurium: TA 1535, TA 1537, TA 97, TA 98, TA 100, TA 1538	10; 50; 100; 1000; 2500 µg/plate	-	-		Stewart, 1991,
40 CFR Part 158 US-EPA-FIFRA, Section 156.340; Complies with OECD 476	Mouse lymphoma L5178Y cells	0, 1.2, 1.7, 2.45, 3.5, and 5.0 mg/ml boric acid	-	-	Concentration related cytoxicity (60% reduction over controls at 5 mg/m)l	Rudd, 1991
1985; NTP protocol. resembles OECD 473	Chinese hamster Ovary (CHO)	With S9: 1000;1600;2000; 2500 µg/ml Without S9: 500; 1500; 2000 µg/ml	-	-		National Toxicology Program (NTP).1987

5.7.2 In-vivo data

No mutagenic activity was seen *in vivo* in a mouse bone marrow micronucleus study on boric acid (O'Loughlin, 1991). Ten mice per sex per group were orally dosed with boric acid in sterile deionised water at concentrations of 900, 1800 and 3500 mg/kg/day. The highest dose was considered to be the maximum practical doses that could be given. The percentage of PCEs among RBCs was not altered significantly by the treatment with boric acid. All boric acid treated groups, when compared to the sterile deionised water control group, had micronucleus counts approximately equal to that of the negative control groups and did not differ statistically from controls at $p < 0.05$. Average micronucleus incidences in male and female mice treated with boric acid were 0.18% and 0.21%, respectively. Male and female mice treated with deionised water alone averaged background micronucleus incidences of 0.23% and 0.25%, respectively.

5.7.3 Human data

Not available

5.7.4 Other relevant information

Not available

5.7.5 Summary and discussion of mutagenicity

All the data *in vitro* indicate no mutagenic activity. In addition the single *in vivo* study on boric acid also indicated no mutagenic activity.

Boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate are not mutagenic.

5.8 Carcinogenicity

5.8.1 Carcinogenicity: oral

Studies in animals

Testicular atrophy with some interstitial cell hyperplasia were the critical effects seen in a US National Toxicology Program (NTP) bioassay in mice fed 0, 2500, 5000 ppm in food equivalent to 0, 446 (75 mg B) and 1150 mg boric acid (200 mg B)/kg bw/d. Splenic extramedullary haematopoiesis occurs naturally in mice and incidences of this effect were reported in males as 3/48, 11/49, 10/48, and in females 10/49, 11/34, 7/50 in the control, low- and high-dose groups, respectively. There is no other mention or discussion about extramedullary haematopoiesis in the rest of the report, so it was not regarded as an important finding. No carcinogenic effects were observed at doses of boric acid of 75 mg B/kg bw/day and 200 mg B/kg bw/day (NTP, 1987). Effects on survival rate and reduced body weight gain were seen at the high doses. The testicular effects noted in these studies are discussed in more detail in Section 5.9.1.

In 2-year feeding studies on boric acid and disodium tetraborate decahydrate in rats, no carcinogenic effects were observed (Weir, 1966a,b). Effects detected in these studies included lowered food consumption, retarded body weight gain, course hair coats, hunched position, swollen pads, inflamed bleeding eyes and changes in haematological parameters at the highest doses (58.5 mg B/kg bw/day). It should, however, be noted that in these rat studies only 10 animlas/sex from control and high dose group were macroscopically and histologically examined. Only the gonads were investigated for all dosed groups. Animals in the low and mid-dose groups were not examined.

From two chronic studies in dogs only 1-2 animals/sex/dose/time were examined, which limit the conclusion that can be made regarding carcinogenicity. No carcinogenic effects were observed.

Table 5.16 Key Carcinogenicity study with Boric acid (mouse)

Route	Species Strain Sex no/group	dose levels frequency of application	Tumours	Reference
Oral in diet	Mouse B6C3F1 50/sex/group	0, 2500, 5000 ppm in food equivalent to 0, 446 (75 mg B) and 1150 mg boric acid (200 mg B)/kg bw/d 103 weeks	No evidence of carcinogenicity was found. At both doses: In males haematopoiesis in the spleen. Other effects in testes: At the high dose increased testicular atrophy and interstitial cell hyperplasia, variable loss of spermatogenia, and various stages of spermatogenesis from the seminiferous tubules.	National Toxicology Program (NTP) 1987.

5.8.2 Carcinogenicity: inhalation data

Not available

5.8.3 Carcinogenicity: dermal data

Not available

5.8.4 Carcinogenicity: human data

Not available

5.8.5 Other relevant information

Not available

5.8.6 Summary and discussion of carcinogenicity

Based on the mouse NTP-study (1987) boric acid is not regarded carcinogenic. Although not carried out according to modern standards, nor to GLP, the 2-year studies in rats and dogs support this finding. While in the 2-year rat studies, only 10 animals/sex of the control and high-dose group were macroscopically and histologically examined, only 1-2 animals/sex/dose/time were examined in the 2-year studies in dogs, which limits the conclusions that can be derived from these studies. However, they are well performed and reported and are adequate to evaluate the carcinogenicity of boric acid and sodium borates. It can be concluded that boric acid and sodium borates are not carcinogenic and there is no concern for carcinogenic effects in humans.

Boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate are not carcinogenic.

5.9 Toxicity for reproduction

5.9.1 Effects on fertility

Studies in animals

Effects on the testis have been observed in both sub-chronic and chronic studies in three species: rats, mice and dogs. Further, a three generation study in rats and a continuous breeding study in mice showed effects on male and female fertility (Fail et al., 1991; Weir, 1966 c, d). A comparison of the key NOAELs and LOAELs for reproduction studies is given in the table 5.17. The effects tend to be similar in all three species, although most data comes from rat studies. The studies by Paynter, 1963a,b and Weir, 1962, 1962b, 1963, 1966a-f, 1967a,b were published in Weir & Fisher (1972). For the present dossier the original studies have been evaluated.

In a 30/60 day study in male Sprague-Dawley rats (18 per group) on disodium tetraborate decahydrate administered in drinking water (0, 500, 1000, 2000 ppm equivalent to 0, 25, 50, 100 mg B/kg bw/day) no reduction of bodyweight or organ weights were observed, with the exception of significantly reduced epididymal weights in all dosed groups after 30 days. After 60 days the weight of testes and liver at 50 and 100 mg B/kg bw/day was also reduced. At these doses a significant loss of spermatocytes and spermatogenic cells and testicular atrophy (60 days > 30 days) concomitant with reduced enzyme activities of hyaluronidase, SDH (dehydrogenase of sorbitol) and LDH-X (lactate dehydrogenase isoenzyme X) and increased enzyme activities of G3P-DH (glyceraldehyde-3-phosphate dehydrogenase) and M-DH (malate dehydrogenase) were observed, correlating well with dose and duration of exposure. Plasma levels of FSH (follicle stimulating hormone) were increased in all treated groups, with both a dose-response and an exposure time-response apparent. LH (luteinizing hormone) and testosterone levels were not significantly altered. Male fertility studies (5 males per group) demonstrated that at the 25 mg B/kg bw/day level, no effects were observed. However, at 50 and 100 mg B/kg bw/day, male fertility was significantly reduced. Infertility was reversible within 5 weeks, with the exception of the 60 days high dose group, which remained sterile. Since no dose-related decrease in litter size or fetal death in utero occurred, it was concluded that infertility was a consequence of germinal aplasia. In this study a LOAEL of 25 mg B/kg bw/day could be identified (Dixon et al., 1979).

In male Sprague-Dawley rats (18 per group) fed disodium tetraborate decahydrate for either 30 or 60 days at 60 or 125-131 mg B/kg bw/day testis weight was reduced, testicular germ cells were depleted, selected testicular enzymes were affected and fertility was reduced. Hyaluronidase, sorbitol dehydrogenase, and lactic acid dehydrogenase isozyme-X were significantly decreased; and glyceraldehyde-3-phosphate dehydrogenase and malate dehydrogenase were significantly increased at 60 and 125-131 mg B/kg bw/day. Further, an increase in plasma FSH levels correlated well with germinal depletion and both effects were dose and time dependent. As might be expected, while recovery from inhibition of spermiation occurred at the lower doses, there was no recovery from testicular atrophy when the germ cells were lost. The serial mating studies in 5 males from each group indicate that the boron induced infertility is attributable to germ cell depletion. Germinal aplasia, elevated FSH-levels and infertility persisted at least for 8 months following cessation of boron exposure for the high dose 60 day group, but was reversible in the lower and shorter dosed groups. A NOAEL of 30 mg B/kg bw/day could be derived (Lee et al., 1978).

In a study on Fischer 344 (CDF (F3449/CrlBr) rats in which 36 animals were treated with boric acid equivalent to 60.9 mg B/kg bw/day in the diet (control group consisted of 30 animals) the reproductive effects started with reversible inhibition of spermiation. Inhibition of spermiation was already observed after 7 days of treatment and after 28 days extreme epithelial disorganisation and sperm cell loss was evident. Reduced testosterone levels were observed in the dosed animals, which could be reversed to control levels by treatment with hCG (human chorionic gonadotropin) and LHRH (luteinizing hormone releasing hormone). Animals were investigated after 4, 7, 10, 14 and 21 days (Treinen and Chapin, 1991).

In male Fischer 344 (CDF (F3449/CrlBr) rats (6 per group) early effects (severe inhibition of spermiation) were seen after 14 days treatment, at doses around 38 mg B/kg, (217 mg boric acid/kg bw/day), but at a lower dose of 26 mg B/kg (149 mg boric acid/kg bw/day) the effects seen by histopathological analysis including staging, took about 28 days to manifest. The severely inhibited spermiation at 38 mg B/kg bw/day was resolved by 16 weeks posttreatment, but areas of focal atrophy were detected that did not recover posttreatment. Also no signs of recovery from atrophy were observed at doses of 52 & 68 mg B/kg bw/day (Ku et al., 1993).

In rat 90 day studies of boric acid all the male rats at 1750 ppm B (88mg B/kg bw/day) had atrophied testis and histologically complete atrophy of the spermatogenic epithelium and a decrease in the size of the seminiferous tubules. One male at 525 ppm (26 mg B kg bw/day) exhibited partial testicular atrophy (Weir 1962). Similar results were observed in a study with disodium tetraborate decahydrate (Weir 1962b). See section 5.6.1 for a detailed description of these studies.

In a three generation study in rats groups of 8 males and 16 females were treated with boric acid or disodium tetraborate decahydrate equivalent to 0, 5.9, 17.5 and 58.8 mg B/kg bw/day. The high dose P1-generation failed to produce litter. Also when females of that group were mated with untreated males they had no offspring, indicating that the female reproduction was affected. A decreased ovulation in the majority of ovaries examined in that group was mentioned not to be sufficient to explain the observed infertility. Only ovaries of high dosed females were examined. Gross necropsy revealed atrophied testes in all P1 males at 58,8 mg B/kg bw/day. No information on F1 and F2 generations for this endpoint is available (Weir, 1966c, d). The NOAEL was 17.5 mg B/kg bw/day, however, as also stated in WHO (1998) the small group size (n=8), low control fertility (60%), limited data reported, and inappropriate statistics all limit the applicability of these data for risk assessment. However, as comparable results were obtained in both studies (boric acid and disodium tetraborate decahydrate) and effects were seen at equivalent concentrations, on the basis of boron equivalents, this gives more value to the data derived from these studies. For a detailed list of effects investigated in this study at the different doses tested see Annex HH II B.

Similar results were seen in two-year rat studies of boric acid and disodium tetraborate decahydrate at 58.5 mg B/kg bw/day conducted at the same dose range as the above described three generation study in the same laboratory (Weir 1966 a,b). Testicular atrophy and seminiferous tubule degeneration was observed at 6, 12 and 24 months at the highest dose level (58.5 mg B/kg bw/day) with both boric acid and disodium tetraborate decahydrate. Microscopic examination of the tissue revealed atrophied seminiferous epithelium and decreased tubular size in the testes. No effects were observed in the control and low dose groups. The NOAEL was 17.5 mg B/kg bw/day. For a detailed list of effects investigated in this study at the different doses tested see Annex HH II B.

Fewer data are available for mice and dogs, but the results support the findings in rats:

In a continuous breeding study of boric acid in mice (NTP, 1990; Fail et al., 1991), the three administered doses were 1000 ppm (26,6 mg B/kg bw/day), 4500 ppm (111,3 mg B/kg bw/day) and 9000 ppm (220,9 mg B/kg bw/day). A dose-related effect on the testis (testicular atrophy and effects on sperm motility, morphology and concentration) was noted; fertility was partially reduced at 111 mg B/kg bw/day, and absent at 221 mg B/kg bw/day.

For cross over mating only the mid dose group (111,3 mg B/kg bw/day) could be mated with control animals, since the high dose produced no litter. Indices of fertility for mid dose males with control females, control males with mid dose females and control males with control females were 5%, 65% and 74%, respectively. The according indices of mating (incidence of copulatory plugs) were 30%, 70% and 79%. This indicates that the primary effect was seen in males, however, slight effects were also noted in females. Live pup weight (adjusted for litter size) was significantly reduced compared to control litters, the average dam weight was significantly lower on postnatal day 0 compared to control dams and the average gestational period of the mid dose females was 1 day longer than in control females. The latter finding has also been observed in the developmental toxicity study by Price et al. (1996, see section 5.9.2).

In task 4 of this continuous breeding study control animals and low-dose F1 animals were mated because in the 9000 ppm groups no litters and in the 4500 ppm group only 3 litters were produced. While mating, fertility and reproductive competence were un-altered compared to control, the adjusted pup-weight (F2) was slightly but significantly decreased. F1 females had significantly increased kidney/adrenal and uterus weights and the oestrus cycle was significantly shorter compared to control females. In F1 males a reduction in sperm concentration was observed, but no other sperm parameters were influenced.

While in this study the NOAEL for females of the F0-generation is 1000 ppm this is a LOAEL for males of the F0-generation (motility of epididymal sperms was significantly reduced: 78% ± 3 in controls vs. 69% ± 5 at 1000 ppm). For the F1-generation 1000ppm can be identified as a LOAEL, based on the 25% reduction of sperm concentration in males and increased uterine and kidney/adrenal weights and the shortened oestrus cycle in females at this dose. Further, though normal in number, the F2-pups had reduced adjusted bodyweights at 1000 ppm, which is therefore also a LOAEL for F2-generation. For a detailed list of effects investigated in this study at the different doses tested see Annex HH II B.

Fail et al., (1989) (reviewed in Moore et al. 1997) evaluated boric acid on male deer mice (*Peromyscus maniculatus*) to test the effects on fertility, reversibility of effect, and to determine if reproductive efficiency was normal in offspring of treated deer mice. Four groups of 30 male deer mice were fed a diet that contained either 4500 or 9000 ppm boric acid for 8 weeks. These doses equal 108,1mg B/kg bw/day and 216,2mg B/kg bw/day, respectively. Two groups of 30 male deer mice were fed an identical diet to which no boric acid was added and served as controls. At the end of the 8-week exposure period, half of the male deer mice were mated with untreated adult female deer mice for 1 week. Following the mating trial these males were killed and necropsied. The other groups of treated male deer mice were fed a diet containing no boric acid for an additional 9-week period to assess any recovery from the boron treatment. After the 9-week recovery period the male deer mice were mated for 1 week with untreated adult female deer mice, then killed and necropsied. After each mating trial the females were allowed to litter and the resulting pups were counted, sexed, and weighed at birth.

Complete infertility was observed in male deer mice exposed to 38,5 mg B/kg bw/day for 8 weeks. No decrease in fertility was observed in deer mice that consumed 19,3 mg B/kg bw/day. Deer mice at the 38,5 mg B/kg bw/day level had decreased testicular and epididymal weights. A reduction in the seminiferous index (i.e. a semiquantitative rating of cell types present) was observed at the high dose level. This was felt to account for the resulting decrease in formation of mature sperm. Body and organ weights, seminiferous index, and litter measurements for the lower dose level deer mice were comparable to controls. Following a

9-week period on control diet, mice that consumed 38,5 mg B/kg bw/day demonstrated a fertility performance similar to untreated mice. Necropsy results and histologic examination of testes were also similar to controls. From this study a NOAEL of 38,5 mg B/kg bw/day for male fertility effects could be derived.

Data in dogs derive from two very limited 90 day and two-year dietary studies. Dogs were dosed for 90 days with dietary levels of 0, 0.01, 0.1, 1.0% boric acid equivalent to 0, 0.4, 4.4, and 33 mg B/kg/day and 0, 0.0154, 0.154, 1.54% disodium tetraborate decahydrate equivalent to of 0, 0.4, 4.1, and 38 mg B/kg/day, based on the actual body weight and food consumption data in the study. At the mid-dose testes of all males showed 'artifactual distortion' of the outer third of the glands which might be a substance related effect, since it was observed in all males of this dose, but not in males from control and low dose groups. The spermatogenic epithelium was intact at this dose. In the high dose animals severe atrophy of the testes was observed. The data from the 90 day studies on boric acid and disodium tetraborate decahydrate has been considered inadequate for risk assessment and is only used as supporting evidence of a reproductive effect and not to contribute to the determination of the NOAEL (EFSA, 2004; US EPA, 2004; IPCS, 1998; ECETOC, 1995; UK EVM, 2003). The severe limitations of this study are further detailed in Annex HH II A.

In the two year dog studies on both boric acid and disodium tetraborate decahydrate, the actual dietary intake was reported in the original study reports allowing a more accurate measure of the dietary intake than presented in the published paper, in which the authors estimated the dietary intakes from standard intake figures. Groups of four male dogs were fed either boric acid or disodium tetraborate decahydrate at doses up to 10.9 mg B/kg bw/day (62.4 mg boric acid/kg bw/day) and 9,6 mg B/kg bw/day (84.7 mg disodium tetraborate decahydrate/kg bw/day) in one study and 41 mg B/kg bw/day (233.1 mg boric acid/kg bw/day) and 39 mg B/kg bw/day (373.2 mg disodium tetraborate decahydrate/kg bw/day) in a second study. The animals were sacrificed at various time periods such that observations were reported on only 1 or 2 animals. At the highest dose, testicular atrophy was observed, however the effects in the only one disodium tetraborate decahydrate treated dog investigated at 38 weeks were less severe than those seen in the control dog. Testicular atrophy was present in three out of four control dogs, so that the significance of the effect in the treated animals is difficult to assess. One boric acid treated and one disodium tetraborate decahydrate treated dog were allowed to recover for three weeks. Some recovery was observed in each dog. Histopathological changes such as decreased spermatogenesis remained which was less obvious in the disodium tetraborate decahydrate treated dog. The NOAEL was deemed to be the equivalent of 10.2 mg B/kg bw/day by the authors (Weir, 1966 e,f; 1967 a, b). Although this data is inadequate for risk assessment, it does confirm the effects seen in other species.

Table 5.17: Comparison of NOAELs and LOAELs for Reproductive Effects

Species	Study type or duration	NOAEL	LOAEL	Effect at LOAEL	Reference
Rat, Sprague Dawley	30 and 60 days, 18 per group	-	25 mg B/kg bw/day	Significant reduction in epididymal weight in all dose groups after 30 days In all dosed groups increase of plasma FSH levels and decrease of diameter of the seminiferous tubules. 60 days: reductions in testes and liver weights ≥ 50 mg B/kg bw/day; 60 days > 30 days: significant loss of germinal elements and testicular atrophy ≥ 50 mg B/kg bw/day Changes of testicular enzyme	Dixon et al., 1979

				activities ≥ 50 mg B/kg bw/day	
Rat, Sprague Dawley	30 and 60 days, 18 per group Serial mating for 12 / 20 weeks	30 mg B/kg bw/day	60 mg B/kg be/day	Testis weight reduced and atrophy, Testicular germ cells depleted, Changes in testicular enzyme activities, Increased FSH levels, Reduced fertiliy (irreversible during the study in the high dose group, 60days)	Lee et al., 1978
Rat, Fischer 344	9 week dietary study, 6 per group	-	26 mg B/kg bw/day	Mild reversible inhibition of spermiation	Ku et al., 1993
Rat, Sprague Dawley	3-generation dietary study, 8 males and 16 females/group	17.5 mg B/kg bw/day	58.5 mg B/kg bw/day	Testicular atrophy reduced fertility (no offspring from high dose females mated with untreated males)	Weir, 1966c,d
Rat, Sprague Dawley	2 year dietary study, 70/control/sex, 35/group/sex	17.5 mg B/kg bw/day	58.5 mg B/kg bw/day	Testicular atrophy with atrophied seminiferous epithelium;	Weir, 1966a,b
Mouse, Swiss CD-1	Continuous breeding dietary study, 40 males and females in control, 20 males and females in dosed groups	-	26.6 mg B/kg bw/day	Reduced sperm motility (F0) Increased uterine weight and kidney/adrenal weight, shortened oestrus cycle and 25% reduction in sperm concentration (F1) Reduced adjusted bodyweight of pups (F2)	Fail et al., 1991 (NTP, 1990)

Table 5.18: Fertility Studies

Route of exposure	Test type Method Guideline	Species Strain Sex no/group	Exposure Period	Doses	Critical effect	NO(A)EL Parental		NO(A)EL F1		NO(A)EL F2		Reference
Fertility Study of Boric acid in Rats						m	f	m	f	m	f	
Oral diet	Predates OECD 3generation 2litter per generation study	Rat Crl:CD Sprague Dawley 8 males 16 females/group	14 weeks pre-treatment then through three generations	0, 670, 2000 or 6700 ppm boric acid (0, 117, 350 and 1,170 ppm boron) in the diet, equivalent to 0, 34 (5.9), 100 (17.5) and 336 (58.5) mg boric acid (mg B)/kg bw	Top dose level caused testes atrophy prior to first mating so no litters produced. Infertility in males and females of the high dose when mated with untreated animals. No adverse effects in mid and low dose groups in any generation.	2000 ppm = 100 mg/kg bw boric acid= 17.5 mgB/kg bw	2000 ppm = 100 mg/kg bw boric acid= 17.5 mgB/kg bw	2000 ppm = 100 mg/kg bw boric acid= 17.5 mgB/kg bw	2000 ppm = 100 mg/kg bw boric acid= 17.5 mgB/kg bw	2000 ppm = 100 mg/kg bw boric acid= 17.5 mgB/kg bw	2000 ppm = 100 mg/kg bw boric acid= 17.5 mgB/kg bw	Weir RJ (1966d).
Fertility Study of Borax in Rats												
Oral diet	Predates OECD 3generation 2litter per generation study	Rat Crl:CD Sprague Dawley 8 males 16 females per group	14 weeks pre-treatment then through three generations	0, 1030, 3080 or 10300 ppm borax (0, 117, 350 and 1,170 ppm boron) in the diet, equivalent to 0, 50 (5.9), 155 (17.5) and 518 (58.5) mg borax (mg B)/kg bw respectively	Top dose level caused testes atrophy prior to first mating so no litters produced. Infertility in males and females of the high dose when mated with untreated animals. No adverse effects in mid and low dose groups in any generation.	350 ppm boron in the diet, equivalent to 155 (17.5) mg borax (mg B)/kg bw	350 ppm boron in the diet, equivalent to 155 (17.5) mg borax (mg B)/kg bw	350 ppm boron in the diet, equivalent to 155 (17.5) mg borax (mg B)/kg bw	350 ppm boron in the diet, equivalent to 155 (17.5) mg borax (mg B)/kg bw	350 ppm boron in the diet, equivalent to 155 (17.5) mg borax (mg B)/kg bw	350 ppm boron in the diet, equivalent to 155 (17.5) mg borax (mg B)/kg bw	Weir RJ (1966c)

Route of exposure	**Test type Method Guideline**	**Species Strain Sex no/group**	**Exposure Period**	**Doses**	**Critical effect**	**LOAEL F0**	**NOAEL F0**	**LOAEL F1**		**LOAEL F2**		**Reference**
Fertility Study of Boric acid in Mice						m	f	m	f	m	f	
Oral diet	Continuous breeding protocol (NTP)	Mouse, Swiss CD1 40 males and females in control, 20 males and females in dosed groups	1 week pre-mating	0, 1000, 45000, 9000 ppm, Equivalent to 0, 26.6, 111.3, 220.9 mg B/kg bw/day	Reduced sperm motility (F0) Increased uterine weight and kidney/adrenal weight, shortened oestrus cycle and 25% reduction in sperm concentration (F1) Reduced adjusted bodyweight of pups (F2)	26.6 mg B/kg be/day	26.6 mg B/kg be/day	26.6 mg B/kg be/day	26.6 mg B/kg be/day	26.6 mg B/kg be/day	26.6 mg B/kg be/day	*Fail et al., 1991 (NTP, 1990)*

Studies in humans

The potential reproductive effects of inorganic borate exposure to a population of workers at a large mining and production facility was assessed using the Standardised Birth Ratio (SBR), a measure of the ratio of observed to expected births. A total of 542 workers completed a reproductive questionnaire. The average exposure for the highest exposure group was 28.4 mg B/day (approximately 0.4 mg B/kg bw/day) for two or more years. The average duration of exposure was 16 years. The number of offspring was actually greater than the US national average, indicating no adverse effects on reproduction in these workers (Whorton et al., 1994). It should be noted that the comparison with the US national average may dilute the effect that the socio-economic status plays on the number of offspring.

In a study of a highly exposed population in Turkey, where exposure comes mainly from naturally high levels of B in drinking water (up to 29 mg B/l) as well as from mining and production, no adverse effect has been reported on fertility over three generations (Sayli, 1998; 2001). Sayli et al. compared fertility in the residents of two Turkish villages with high levels of boron in their drinking water (8.5 to 29 mg B/L and 2.05 to 2.5 mg B/L), with their nearby villages with low boron levels (0.03 to 0.40 mg B/L). The authors compared the reproductive history of families living in the high boron region with families in the low boron region by identifying married adults who provided information about each spouse's family pedigrees covering three generations. In the high boron region, 159 three-generation kindreds containing 1068 families were ascertained. In the low-boron region, 154 three-generation kindreds containing 610 families were ascertained. No significant difference in fertility was noted between the high and low exposure groups. The gender ration (M:F) of offspring was 0.89 in the high exposure region compared to 1.04 in the low boron region, although the difference was not statistically significant ($p > 0.05$) (Sayli, 1998; 2001).

Tarasenko et al. (1972) investigated reproductive effects of borates in a group of 28 workers aged between 30 and 40. They had worked in boric acid production plants for more than 10 years. 50% of air samples taken at the work place revealed concentrations ≤ 1,75mg B/m^3, with maximum values ranging from 3,5 – 14,5 mg B/m^3. A questionnaire, recommended by the Moscow Science Research Institute of the Psychiatric Ministry of Public Health USSR, which permits answers to be objectively evaluated and yields quantitative results, was used to assess the sexual function (SFM) of the exposed group compared to 10 un-exposed individuals. While the exposed groups had an SFM of 28,5 ± 1,2, the un-exposed men had an SFM of 31,4 ± 0,83 ($P < 0,05$). Semen analysis of 6 men from the exposed group showed reduced values for volume (4 cases: 1,1-2,2ml compared to normal values of 3-5ml), reduced number of spermatozoa (5 cases: 33-42 mill compared to normal values of 60-100 mill.) lower percentage of mobile spermatozoa (2 cases: 11-66% compared to normal values of 75-80%), reduced fertilizing power (4 cases: 40, 50, 77, & 106 compared to normal values of > 200) and increased fructose content in 5 cases. No effects on the number of pregnancies of women of the exposed men could be observed. Overall the study is of minor value since information on exposure (concentration & duration) is insufficient and the investigated group is rather small.

Two other reports need to be mentioned, however, as descriptions of these two cases are rather scarce they can only be judged as supportive and mentioned for reasons of completeness. One observation by Truhaut et al. (1964) reported germinal aplasia in men exposed to the boron containing tranquilizer methyl-5-n-propyl-5-R-tolyl-2-dorborane. Further, reports from the USSR indicate that water containing 0,3 mg/kg B decreased sexual function of men (Krasovskii et al., 1976).

5.9.2 Developmental toxicity

Studies in animals

Only boric acid has been tested in developmental studies. Visceral and skeletal malformations were observed dose and species dependent in rats, mice and rabbits. Rats were more sensitive than mice and rabbits (Price et al., 1996ab, Heindel1992). The studies by Price et al. (1996a) and Heindel et al. (1992) in rats were chosen as critical developmental studies because they were well-conducted studies of a sensitive endpoint that identified both a NOAEL and LOAEL. A comparison of the key NOAELs and LOAELs for developmental studies is given in the Table 5.19.

In a dietary study groups of Sprague-Dawley rats were dosed with 0, 3.3, 6.3, 9.6, 13.3, or 25 mg B/kg bw/day from gestational day 0 to 20 (phase 1) or 0, 3.3, 6.3, 9.8, 12.9, or 25.4 mg B/kg bw/day from gestational day 0 to 20 (phase 2). In phase 1, which was conducted according to OECD guideline 414, dams were terminated and uterine contents examined on gestational day 20. For the low to high-dose groups, fetal body weights were 99, 98, 97, 94, and 88% of controls, the reduction was significant only in the 13.3 and 25 mg B/kg bw/day groups. At non-maternally toxic doses, there was a reduction on foetal weight and skeletal malformations (increase in incidence of wavy ribs and short rib XIII, decreased incidence of rudimentary extra rib on lumbar 1). In phase 2 boric acid exposure stopped at birth and dams were allowed to deliver and rear their litters until postnatal day 21. On postnatal day 0 of phase 2 there were no effects of boric acid on offspring body weight, nor were any differences seen through postnatal day 21. On post natal day 21 the percentage of pups per litter with short rib XIII was elevated only in the 25.3 mg B/kg bw/day group, but there was no treatment-related increase in wavy rib or extra rib on lumbar 1. Maternal liver weight (absolute and relative to body weight) and maternal right kidney weight (absolute) were not affected. Relative kidney weight was increased at 25 mg B/kg bw/day in the diet on gd 20, with no treatment-related effects on post natal day 21. The NOAELs for developmental toxicity in rat for the prenatal (Phase 1) and postnatal phase (Phase 2) were 9.6 and 12.9 mg B/kg bw/day, respectively. There was little evidence of maternal toxicity at any of the doses tested (Price et al., 1996a).

Average doses for Sprague-Dawley rats were 0, 13.7, 28.5, 57.8 (on gestation day 0-20) and 94.3 (gestation day d 6-15) mg B/kg bw/day (Heindel, et al., 1992). The NOAEL for developmental toxicity in rats was determined to be < 13.7 mg B/kg bw/day. Prenatal mortality was increased in the highest dose group compared to control (36% resorption per litter versus 4%). The reduction in fetal body weight from independent studies at 0.1% or 0.2% boric acid in feed from gd 0 to 20 was comparable (Price et al., 1996a; Heindel et al., 1992).

Similar findings were observed in Swiss albino mice receiving estimated doses of 0, 43, 79, and 175 mg B/kg bw/day on gestation days 0-20 in feed (Heindel et al, 1992). Maternal toxicity was indicated by mild renal lesions and at the highest dose increases in the relative kidney weight and food and water intake. A NOAEL for maternal toxicity was not reached in the mouse study. The key developmental effects in mice observed were similar to those seen in rats, which were investigated in the same study as well, i.e. a reduction in foetal body weight at the mid dose (79 mg B/kg) and an increase in skeletal malformations (missing lumbar vertebrae, fused vertebral arches and short rib XIII) and resorptions at the highest dose, where slight maternal toxicity was recorded. The NOAEL for developmental effects in mice was 43 mg B/kg bw/day, the LOAEL was of 79 mg B/kg bw/day (Heindel et al., 1992). Maternal toxicity in mice and rats were not striking (Heindel et al., 1992), since the effects on food and water consumption were minimal. Weight gain seemed to be secondary to developmental toxicity (i.e. body weight gain corrected for gravid uterine weight was not significant reduced). Both studies (mice/rat) failed to provide evidence for any treatment related renal pathology (Price et al., 1996a). Neither the incidence nor the severity of the minimal nephropathy was dose related. In rat, developmental toxicity (decreased foetal weight: at 13.7 mg B/kg bw/day) occurred in the absence of marked maternal toxicity.

New Zealand White (NZW) rabbits were administered once daily at doses of 0, 10.9, 21.9 and 43.8 mg B/kg bw/day by gavage during major organogenesis on gestation days (gd) 6-19 (Price et al, 1996b). Rabbits exposed to 43.8 mg B/kg bw/day on gestation day 6-19 were associated with decreased food intake (during treatment), relative but not absolute kidney weight increase and vaginal bleeding. Prenatal mortality at the highest dose was increased (90% resorption/litter versus 6% controls). In this dose group 14 live fetuses (6 live litters) were available for evaluation, compared to 153-175 live fetuses (18-23 live litters) in the other groups. The resoprtion rate was consistent with other studies, but the incidence of resoprtions was disproportional high in boric acid-exposed rabbits relative to rabbits with even greater restriction of food intake (Parker et al, 1986; Matsuzawa et al, 1981). Development of the cardiovascular system was particular sensitive. The types of malformations (primarily cardiovascular) were dissimilar to those reported after diet restriction in other rabbit studies. Decreased maternal food intake may have been a contributing factor, but cannot be solely responsible for the range and severity of adverse developmental effects observed at the high dose of boric acid. Malformed fetuses/litters increased in 72% of the high-dose fetuses versus 3% of controls. The only skeletal effect observed was a decreased incidence of rudimentary extra rib on lumbar 1 which was not considered biologically significant. Mild maternal effects, but severe developmental toxicity were observed at 43.8 mg B/ kg bw/day (Price et al., 1996b).

Table 5.19 Comparison of NOAELs and LOAELs for Developmental Effects

Species	mg/Boron/kg bw/day			Effect at LOAEL	Reference
	Maternal NOAEL	NOAEL	LOAEL		
Rat	No maternal toxicity observed	9.6 * 12.9**	13.3* 25.3**	Decreased foetal body weight; skeletal malformations (short rib XIII, wavy rib, extra rib on lumbar I)	Price et al., 1996a
Rat	13.7*	< 13.7	13.7	Decreased foetal body weight, skeletal malformations (short rib XIII)	Heindel et al., 1992
Mice	Not identified**	43	79	Decreased foetal body weight, skeletal malformations	Heindel et al., 1992
Rabbits	21.9	21.9	43.8	Mild maternal toxicity; resorptions; Visceral malformations: cardiovascular system (interventricular septal defect)	Price et al., 1996b

* prenatal (Phase 1); **postnatal (Phase 2)

Table 5.20 Key Developmental studies with Boric acid

Route of exposure	Test type Method Guideline	Species Strain Sex no/group	Exposure Period	Doses (mg boron/ kg body weight per day)	Critical effects fetuses	NO(A)EL maternal	NO(A)EL Teratogenicity Embryotoxicity	Reference
Oral in diet	GLP, FIFRA, Federal Register 54, 3401-34074	Rat Female Sprague-Dawley and Male Cr1:CD (SD) BR VAF/ Plus	Day 0-20 of gestation (Exposure limited to gd 0-20)	Phase 1: (gd 0-20) 0; 3.3; 6.3; 9.6; 13.3; 25.0 Phase 2: (pnd 0-21) 0; 3.3; 6.3; 9.8; 12.9; 25.4	Phase 1: Reduction of foetal body weight on gd 20 in 13.3 and 25 mg/kg bw/day, malformations: incidence of short rib XIII or wavy ribs increased. Phase 2: No decreased foetal body weights effect. Short rib XIII, but no wavy rib or extra rib on lumbar I (pn d 21)	No maternal toxicity observed	NOAEL for foetal skeletal effects is 9.6 mg B/kg bw/day	Price et al, 1996a
Oral in diet	GLP	Rat Female Sprague-Dawley and Male Cr1:CD (SD) BR VAF/ Plus	Day 0-20 of gestation (highest dose to one group on Day 6-15 of gestation)	0; 13.7; 28.5; 57.8; 94.3;	Reduction of foetal body weight, malformations: Incidence of short rib XIII	13.7 mg/kg bw/day	< 13.7 mg/kg bw/day, foetal body weight decrease	Heindel et al., 1992
Oral in diet	GLP	Mice Swiss albino CD-1	Day 0-17 of gestation	0, 43, 79, 175	Reduced bodyweight; skeletal malformations including short rib XIII.	Not identified	43 mg B /kg bw/day	Heindel et al, 1992.
Oral Gavage in water	GLP	Rabbits NZW 30 per group	Day 6-19 of gestation, termination on gd 30	0, 10.9, 21.9 ,43.8	Prenatal mortality increased, malformations increased primarily cardiovascular defects (interventricular septal)	43.8 mg B/kg bw/day	21.9 mg B/kg bw/day	Price et al, 1996b

Phase 1/2: prenatal/postnatal period; gd gestation day; pnd postnatal day

Studies in humans
No studies available

5.9.3 Summary and discussion of reproductive toxicity

Effects on Fertility

Although the available human data are not sufficient to allow judgments about reproductive toxicity, the experimental data from different animal species gave consistent results indicating that boric acid and tetraborates might cause reproductive toxicity in humans.

Effects on male fertility have been investigated in detail. A dose related effect on the testis was observed in rats, mice and deer mice, with confirmation from limited studies in dogs. Effects in rats start with reversible inhibition of spermiation after 14 days (at 39 mg B/kg bw/day) and 28 days (at 26 mg B/kg bw/day). At doses equal to and above 26 mg B/kg bw/day testicular atrophy, degeneration of seminiferous tubules and reduced sperm counts were observed. Male fertility was further investigated in two serial mating studies of treated male rats with untreated female rats. Infertility of treated males correlated well with germinal aplasia. Similar effects on male fertility were described in deer mice (*Peromyscus maniculatus*) after treatment with boric acid. Fertility studies in rats (two three-generation study with for boric acid and disodium tetraborate decahydrate) and mice (a continuous breeding study with boric acid) further support effects on testes as the underlying cause for reduced male fertility.

In the latter two studies it could be demonstrated that female fertility is also affected: Female rats treated with 58.8 mg B/kg bw/day produced no offspring when mated with control males, a NOAEL of 17,5mg B/kg bw/day was derived for this effect from two 3-generation studies for boric acid and disodium tetraborate decahydrate. Reduced fertility was also seen in female mice treated with 111,3 mg B/kg bw/day in a continuous breeding study. This study further described reduced average dam weight on PND 0, reduced average gestational period, significantly reduced adjusted litter weight of F0 females at 111,3 mg B/kg bw/day and reduced oestrus cycle length and significantly reduced adjusted litter weight of F1 females at 26,6 mg B/kg bw/day. In this study no NOAEL for effects on female fertility could be derived.

Diminished sperm production may be due to testicular effects on germ cell, Sertoli cell, or Leydig cell function or act via an alteration of the pituitary-hypothalamic axis. There is an indication that LH and FSH are elevated under boric acid treatment (Lee et al., 1978) and that serum testosterone may be decreased in CD-1 mice and F344 rats (Grizzle et al., 1989; reviewed in Fail et al., 1991; Treinen & Chapin, 1991). The decrease in prostate weight at 111,3mg B/kg be/day observed by Fail et al. (1991) might be caused by reduced testosterone levels.

Several attempts were carried out to evaluate possible endocrine effects of boron compounds, however, no final conclusion can be drawn to date (Wang et al., 2008; Fail et al. 1998; Sauls et al., 1992; Anderson et al., 1992; Fail et al., 1992, Fail et al., 1991; Treinen & Chapin, 1991; Linder et al., 1990; Grizzle et al., 1989; Lee et al., 1978).

A NOAEL of 17,5 mg B/kg bw/day for effects on testis and male fertility can be derived from two rat 3-generation studies (Weir, 1966c,d) and two 2-year studies in rats (Weir, 1966a,b). It can be summarised that the dose-response curve is quite steep with a NOAEL at 17,5 mg B/kg bw/day (Weir, 1966a-d), reversible effects at 26/39 mg B/kg bw/day (Ku et al., 1993) and serious, irreversible effects at 58,5 mg B/kg bw/day (Weir, 1966a-d).

Though not studied as detailed as the effects in males, a NOAEL of 17,5 mg B/kg bw/day for effects on female fertility can be derived from Weir (1966a-d).

Developmental Effects

Developmental effects have been observed in three species, rats, mice and rabbits. The most sensitive species being the rat with a NOAEL of 9.6 mg B/kg bw/day. This is based on a reduction in mean foetal body weight/litter, increase in wavy ribs and an increased incidence in short rib XIII at 13.3 mg B/kg bw/day. The reduction in foetal body weight and skeletal malformations had reversed, with the exception of short rib XIII, by 21 days post natal. At maternally toxic doses, visceral malformations observed included enlarged lateral ventricles and cardiovascular effects.

Moore et al. (1997) noted that boric acid exposure in rats, mice and rabbits appeared to be influencing segmentation in the thoraco-lumbar area, in that the total number of ribs tended to decrease with dose. The fact that a similar type of change occurred in all three species may indicate a common mechanism involving genetic control or regulation of segmentation. They noted that literature on homeobox genes and altered expression concomitant with disrupted segmentation provides a conceptual basis for such a consideration. Di Renzo et al. (2007) further support this hypothesis. They described possible inhibiting effects of boric acid on histone deacetylase. It was reported that inhibition of this enzyme was associated with skeletal malformations. They could detect hyperacetylation as a consequence of inhibited histone deacetylase activity in nuclei of somites of mouse embryos exposed to boric acid. Similar observations were made after treatment of mice with valproic acid or trichostatin-A, known inhibitors of histone diacetylase.

The NOAEL for this endpoint is 9.6 mg B/kg bw/day corresponding to 55 mg boric acid/kg bw/day; 85 mg disodium tetraborate decahydrate/kg, 65 mg disodium tetraborate pentahydrate/kg and 44.7 mg disodium tetraborate anhydrous/kg.

5.10 Derivation of DNELs or other quantitative or qualitative measure for dose response

Based on the hazardous properties of boric acid and disodium tetraborate anhydrous, pentahydrate and decahydrate and the expected exposure scenarios relevant for humans, the following DNELs need to be derived:

Worker-$\text{DNEL}_{\text{acute, inhalation, local}}$

Worker-$\text{DNEL}_{\text{long-term, inhalation, systemic}}$

General population $\text{DNEL}_{\text{long-term, oral, systemic}}$

Worker-$\text{DNEL}_{\text{long-term, dermal, systemic}}$

Local effects – respiratory tract

Worker-$\text{DNEL}_{\text{acute, inhalation, local}}$

Local effects of borates on the respiratory system have been investigated in animals in four acute inhalation studies (Wnorowski, 1994a,b, 1997) and one Alarie-test (Krystofiak & Schaper, 1996). Further, studies in humans were conducted, two small studies (12 probands) under laboratory conditions (Cain et al., 2004, 2008) and three studies on exposed workers (Garabrant et al., 1984, 1985, Wegman et al., 1991). In two studies by Woskie et al. (1994, 1998) the methods used by Wegman et al. (1991) were evaluated and determinants of human susceptibility to the irritant effect of borates were examined.

Borates act as sensory irritants, indicated by the effects observed in humans (i.e. nose, eye and throat irritation; sneezing) and by the results of the Alarie-test by Krystofiak & Schaper (1996), which demonstrated a depression of the respiratory frequency in mice after exposure to boric acid. Many of the irritant symptoms (sensory irritation of the nose and throat, cough, phlegm production and broncho-constriction, as evidenced by a decrease in FEV1) are part of the respiratory defense reflex, the function of which is to protect the body from inhaled irritants. This reflex can be triggered by agents that stimulate receptors in the respiratory tract e.g. on the trigeminal nerve (Wegman et al., 1991, Nielsen et al., 2007, Krystofiak & Schaper, 1996). The actual mechanism, however, has not yet been elucidated.

Chapter R.8 of the Guidance on IR and CSA states that sensory irritation experienced in humans can build the basis for the Worker-DNEL$_{\text{acute, inhalation, local}}$. Several of current OELs are based on this effect and therefore this endpoint might be the leading human health effect in the risk characterisation.

A NOEC of 0,4 mg B/m^3 can be derived from the key-study by Wegman et al. (1991). It is based on the incidence of any symptom of nose, eye and throat irritation, sneezing, breathlessness and coughing during exposure periods of 15 minutes. Despite certain deficiencies of the study (see Annex HH I) the results of the study allow the derivation of a useful dose-response curve (see Figure 5.1). Since the number of individuals tested was large enough and as the investigation was carried out in a population of workers no assessment factor is needed to come up for inter-individual variability. A correction factor of 2 has to be applied, as the methodology used in this study underestimated the actual exposure levels. The DNEL can therefore be described with the following equation:

$$\boxed{\text{Worker-DNEL}_{\text{acute, inhalation, local}} = 0{,}4 \times 2 = 0{,}8 \text{ mg B/m}^3}$$

This DNEL is further substantiated when performing a weight of evidence evaluation considering all available studies carried out in humans.

The acute irritant effects which build the basis for the NOEC of the Wegman-study have been reported by several authors as a consequence of borate exposures. Garabrant et al. (1984 & 1985) who investigated large numbers of borate exposed workers reported dryness of mouth, nose and throat, eye irritation, dry cough, nosebleeds, sore throat, productive cough, shortness of breath, and chest tightness. A NOEC for respiratory irritation of 0,6 mg B/m^3 was derived by Garabrant et al. (1985).

NOECs and LOAECs from other studies in humans also lie in the same range as in the key-study. For example, from Cain et al. (2004) a NOEC of 0,75 mg B/m^3 with a LOEC of 1,4 mg B/m^3 based on respiratory symptoms of irritation of nose and throat and increased nasal secretion can be derived. The same authors came up with a LOEC of 0,44 in a comparable study in 2008. Due to the described deficiencies of the above mentioned studies several assessment factors would need to be applied to arrive at a DNEL covering these uncertainties.

A Minimal Risk Level (MRL) has been derived by the Agency for Toxic Substances and Disease Registry (ATSDR) based on the study by Wegman et al. (1991). The value derived in the draft Toxicological Profile for Boron (ATSDR, 2007) appears over-protective, as an assessment factor of 3 for LOEC to NOEC extrapolation and another factor of 10 for intra-species difference was applied (for more details on the draft ATSDR MRL see Regulations, guidelines applicable on TWA values are available under http://atsdr.cdc.gov/toxprofiles/tp26-c8.pdf.). In the current dossier it could be demonstrated that the value of 0,4 mg B/m^3 is a NOEC instead of a LOEC and it was further decided that as the study by Wegman investigates humans exposed at the workplace no further factor for intra-species variability is needed.

The study by Wegman et al. (1991) is reliable in relation to number of subjects investigated and exposure scenarios are well documented and realistic for the workplace situation. Therefore no additional uncertainty has to be considered. As the values used for the NOEC derivation were the lower limits of the according exposure range and as the observed effects are not to be seen as severe effects the derived DNEL is considered sufficient to protect the working population.

<u>Local effects – eye irritation</u>

Disodium tetraborate anhydrous, pentahydrate and decahydrate meet the criteria in Annex VI of Directive 67/548/EEC to self classify as eye irritants, based on acute eye irritation studies in rabbits. These studies are not well suited for DNEL-derivation, but the above described DNEL for irritant effects on the respiratory tract can be regarded as sufficient to protect workers from the eye irritant properties of tetraborates.

International and national recommendatiosn regarding boron in air:

Occupational exposure limits for respiratory irritation by boric acid and borates have been derived by the German federal institute for occupational safety and health (BAuA), in march 2007 (BAuA, 2007).

Based on mild effects in the lowest exposure group BAuA derived a NOAEL from Wegman et al., (1991). This NOAEL equals 0,5mg B/m3 after correction for underestimations of boron exposure measurements in this study. Table lists the corresponding values for the different boron compounds.

The time weighted average (TWA) values according to the National Institute for Occupational Safety and Health (NIOSH, 2005) to protect irritation of eyes and respiratory system are: sodium tetraborate anhydrous 1 mg/m^3, sodium tetraborate pentahydrate 1mg/m^3 and sodium tetraborate decahydrate 5 mg/m^3.

Table 5.21: International/national recommendations regarding boron (boric acid & borates) in air

Organisation	Standard	Remarks	Reference
BAuA, Germany, Europe	AGW: 0.5 mg boron/m^3 boric acid 2.6 mg/m^3, sodium-tetraborate anhydrous 2.1 mg/m^3, sodium-tetraborate pentahydrate 3.0 mg/m^3, sodium-tetraborate decahydrate 4.0 mg/m^3.	based on Wegman et al. 1994 and Culver et al. 1994	BAuA, 2007
ACGIH, USA	Borate compounds, inorganic (*) (borax, boric acid and sodium tetraborates) TLV (8-hour TWA): 2 mg/m^3 STEL (15 min TWA): 6mg/m^3		ACGIH, 2006
NIOSH, USA	Borax (*) REL TWA (10 hours): 5 mg/m^3		NIOSH, 2005

AGW Arbeitsplatzgrenzwert = Occupational Exposure Level; MRL = Minimal risk level, TWA time weighted average; STEL Short term exposure limit; TLV Threshold Limit Value; REL recommended exposure limits.

(*) These values are not enforceable regulatory values and are only recommended exposure limts.

Minimal Risk Level (MRL)—an estimate of daily human exposure to a hazardous substance that is likely to be without an appreciable risk of adverse noncancer health effects over a specified route and duration of exposure to the general population.

Systemic effects

Boric acid and disodium tetraborate anhydrous are classified as toxic to reproduction category 2 and are assigned the risk phrases R60 (May impair fertility) – 61 (May cause harm to the unborn child). On the basis of the sub-chronic and chronic studies evaluated in this transitional dossier, these effects are identified as the leading health effects that support DNELs for long-term systemic effects.

General population DNEL$_{\text{long-term, oral, systemic}}$

With regard to developmental effects no human data exist. The available data from animal studies are sufficient to conclude that prenatal exposure to boron (specifically boric acid and disodium tetraborates) by the oral route can cause developmental toxicity. Developmental effects were seen in three different mammalian species, rat, mouse, rabbit, with the rat being most sensitive. From the most robust study in rats (Price et al., 1996) the lowest NOAEL = 9,6 mg B/kg bw/day can be derived for reduced foetal body weight per litter, increase in wavy ribs and increased incidence in short rib XIII. Other effects seen at maternally toxic doses were visceral malformations like enlarged ventricles and cardiovascular effects.

Moore et al. (1997) noted that boric acid exposure in rats, mice and rabbits appeared to be influencing segmentation in the thoraco-lumbar area, in that the total number of ribs tended to decrease with dose. The fact that a similar type of change occurred in all three species may indicate a common mechanism involving genetic control or regulation of segmentation. This findings were further supported in a recent study by Di Renzo et al. (2007). For more detail on the underlying mechanism see section 5.

Several epidemiological studies on fertility effects of borates have been carried out in workers and populations living in areas with high environmental levels of boron. Truhaut et al., 1964, Tarasenko, 1972, Krasovskii et al., 1976, Whorton, 1994, Tuccar, 1998 and Sayli, 1998, 2001, 2003 were available at the time the Commission Working Group of Specialized Experts in the field of Reprotoxicity (Ispra, October 5-6, 2004) was held. They came to the conclusion that the epidemiological studies available at that time were of insufficient quality to demonstrate presence or absence of fertility effects.

In general the need for good epidemiological studies on male and female fertility, as well as on developmental toxicity was clearly identified by several national and international panels (BfR, 2005; EFSA, 2004; Commission Working Group Reprotoxicity, 2004; WHO, 1998; ECETOC, 1995; US EPA, 2004).

A study in Chinese boron mine workers focused on the evaluation of adverse male reproductive effects was described in several publications between 2002 and 2008. These studies are currently being evaluated by an expert panel consisting of experts in the fields of reproductive health and epidemiology, sponsored by Rio Tinto Minerals. The outcome of this panels work shall be a review paper of the publications generated in the time between 2002 and 2008. Though most of the more than 30 publications under review are publicly available, they are published in Chinese. Translations of the Chinese papers were made available to the panel, but were not available to the rapporteur. Chang et al. (1996) and Robbinson et al. (2008) are English publications on the study under review. Based on the two publications in English the rapporteur has certain doubts that the panel will be able to draw a definite conclusion on effects on male fertility in humans. However, this opinion is only based on restricted information on the study and the opinion of the expert panel currently at work has to be awaited. The review paper is expected in the first quarter of 2009. Effects on female fertility and developmental toxicity were not investigated in this study.

Although human data are not sufficient to allow judgments about reproductive toxicity, the experimental data from different animal species gave consistent results indicating that boric acid and tetraborates might cause reproductive toxicity in humans (Moore et al, 1997).

Male infertility was observed in breeding studies in rats, mice and deer mice. The underlying cause for male infertility was identified to be testicular atrophy. A series of studies has been published that provide insight as to the mechanistic nature of the lesion in rats. Good correlation between doses inducing spermatogenic arrest and infertility could be derived. The effects were reversible at lower doses, but no recovery was possible at doses at which germ cell loss was observed. Germinal depletion correlated well with increased plasma levels of FSH. Levels of other hormones, like testosterone and LH were not always affected. A NOAEL of 17,5 mg B/kg bw/day in rats (Weir, 1966a,b) could be derived.

Two 3-generation studies in rats with boric acid and disodium tetraborate decahydrate (Weir, 1966c,d) and a continuous breeding study in mice with boric acid (Fail et al., 1991) further substantiate the effects seen in males, but they also revealed effects in female animals. The underlying mechanism is, however, much less investigated. Effects observed were infertility in female rats (58,8mg B/kg bw/day, Weir, 1966c,d) and reduced fertility in female mice (111,3mg B/kg bw/day, Fail et al. 1991). The continuous breeding study also detected the following effects at the lowest dose at which these effects were investigated: reduced average dam weight on PND0, reduced average gestational period, significantly reduced adjusted litter weight of F0 females at 111,3 mg B/kg bw/day and reduced oestrus cycle length and significantly reduced adjusted litter weight of F1 females at 26,6 mg B/kg bw/day.

The available data on toxicokinetics do not indicate major differences between laboratory animals and humans. It is not known whether there are significant differences in the toxicodynamics between humans and laboratory animals and in the absence of such knowledge it must be assumed that the developmental and fertility effects seen in animals could also occur in humans. The assessment factor for species differences between rat and human was reduced from 10 to 7,5. This can be explained by the fact that the effects of borates are driven by renal clearance, which is a physiological process that is affected by the basal metabolic rate. As the available data on toxicokinetics in rats and humans indicate that humans clear borates at a 3-times slower rate than rats rather than at a 4-times slower rate, the factor for allometric scaling was reduced from the default value of 4 to 3. The default of 2,5 for remaining uncertainties was not reduced as not enough knowledge on toxicodynamic differences is available.

Most of the risk assessments of boric acid and tetraborates identified the NOAEL of 9,6mg B/kg bw/day for developmental effects from a good quality rat study by Price et al. (1996) as the leading dose descriptor for systemic human health effects. When applying the assessment factor of 7,5 for interspecies differences and 10 for intraspecies variation a DNEL of 0,13mg B/kg bw/day is obtained. When considering effects on fertility, based on the uncertainty described for effects on female fertility, the need for an additional assessment factor of 2 to cover this uncertainty was identified. Applying this factor to the rat NOAEL = 17,5mg B/kg bw/day from Weir, (1966a-d) a DNEL of 0,12mg B/kg bw/day is achieved, which is very close to the DNEL derived for developmental effects. Therefore the DNEL for effects on fertility is identified as the leading systemic DNEL and can be described with the following equation:

$$\text{General population-DNEL}_{\text{long-term, oral, systemic}} = \frac{17{,}5 \text{ mg B/kg bw/day}}{7{,}5 \times 10 \times 2} = 0{,}12 \text{ mg B/kg bw/day}$$

Worker-DNEL$_{\text{long-term, inhalation, systemic}}$

This route is not relevant for systemic effects in the general population, but in the occupational setting considerable boron dust concentrations may arise. As no animal studies for the inhalation route or human data of sufficient quality are available a NOAEC had to be extrapolated from the oral key study with the NOAEL = 17,5mg B/kg bw/day. This DNEL is only relevant for the working population. An eight hour workday and an according respiratory volume of 10m^3 are assumed. Information available on workplace scenarios, work tasks and activities is not sufficient at the time writing this transitional dossier. For this reason it is not known whether the value of 10m^3 for light work covers all working conditions to be expected. Therefore the according DNELs for moderate and heavy work are included in a ANNEX HH III of this dossier.

As recommended by Chapter R.8 from the Guidance on IR and CSA the following equation was applied:

$$\text{corrected inhalatory NOAEC} = \text{oral NOAEL} \times \frac{1}{\text{sRV}_{\text{rat}}} \times \frac{\text{ABS}_{\text{oral-rat}}}{\text{ABS}_{\text{inh-rat}}} \times \frac{\text{sRV}_{\text{human}}}{\text{wRV}}$$

$$\text{corrected inhalatory NOAEC} = 17{,}5 \text{ mg B/kg bw/day} \times \frac{1}{0{,}38} \times \frac{100\%}{100\%} \times \frac{6{,}7}{10}$$

$$\text{corrected inhalatory NOAEC} = 30{,}86 \text{ mg B/m}^3$$

sRV: standard Respiratory Volume, ABS: Absorption, wRV: worker Respiratory Volume

$\text{sRV}_{\text{rat}} = 0{,}38 \text{ m}^3/\text{day}$

$\text{sRV}_{\text{human}} = 6{,}7 \text{ m}^3/\text{day (8h)}$; $\text{sRV}_{\text{human, moderate work}} = 10 \text{ m}^3/\text{day (8h)}$

$\text{ABS}_{\text{oral-rat}} = \text{ABS}_{\text{inh-human}} = 100\%$

Section 5.1. outlines that absorption of boric acid and tetraborates via the oral route is close to 100%. Due to the good water solubility of the compounds and studies in animals and humans a realistic worst case assumption of 100% absorption via the inhalation route is justified. Borates exist predominantly as un-dissociated boric acid in dilute aqueous solution at physiological pH, it is not further metabolized, therefore it can be concluded that the main species in the plasma of mammals is un-dissociated boric acid, and as such can exert its toxic effects in the target organs. As outlined in the section 5.1. toxicokinetics of boric acid and disodium tetraborates are similar in rats and humans with regard to absorption, distribution, and metabolism. Differences exist for renal clearance, which is approximately 3-4 times faster in rats compared to humans. The physiological process of renal clearance is affected by the basal metabolic rate. In the above stated formular differences with regard to metabolic rate between rats and humans are considered. The remaining inter-species differences are covered by applying the factor 2,5 for toxicodynamic differences. An additional factor for uncertainties caused by route-to-route extrapolation was therefore considered not necessary. The factor 2 for uncertainties concerning effects on female fertility and the factor 5 for intraspecies variability within the working population were applied.

$$\text{Worker-DNEL}_{\text{long-term, inhalation, systemic}} = \frac{30{,}86\ \text{mg B/m}^3}{2{,}5 \times 5 \times 2} = 1{,}2\ \text{mg B/m}^3$$

Worker-DNEL$_{\text{long-term, dermal, systemic}}$

Dermal absorption through intact skin is very low. For risk assessment of borates a dermal absorption of 0,5% is used as a realistic worst case approach (see section on toxicokinetics). Dermal absorption is not regarded relevant for the general population, however, it is considered for workers and a Worker-DNEL$_{\text{long-term, dermal, systemic}}$ is derived. In the absence of an appropriate long-term study a NOAEL was extrapolated from the oral NOAEL = 17,5mg B/kg bw/day. The assessment factors applied are for interspecies variability (7,5), intraspecies variability (5) and uncertainties with regard to effects on female fertility (2). A DNEL of 0,23mg B/kg bw/day was obtained for workers. A body weight for workers of 70 kg was assumed for the following equation.

$$\text{Worker-DNEL}_{\text{long-term, dermal, systemic}} = \frac{17{,}5\ \text{mg B/kg bw/day}}{7{,}5 \times 5 \times 2} \times 70 = 16{,}3\ \text{mg B/day}$$

Table 5.22: Overview on the derived DNELs

DNELs	Boron equivalents	Boric acid	Disodium tetraborate		
			anhydrous	pentahydrate	decahydrate
Worker-DNEL$_{\text{acute, inhalation, local}}$ [mg/m^3]	0,8	4,6	3,7	5,4	7,1
Worker-DNEL$_{\text{long-term, inhalation, systemic}}$ [mg/m^3]	0,12	0,7	0,6	0,8	1,1
General population DNEL$_{\text{long-term, oral, systemic}}$ [mg/kg bw/day]	1,2	6,9	5,6	8,1	10,6

Worker-DNEL$_{\text{long-term, dermal, systemic}}$ * [mg/day]	16,3	93,1	75,8	110,1	144,2

* The worker-DNEL$_{\text{long-term, dermal, systemic}}$ refers to the intake of boron and considers a dermal absorption of 0,5% through intact skin (see section on toxicokinetics 5.1).

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

6.1 Explosivity

No human health hazards

6.2 Flammability

No human health hazards

6.3 Oxidising properties

No human health hazards

7 ENVIRONMENTAL HAZARD ASSESSMENT

Sources of ecotoxicological data

The ecotoxicological data in this report are derived from original papers on the subject, gathered from the industry, environmental agencies or published in international journals.

Selection of ecotoxicological data

The toxicity data are from tests that study common ecotoxicological parameters such as survival, growth and/or reproduction.

All data are screened for their relevancy and reliability. Relevancy points to the appropriatness of the data for a particular hazard identification or risk characterization, while reliability is based on the inherent quality of the test method and report. Reliability is addressed through Klimisch criteria.

Relevance

The relevance of all data was evaluated. This included evaluating the choice of species, the route of exposure/application of test media, and tested concentrations.

Relevancy of the test substance

Studies on the ecotoxicity of boron have been performed with various compounds, such as boric acid (H_3BO_3), anhydrous sodium tetraborate ($Na_2B_4O_7$), and hydrated sodium tetraborates ($Na_2B_4O_7.xH_2O$). For the purpose of this evaluation, all endpoints are converted to concentrations of elemental boron (B) using the relative molar mass.

Test duration

What comprises "chronic exposure" is a function of the life cycle of the test organisms. A priori fixed exposure durations are therefore not relevant. The duration should be related to the typical life cycle and should ideally encompass the entire life cycle or, for longer-lived species the most sensitive life stage. Retained exposure durations should also be related to recommendations from standard ecotoxicity (e.g. ISO, OECD, ASTM) protocols.

Reliability

Scoring system

Evaluations of study reliability were made for the studies discussed in this report following the Klimisch et al. (1997) codes. These evaluations follow the TGD guidelines regarding reliability and relevancy.

Klimisch 1: The studies most closely following accepted standard protocols were rated "*Reliable without restriction*".

Klimisch 2: High quality studies that did not strictly follow standard protocols were rated "*Reliable with restriction*".

Klimisch 3: Studies with significant deviations from current scientific standards or protocol practices were rated "*Not reliable*".

Klimisch 4: Some reported test results could not be evaluated because the studies do not give sufficient experimental details or the data are only listed in short abstracts or secondary literature (books, reviews, etc.) and therefore these studies were rated "Not assignable".

Only the toxicity data that received a Klimisch score of 1 or 2 and that are considered relevant will be used as the basis for the derivation of the HC5-50 and PNEC value.

Type of test

Both standard test organisms and non-standard species can be used in the framework of a risk assessment. In general, toxicity data generated from standardised tests, as prescribed by organizations such as OECD and USEPA will need less scrutiny than non-standardised test data, which will require a more thorough check on their compliance with reliability criteria before being used. GLP and non-GLP tests can be used provided that the latter fulfill the stipulated requirements.

Concentration-effect relationships

Because effect concentrations include statistically derived values, information concerning the statistics should be used as a criterion for data selection. Data from studies with insufficiently described methodology or data derivation were considered unreliable. Effect levels derived from toxicity tests using only 1 test concentration were thus considered unreliable, and only data from toxicity test using at least 2 boron concentrations and 1 control group were retained.

Chemical analysis

There is a strong preference for using measured data. The data used in the effect assessment should therefore ideally be based on measured concentrations. This would however considerably reduce the amount of data to be used. Therefore, in this effects assessment, both nominal and actual (measured) effect concentrations were selected for PNEC derivation. If it is not mentioned whether the NOEC/L(E)C_{10} values are based on measured or nominal concentrations, they were considered as nominal concentrations.

Tests that do not comply with the above-mentioned stipulations are rated as not reliable and are not recommended for use in the risk assessment exercise.

Derivation of NOEC/L(E)Cx values

Test reports of acceptable quality are anticipated to provide statistically derived endpoints, such as EC50 or NOEC or EC10 values and these will be reported as calculated by the study authors.

Following regulatory guidance and current practice, the preferred value for acute effect endpoints (such as mortality) are EC50 values. The preferred values for chronic effect endpoints (such as growth) are NOEC or EC10 values. (For simplicity, endpoints calculated from a concentration-response model will be called ECx values, although they are also referred to as LCx or ICx values.)

In some standard test methods, statistical analysis is prescribed, e.g., an ANOVA should be used to evaluate the presences of a significant difference from control response, and a pairwise procedure, such as Dunnett's test, can be used to identify test groups differing from controls. It is important to evaluate the nature of the concentration-response pattern to use such statistics, or to justify the use of alternative statistics.

The variability in ecotoxicity tests has been a matter of extensive discussion. For many standardized tests, inherent variability is considered to be about 10%, e.g., a change in response of 10% or less cannot be reliably distinguished from typical control responses. Consequently, 10% inhibition is often used as a surrogate estimate for a maximally acceptable response (e.g., LOECs are determined if they exhibit an inhibition of the control response of > 10%). Similarly, for ECx calculations, the value of x is usually taken as 10%. However, some test guidelines acknowledge that the inherent variability of the test exceeds 10% and may recommend an alternative threshold, e.g., x = 20%.

In some tests, the lowest (non-control) test group showed a significant response. This results in the lowest group being identified as the LOEC, termed an "unbounded" LOEC and the value will be indicated by "<". According to Guidance on IR and CSA Chapter R.10 (2008), the NOEC could be derived in specific cases from the LOEC. Indeed, if the EC10 or the NOEC is not reported and cannot be calculated due to lack of suitable effect concentrations, the NOEC is derived from the LOEC using the following extrapolation factors:

(a) NOEC = LOEC/2, in case inhibition is >10% but ≤20%. Following that reasoning, NOEC values could also be calculated from EC20 values, i.e. NOEC = EC20/2. Estimation of EC20 values outside the measured concentration range introduces a great deal of uncertainty (i.e. extrapolation outside the range of the data) and should therefore be avoided. Indeed, if EC20 is below the lowest dose tested (meaning that there is >20% effect at the LOEC), no NOEC is derived.

(b) If the percentage inhibition at the LOEC is >20% or in the case that the percentage inhibition is not known, no NOEC is derived.

In a related manner, the highest test group may show no significant response, resulting in an unbounded NOEC, indicated by "≥". Unbounded NOEC values are not further used for the PNEC derivation but could be used as supportive information in the weight of evidence approach.

If the EC50 or EC10 is outside the range of tested concentrations, the accuracy of the underlying model should be questioned, and the result expressed as an unbounded result. For example, if the EC50 exceeds the highest tested concentration, the results are difficult to use quantitatively. Similarly, if the EC10 is below the lowest test concentration, the precision of the result may be questioned.

Approach for PNEC derivation

Averaging thresholds for same process/species

The geometric mean of the retained quality screened toxicity data for a process/species was calculated to avoid over-representation of ecotoxicological data from one particular species or function. This approach is relevant if there is more than one set of data on the same species, (strain if known), endpoint, duration, life stage and testing condition. In this case the greatest weight is attached to the most reliable and relevant one. When there is more than one set of data with the same reliability rating, it might be necessary to look into more detail and the study reports to see whether a specific reason could explain the difference. If no explanation can be found and the results are for the same species and endpoints and are not more than one order of magnitutde apart, they can be harmonized by a geometric mean. The approach used in this dossier is outlined hereunder:

If for one process/species several chronic NOEC or EC10 values based on the same toxicological endpoint are available, these values are averaged by calculating the geometric mean, resulting in the "species mean" NOEC or EC10.

If for one species several chronic NOEC or EC10 values based on different toxicological endpoints are available, the value for the most sensitive endpoint is selected. This value is determined on the basis of the geometric mean if more than one value for the same endpoint is available.

Calculation of PNEC using assessment factors

The derivation of the PNEC depends on the available data. PNECs are estimated by division of the lowest value for the toxicity with the relevant assessment factor.

The assessment factors used were chosen following the relevant chapters of the Guidance on IR and CSA, chapter 10 document.

Calculation of PNEC using statistical extrapolation techniques

The effect assessment performed with assessment factors can be supported by a statistical extrapolation method if the database on species sensitivity distributions (SSDs) is sufficient for application. If a large data set from long-term tests for different taxonomic groups Is available, statistical extrapolation methods may be used to derive a PNEC. This approach is still under debate and needs further validation. According to the Guidance on IR and CSA chapter 10, a minimum species requirement is given only for a few endpoints (e.g. freshwater), and a minimum set of at least 10 NOECs for different species covering at least 8 taxonomic groups is required. The Guidance on IR and CSA document only sets out a minimum species requirement for the derivation of PNEC for freshwater, and indicates a similar approach for all other environmental compartments. The minimum species requirements when using the SSD method are:

- Fish (species frequently tested include salmonids, minnows, bluegill sunfish, channel catfish, etc.);
- A second family in the phylum Chordata (fish, amphibian, etc.);
- A crustacean (e.g. cladoceran, copepod, ostracod, isopod, amphipod, crayfish etc.);
- An insect (e.g. mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge, etc.);
- A family in a phylum other than Arthropoda or Chordata (e.g.Rotifera, Annelida, Mollusca, etc.);
- A family in any order of insect or any phylum not already represented;
- Algae

Higher plants

For some of the taxa mentioned above, no internationally standardized test guidelines for long-term tests are currently available. The applicability of existing test data and the fulfillment of the above requirements thus need to be assessed on a case-by-case basis. This also accounts for the other environmental compartments.

7.1 Aquatic compartment (including sediment)

7.1.1 Freshwater compartment

7.1.1.1 Toxicity test results

Data on toxicity tests

In the following section toxicity tests relevant for hazard assessment of boric acid are summarized and rated according to the Klimisch criteria. Several taxonomic groups are described in this compilation including fish, crustacea, algae , higher plants, bacteria, cyanobacteria, amphibia, insects, annelida and protozoa. A summary of toxicity data is given in table 7.1. The value taken for PNEC-derivation is put in bold.

Klimisch 1:

Hanstveit and Oldersma, 2000

This study was performed at the request of Borax Europe limited and was carried out according to the OECD Guideline No. 201, EU C.3 and the OECD Principles of Good Laboratory Practice (GLP). Test animal was the fresh-water green alga *Selenastrum capricornutum*. The medium was prepared in ultra pure water, it contains 185 µg/L boric acid, hardness in $CaCO_3$ is 24.2 mg/L. Boron was added as boric acid, manufacturing grade (+99.9%). Concentrations were chemically analyzed and were within ±20% of the nominal concentrations and in linear relation with the nominal concentrations, which allows according to the guidelines to base the results on the nominal concentrations. Range-finding tests were conducted first as simplified test, then growth inhibition test were performed according to the guidelines. EC values were calculated with respect to the growth rate and logistic growth (ErC values) as well as EC values with respect to the area under the growth curve (EbC values), according to the OECD guideline. Raw data and calculation details are given in the annexes, statistics are described. The outcome of the range finding test was that inhibiting effects could be expected at concentrations ≥ 100 mg /L. The pH of the medium during the growth inhibition test varied between 7.5 and 8.3, the test duration was 74.5 hrs. The ECs found in this test were an ErC50 of 52.44 mg B/L (300 mg Boric acid/L) and an EbC50 of 40.21 mg B/L (230 mg Boric acid/L). The NOEC was 17.48 mg B/L (100 mg Boric acid/L). The experiments were done according to guidelines and meets their validity criteria; additionally the study is well documented. Therefore the study is rated as reliable without restriction – Klimisch 1.

Hooftman et al., 2000a

This study was performed at the request of Borax Europe limited and was carried out according to the OECD Guideline No. 210 Fish Early Life Stage Toxicity Test (ELS) and the OECD Principles of Good Laboratory Practice (GLP). Test animal was zebra fish *Brachydanio rerio*. Boron was added as boric acid, manufacturing grade (+99.9%). Concentrations were chemically analyzed and were within ±20% of the nominal concentrations, which allows according to the guideline to base the results on the nominal concentrations. Raw data and calculation details are given in the annexes, statistics are described. The medium contained 46.25 µmol B/l, but the results were corrected for this background. The 34-day LC_{50} observed according to mortality was 24 mg B/l (137 mg H_3BO_3/l). Mortality, growth (length and width) as well as condition were used to determine NOEC and LOEC values. The 34-day NOEC was 5.6 mg B/l (32 mg H_3BO_3/L) and the 34-day LOEC was 18 mg B/l (103 mg H_3BO_3/L), both for mortality. The 34-day NOEC for growth measured by length was 5.6 mg B/L and the 34-day LOEC was 18 mg B/L, if measured by dry weight, the 34-day NOEC was 1.8 mg B/L and the 34-day LOEC was 5.6 mg B/L. The experiments were done according to a guideline and the study is well documented. Therefore the study is rated as reliable without restriction – Klimisch 1.

Note: In the results section the NOEC and LOEC with respect to growth were 1.8 mg B/l and 5.6 mg B/l due to dry weight measurements. One value in these measurements was considered an outlier. Nevertheless in the results section the authors concluded that NOEC and LOEC with respect to growth were 1.8 mg B/l and 5.6 mg B/l, respectively The values in the summary differ from the conclusions drawn in the results section, as the 34d NOEC for growth is stated to be 5.6 mg B/L, and the LOEC 18 mg B/l. It can be assumed that in the summary only the values for growth measured by length were included. Though, in the report itself no explanation is given for this discrepancy.

Hooftman et al., 2000c

This study was performed at the request of Borax Europe limited and was carried out according to the OECD Guideline No. 211 "Prolonged toxicity study with *Daphnia magna* (inhibition of reproduction)" and the OECD Principles of Good Laboratory Practice (GLP). Test animal was the fresh-water crustacean *Daphnia magna,* which was fed with algal cells and yeast. Medium was replaced at least once per week. As dilution water DSWL-E prepared from ground-water was used, the pH was 7.2 – 8.0, the temperature 19.3 – 20.9 °C, hardness was 212 mg/L as $CaCO_3$. Boron was added as boric acid, manufacturing grade (+99.9%). Concentrations were chemically analyzed and were within ±20% of the nominal concentrations, which allows according to the guideline to base the results on the nominal concentrations. Raw data and calculation details are given in the annexes, statistics are described. The medium contained 46.25 µmol B/L, but the results were corrected for this background. The 21-day EC_{50} (reproduction) was 22 mg B/L, The NOEC (reproduction) was 10 mg B/L and the LOEC (reproduction) was 18 mg B/L. At 56 mg B/L all animals died before they could reproduce.

The NOEC (condition, which includes observable morphological or behavioural criteria) was 18 mg B/L, the LOEC (condition) was 32 mg B/L. The 21-day LC_{50} (mortality) was 34 mg B/L (7-day LC_{50} = 60 mg B/L, 14-day LC_{50} = 54 mg B/L). The 21-day NOEC (mortality) was 32 mg B/L, the LOEC was 56 mg B/L. The experiments were done according to a guideline and the study is well documented. Therefore the study is rated as reliable without restriction – Klimisch 1.

Klimisch 2

Black et al., 1993

The authors performed boron toxicity studies on rainbow trout (*Oncorhyncus mykiss*) and largemouth bass (*Micropterus salmoides*) in laboratory and natural dilution waters. Toxicity was evaluated in terms of mortality and teratogenesis. When reconstituted water was used for dilution, it was prepared by addition of reagent grade major cations and anions in distilled, deionized water. Boron was added as reagent grade boric acid. Water samples were tested for their boron concentration. For largemouth bass in reconstituted water an LC_{50} of 92 (84-100) mg boron/l was found and teratogenesis at hatching was found to be statistically significant at concentrations above 1.39 mg boron/L. The NOEC based on mortality plus teratogenesis for largemouth bass was 1.39 mg boron/L, the LOEC was 12.17 mg/L.

All other studies were performed with different strains of rainbow trout. The Soap Lake strain in reconstituted water had a LC_{50} of 138 (126-150) mg boron/L, Teratogenesis at hatching was found to be statistically significant at concentrations above 0.009 mg boron/L. The measured values for the LOEC (mortality plus teratogenesis) were 0.1 mg boron/L, the NOEC 0.009 mg B/L.

In comparative studies of boron toxicity on the rainbow trout Whytheville strain embryo-larval stages in either reconstituted or three different natural waters a LOEC of 1 mg added boron/l was observed, with no statistically significant differences between reconstituted and natural waters, the NOEC was 0.1 mg B/L. This is especially interesting since the natural waters contained boron background concentrations of 0.023 – 0.75 mg/L. Therefore the authors conclude that it might be possible that certain characteristics like the natural chemical composition of natural waters may enhance the potential toxicity of boron. The last part of the article describes a study with well water, where an 87-day NOEC of 2.1 mg boron/L is observed. When conditions with the highest test concentration (added later with 20-day old embryos) are included, a NOEC of 18 mg boron/L is observed. These 87-day NOEC data have to be seen critically since no LOEC could be derived because 18 mg B/L was the highest concentration tested here. The testing procedures were not according to a guideline but well and satisfyingly described for each testing condition. Some data are missing (eg number of fish), only frequencies of test responses are given and data could have been evaluated more intensively. Therefore the article is rated as Klimisch 2 – reliable with restriction.

Black et al. observed that their LOEC values ranged from 0.1 to > 18 mg B/L and that their tests with natural water indicated less toxicity than tests with reconstituted water. The variability in the results seen in these studies with rainbow trout limits their reliability in developing a PNEC-aquatic. As contributing factors the authors identified a flat concentration-response curve observed in the trout toxicity tests, the effects of different dilution waters on boron toxicity and differential sensitivity of the several strains of trout tested. WHO, 1998 provides as a hypothesis to explain, at least in part, the differences in reconstituted versus natural water responses the better health experienced by organisms exposed to boron in natural water. The causative agents for this lack of health in laboratory water are not certain but may include nutrient deficiencies.

For eventual limitations to the study-design see also Studies by Birge and Black (1977 & 1981), Birge et al. 1984 and recalculated endpoints according to Dyer 2001.

Studies by Birge and Black (1977 & 1981), Birge et al. 1984 and recalculated endpoints according to Dyer 2001:

Birge and Black, 1977

In this study a broad range of species were tested for their susceptibility to boron. Test animals used were rainbow trout *Salmo gairdneri*, channel catfish *Ictalurus punctatus*, the goldfish *Carassius auratus,* the leopard frog *Rana pipiens* and Fowler's toad *Bufo fowleri*. Boric acid and borax were used as test substances, both from Fisher Scientific Company at certified ACS grade. The actual boron content was determined chemically (curcumin method). Results were calculated in ppm boron. Synthetic water prepared from distilled, double deionized water was used for the bioassay; no background boron could be detected. Teratogenesis in aquatic embryos was studied additionally to lethality. Toxicity results were dependent on the water hardness and the boron compound administered. Developmental stages of the rainbow trout were treated continuously for 28 days, with hatching occurring at 24 days (13-14°C). Combined test responses boric acid LC1 and LC50 values, were 0.1 mg B/L and 100 mg B/L in soft water and 0.001 mg B/L and 79 mg B/L in hard water. With borax these values were 0.07 mg B/L and 27 mg B/L in soft water, and 0.07 mg B/L and 54 mg B/L in hard water. Embryonic and posthatched stages of the channel catfish (*Ictalurus punctatus*) were exposed continuously for 9 days, with hatching occurring on day 5 (25-29°C). The LC1 and LC50 values for boric acid were 0.5 mg B/L and 155 mg B/L in soft water, and 0.2 mg B/L and 22 mg B/L in hard water. For borax these values were 5.5 mg B/L and 155 mg B/L in soft water and 1.7 mg B/L and 71 mg B/L in hard water. Embryos and early fry of the goldfish (*Carassius auratus*) were treated continuously for 7 days, with hatching occurring on day 3 (25-27°C). Boron LC1 and LC50 values for boric acid were 0.6 mg B/L and 45 mg B/L in soft water, and 0.2 mg B/L and 75 mg B/L in hard water. For borax, they were 1.4 mg B/L and 65 mg B/L in soft water, and 0.9 mg B/L and 59 mg B/L in hard water.

Developmental stages of the leopard frog (*Rana pipiens*) received continuous exposure for 7.5 days, with hatching occurring at 3.5 days (24-25°C), The LC1 and LC50 values for boric acid were 13 mg B/L and 130 mg B/L in soft water, and 22 mg B/L and 135 mg B/L in hard water. In bioassays with borax, these values were 5 mg B/L and 47 mg B/L in soft water, and 3 mg B/L and 54 mg B/L in hard water. Embryos and larvae of Fowler´s toad (Bufo fowleri) were given continuous exposure for 7.5 days, with hatching occurring by 3.5 days (24-25°C). The LC1 and LC50 values for boric acid were 25 mg B/L and 145 mg B/L in soft water, and 5 mg B/L and 123 mg B/L in hard water, taken at 4 days posthatching.

The study was not done according to a guideline, but is well documented and described. Nevertheless these tests were reviewed critically during other risk assessments and methodological concerns were raised. According to the European Union Risk Assessment Report on trisodium nitrilotriacetate, 2005, LC1 - values determined by the embryo-larval tests conducted by Birge et al. are usually very low compared to effect values found by other authors. No explanation for these discrepancies could be found. A careful examination of the entire information provided by Birge et al. gave no plausible reason for the inconsistency of the data. As it was not possible to reproduce the effect values, it was decided by the EU member states not to use these data for a derivation of a PNECaqua if other valid fish early life stage tests are available. Therefore, the effect values found by Birge et al. were not employed in the further effects assessment of trisodium nitrilotriacetate.

Dyer (2001) obtained the original data from Birge and Black and used it to calculate LC10 or NOEC values, consistent with currently used statistical approaches. Dyer then calculated a species mean value for Birge and Black (1977), (1981) and Birge et al. (1984) data because all the data were generated using the same test methods in the same laboratory, and there were no significant effects of borate compounds or hardness.

Since Dyer was able to recalculate the endpoints using current approaches (e.g., LC10), the recalculated values can be considered as reliable with restriction – Klimisch 2. The original values should not be considered reliable.

Birge and Black, 1981

In this study the toxicity of boron to embryonic and larval stages of largemouth bass *Micropterus salmoides* and rainbow trout *Salmo gairdneri* were tested. As test system a flow-through system was used. Boron concentrations were either determined with a Perkin-Elmer atomic absorption spectrophotometer or by the curcumin method. No boron was detected in the water for control populations. Test responses were evaluated as teratogenesis and mortality. Statistics used are described. The toxicity of boric acid to embryo-larval stages of largemouth bass resulted in a LC_{50} of 485 mg B/l at hatching and 92 mg/l 8 days posthatching. For rainbow trout the LC_{50} at hatching was 140 mg B/l and 8 days posthatching was 138 mg B/l. The study was not performed according to a guideline but is sufficiently documented and can therefore be rated as reliable with restriction – Klimisch 2.

Similar limitations apply to these data as described for the studies of Birge and Black, 1977, also no LC1 data were generated. Since Dyer was able to recalculate the endpoints using current approaches (e.g., LC10), the recalculated values can be considered as reliable with restriction – Klimisch 2. The original values should not be considered reliable.

Birge, Black et al., 1984

This study deals with the toxicity of boron to embryonic and larval stages of rainbow trout *Salmo gairdneri* (Wytheville strain) in comparison of reconstituted to natural waters. The tests were performed in a flow-through system. Natural waters used were from the Erwin National Fish Hatchery in Tennessee, Brookville Lake in Indiana, and the Firehole River in Yellowstone National Park. Their natural boron contents were 0.023, 0.091 and 0.75 mg B/L, respectively. Boron was added as reagent grade boric acid. Reconstituted water was made from distilled, deionized water. Test responses were evaluated as teratogenesis and mortality. Methods and statistics used are described, raw data are included. Boron concentrations were determined by the azomethine-H method. The authors conclude that added boron may be more toxic to trout embryo-larval stages than is naturally occurring boron. No endpoints are calculated, only frequencies of responses are given in tables.

Similar limitations apply to these data as described for the studies of Birge and Black, 1977, also no LC1 data were generated. Since Dyer was able to recalculate the endpoints using current approaches (e.g., LC10), the recalculated values can be considered as reliable with restriction – Klimisch 2.

Dyer, 2001

The author of this article, published in the journal Chemosphere, is a scientist working at Procter & Gamble Company. He reanalyzed raw data from Birge and Black, 1977 and 1981 and Birge et al., 1984, on rainbow trout *Oncorhynchus mykiss*, *Salmo gairdneri*, channel catfish, *Ictalurus punctatus*, goldfish *Carassius auratus,* largemouth bass (Micropterus salmoides), leopard frog *Rana pipiens* and Fowler's toad *Bufo fowleri* and used Probit ananlysis to determine the LC10, LC20 and LC50 of boron for embryo-larval survival. Birge and Black originally reported in their 1977-study their chronic endpoints as LC1 values, which is an endpoint that is no longer used.

Additionally data from Guhl 1992a, 1992b, Gersich 1984, Lewis and Valentine 1993, Hickey 1989, Maier and Knight 1991, Rowe et al. 1998, and Laposata and Dunson 1998 were used in a derivation of species means.

The boric acid toxicity values calculated for *Oncorhynchus mykiss* were an LC_{10} of 2 mg B/L, an LC_{20} of 44 mg B/L, an LC_{50} of 125 mg B/L (all in soft water) and an LC_{50} of 104 mg B/L (hard water) from the 1977 study. From the 1981 study the boric acid toxicity values calculated for *Oncorhynchus mykis*s were an LC_{10} of 30 mg B/L, an LC_{20} of 53 mg B/L and an LC_{50} of 97 mg B/L (in hard water); from the 1984 study the calculated LC_{10} was 0.70 mg B/L and the LC_{50} was 3.63 mg B/L (in hard water). Borax toxicity calculated from the 1977 study for *Oncorhyncus mykiss* resulted in an LC_{10} of 8 mg B/L, an LC_{20} of 16 mg B/L and an LC_{50} of 32 mg B/L (in soft water) as well as an LC_{10} of 15 mg B/L, an LC_{20} of 28 mg B/L and an LC_{50} of 53 mg B/L (in hard water). The boric acid toxicity values calculated for *Ictalurus punctatus* were an LC_{10} of 5 mg B/L, an LC_{20} of 41 mg B/L, an LC_{50} of 108 mg B/L (all in soft water) and an LC_{20} of 9 mg B/L and an LC_{50} of 33 mg B/L (hard water) from the 1977 study. Borax toxicity calculated from the 1977 study for *Ictalurus punctatus* resulted in an LC_{10} of 33 mg B/L, an LC_{20} of 62 mg B/L and an LC_{50} of 118 mg B/L (in soft water) as well as an LC_{10} of 16 mg B/L, an LC_{20} of 38 mg B/L and an LC_{50} of 79 mg B/L (in hard water). The boric acid toxicity values calculated for *Micropterus salmoides* were an LC_{10} of 6 mg B/L, an LC_{20} of 45 mg B/L, an LC_{50} of 121 mg B/L (in hard water) from the 1981 study. The boric acid toxicity values calculated for *Carassius auratus* were an LC_{10} of 16 mg B/L, an LC_{20} of 28 mg B/L, an LC_{50} of 51 mg B/L (all in soft water) and an LC_{10} of 15 mg B/L, an LC_{20} of 35 mg B/L and an LC_{50} of 73 mg B/L (hard water) from the 1977 study. Borax toxicity calculated from the 1977 study for *Carassius auratus* resulted in an LC_{10} of 20 mg B/L, an LC_{20} of 33 mg B/L and an LC_{50} of 59 mg B/L (in soft water) as well as an LC_{10} of 16 mg B/L, an LC_{20} of 27 mg B/L and an LC_{50} of 49 mg B/L (in hard water).

The boric acid toxicity values calculated for *Rana pipiens* were an LC_{10} of 48 mg B/L, an LC_{20} of 76 mg B/L, an LC_{50} of 130 mg B/L (all in soft water) and an LC_{10} of 56 mg B/L, an LC_{20} of 83 mg B/L,an LC_{50} of 134 mg B/L (hard water) from the 1977 study. Borax toxicity calculated from the 1977 study for *Rana pipiens* resulted in an LC_{10} of 18 mg B/L, an LC_{20} of 29 mg B/L and an LC_{50} of 50 mg B/L (in soft water) as well as an LC_{10} of 15 mg B/L, an LC_{20} of 31 mg B/L and an LC_{50} of 62 mg B/L (in hard water). The boric acid toxicity values calculated for *Bufo fowleri* were an LC_{10} of 55 mg B/L, an LC_{20} of 75 mg B/L, an LC_{50} of 112 mg B/L (all in soft water) and an LC_{10} of 30 mg B/L, an LC_{20} of 53 mg B/L and an LC_{50} of 97 mg B/L (hard water) from the 1977 study.

In his calculation the author used mean chronic values (NOEC, LC_{10}) to obtain a $PNEC_{0.05}$. In this approach he retrieved a $PNEC_{0.05}$ of 4.28 mg B/L (18 species) whereas in a second calculation he used no mean, but 1 mg B/L for rainbow trout (as a upper safe limit for rainbow trout gained by expert judgement) and consequently derived a $PNEC_{0.05}$ of 3.45 mg B/L. Inclusion of EC_3 values led to a $PNEC_{0.05}$ of 1.74 mg B/L (21 species), if mean value for rainbow trout was taken, and 1.34 mg B/L if 1 mg B/L for rainbow trout was included.

The report itself has to be classified as a review, nevertheless the recalculated endpoints from Birge and Black, 1977 and 1981 and Birge et al., 1984, can be considered as reliable with restriction – Klimisch 2. The original values should not be considered reliable.

Note: The tests performed as described in Birge and Black (1977 & 1981), Birge et al. 1984 and eventually Black et al. 1993 are rated with Klimisch 2 – reliable with restriction. Nevertheless these datasets have to be used with caution. Although Dyer recalculated the data provided by Birge and Black (1977 & 1981) and Birge et al. 1984, there still might be some methodological restrictions.

Bringmann and Kühn, 1977a: Befunde der Schadwirkung wassergefährdender Stoffe gegen Daphnia magna

Toxicity tests for 173 substances potentially hazardous to water were performed in 24 hr tests for 24-hr old animals of Daphnia magna. The test animals were fed with green alga. Test medium was tap water (hardness 16 °C German hardness scale, pH 7.6 – 7.7, temperature 20 – 22 °C), the boron species tested was Disodiumtetraborate ($Na_2B_4O_7$). Results obtained were the maximum concentration at which all used Daphnids had still their ability to swim (LC_0) as well as the minimum concentration at which all used Daphnids lost their swimming abilites (LC_{100}). From these data a LC_{50} was calculated. The LC_0 for Disodiumtetraborate (concentration referring to acting ion $B_4O_7^-$) was 17 mg B/L, the LC_{100} was 538 mg B/L and the calculated LC_{50} was 95 mg B/L. The study was not performed according to a guideline, some data on the test substance are missing, the test duration of 24 hours is rather short and no data are shown. Still the documentation is sufficient and methods scientifically acceptable. Thus, the study is rated as Klimisch 2 – reliable with restriction.

Bringmann and Kühn, 1977b: Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Bakterien (Pseudomonas putida) und Grünalgen (Scenedesmus quadricauda)

Toxicity tests (cell multiplication inhibition test) for 190 substances potentially hazardous to water were performed. Test animals were the bacteria *Pseudomonas putida* and the green alga *Scenedesmus quadricauda*. The agar for Pseudomonas and the medium for Scenedesmus contain boric acid. Pseudomonas tests were performed over 16 hrs, Scenedesmus tests were performed over 8 days. Cell multiplication in both cases was observed by measuring extinction. Test medium was bi-distilled water, the boron species tested was Disodiumtetraborate ($Na_2B_4O_7$). The concentration of sodium tetraborate at which an inhibitory action of a substance starts is determined at the extinction value ≥ 3% below the value for negative control. The growth inhibition was measured turbidimetrically. The TT for Pseudomonas was 290 mg B/L (1040 mg $Na_2B_4O_7$/L, concentration referring to acting ion $B_4O_7^-$), for Scenedesmus it was 0.16 mg B/L (0.58 mg $Na_2B_4O_7$/L, concentration referring to acting ion $B_4O_7^-$). $Na_2B_4O_7$ was more toxic to Scenedesmus than to Pseudomonas. The study was not performed according to a guideline, some data on the test substance are missing, no data are presented besides a single endpoint and the TTs are no longer used. Still the documentation is sufficient and methods scientifically acceptable. Thus, the study is rated as Klimisch 2 – reliable with restriction.

Bringmann and Kühn, 1978a: Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Blaualgen (Microcystis aeruginosa) und Grünalgen (Scenedesmus quadricauda) im Zellvermehrungstest & Bringmann and Kühn, 1978b: Testing of substances for their toxicity treshold: Model organisms Microcystis (Diplocystis) aeruginosa and Scenedesmus quadricauda

These two studies refer to the same data, once presented in English, once in German. For this reason, they are evaluated here together. The authors aim to compare the toxicity of 180 different substances to blue-green algae *Microcystis aeruginosa* and green algae *Scenedesmus quadricauda* (Data on Scenedesmus quadricauda have already been published in Bringmann and Kühn, 1977: Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Bakterien (Pseudomonas putida) und Grünalgen (Scenedesmus quadricauda). The organisms were tested with cell multiplication inhibition tests and the toxicity threshold (TT, in German TGK = toxische Grenzkonzentration) was determined, the TT is defined as the concentration, at which the inhibition of cell multiplication starts (3 % change from negative control). Culture conditions were standardized according to the authors. The substances were diluted in sterile, bi-distilled water, pH 7. The medium for the cultures contained boric acid (to provide trace elements). To obtain results, the extinctions of the cultures were determined, for comparisons the TT of Microcystis was set to 1 and then put in relation to the TT of Scenedesmus. The boron species tested was di-sodiumtetraborate ($Na_2B_4O_7$). The TT for *Microcystis aeruginosa* was 20.4 mg B/L (73 mg $Na_2B_4O_7$/L, concentration referring to acting ion $B_4O_7^-$), for Scenedesmus quadricauda it was 0.16 mg B/L (0.58 mg $Na_2B_4O_7$/L, concentration referring to acting ion $B_4O_7^-$). The concentrations $Na_2B_4O_7$ was more toxic to Scenedesmus than to Microcystis. The study was not performed according to a guideline, some data on the test substance are missing, no data are presented besides a single endpoint and the TTs are no longer used. Still the documentation is sufficient and methods scientifically acceptable. Thus, the study is rated as Klimisch 2 – reliable with restriction.

Bringmann, 1978: Bestimmung der biologischen Schadwirkung wassergefährdender Stoffe gegen Protozoen I

Cell multiplication inhibition tests for 171 substances potentially hazardous to water organisms were performed. Test organism was the flagellate *Entosiphon sulcatum*. These protozoans feed on aquatic bacteria from water. In the tests they were fed with *Escherichia coli*. Tests were performed over 72 hrs. Cell multiplication was observed with an electronic cell counter. Test medium was sterile bi-distilled water (pH 6.9), the boron species tested was Disodiumtetraborate ($Na_2B_4O_7$). The TT (5% change from control) for Entosiphon was 0.28 mg B/L (1 mg $Na_2B_4O_7$/L, concentration referring to acting ion $B_4O_7^-$). The study was not performed according to a guideline, some data on the test substance are missing, no data are presented besides a single endpoint and the TTs are no longer used. Some concerns about the feeding with dead bacteria and consequently suboptimal test conditions are raised by Guhl, 2002. Still the documentation is sufficient and methods scientifically acceptable. Thus, the study is rated as Klimisch 2 – reliable with restriction.

Bringmann and Kühn, 1980b: Bestimmung der biologischen Schadwirkung wassergefährdender Stoffe gegen Protozoen II. Bakterienfressende Ciliaten

Cell multiplication inhibition tests which were established for Entosiphon sulcatum were used for the protozoan Uronema parduczi. These protozoans take up bacteria from water and so help to clean the water. 169 substances potentially hazardous to water organisms were tested. The test animals were fed with *Escherichia coli*. Tests were performed over 20 hrs. Cell multiplication was observed with an electronic cell counter. Test medium was sterile bi-distilled water (pH 6.9), the boron species tested was Disodiumtetraborate ($Na_2B_4O_7$). The TT (based on 5% change) for Uronema parduczi was 30.3 mg B/L (109 mg $Na_2B_4O_7$/L, concentration referring to acting ion $B_4O_7^-$). The study was not performed according to a guideline, some data on the test substance are missing, no data are presented besides a single endpoint and the TTs are no longer used. Still the documentation is sufficient and methods scientifically acceptable. Thus, the study is rated as Klimisch 2 – reliable with restriction.

Davis et al., 2002

Since duckweed *Spirodella polyrrhiza* is used in waste treatment wetlands to remove nutrients and/or contaminants from secondarily treated wastewater, boron toxicity was tested on these plants. Boron is essential for plants, where concentrations of 0.2 mg B/L are known to be beneficial. Three endpoints were used in this study: frond production, growth rate, and percentage of abnormal fronds (chlorotic, necrotic, and dead). The test procedure was a 10-day static renewal evaluation on duckweed *Spirodella polyrrhiza*, which was conducted with a modified USEPA protocol (Ecological Effects Test Guidelines. Aquatic Plant Toxicity Test Using Lemna Spp., Tiers I and II, 1996). Boron was added as boric acid, the dilution water was a pH stabilized nutrient media. Samples were analyzed for Boron using the curcumin method. Statistical methods used are described. The toxicity results for frond production gave an EC_{50} of 14.3 mg B/L and a LOEC of 3.5 mg B/L (lowest test concentration). The EC_{50} for growth rate was 11.7 mg B/L, the NOEC 6.1 mg B/L, and the LOEC was 18.9 mg B/L. When abnormal fronds were used for endpoint determination, an EC_{50} of 17.7 mg B/L could be calculated, the NOEC was 18.9 mg B/L and the LOEC was 22.4 mg B/L. The tests were partly done according to guidelines, the study is published and the documentation is detailed. Thus, the study can be rated as Klimisch 2 – reliable with restriction.

Eckhert, 1998

Eckhert investigated the boron effects on growth of embryonic rainbow trout (*Oncorhynchus mykiss*). He found that boron stimulates rainbow trout growth in a dose-dependent manner. Eckhert conducted two studies using the Mt. Shasta strain of rainbow trout using the same procedures as reported in Rowe et al. 1998. Fertilized eggs were maintained in test solutions for 5 weeks (until hatching) and for 2 weeks post-hatch. Survival and post-hatch length were monitored. In the first study, no toxic effects of boron were observed over the treatment range of 0.9 to 936.1 µmol B/L (9.7 to 10120 µg B/L) Deficiency was evident at low concentrations (less than 11.4 µmol B/L (123 µg B/L) shown as shorter larvae. In the second study, no toxic effects of boron were observed over the treatment range of 2.2 to 90.6 µmol B/L (24 to 980 µg B/L) as shown in survival at eye and hatch stage, and as embryonic and larval trout lengths. Deficiency, shown as reduced length, was significant for embryos at less than 2.9 µmol B/L (31 µg B/L), and for larvae at less than 2.5 µmol B/L (27 µg B/L). The highest exposures in these tests also represent no-observed-effect-concentrations for toxicity for rainbow trout of 936 µmol B/L (10120 µg B/L) and 90.6 µmol B/L (980 µg B/L). However, these values are unbounded NOECs – no LOEC-toxicity was found. The usability of these data in derivation of PNEC-aquatic is therefore limited. The study is well documented, but the study design did not aim to derive toxicity data. It can be rated Klimisch 2 – reliable with restriction.

Fort et al., 1998

This article deals with the deleterious effects of low boron exposure on the Xenopus frog embryo-larval development model. The test used is called frog embryo teratogenesis assay – Xenopus (FETAX, performed according to ASTM E1439-91), which is a 4 day, whole-embryo bioassay to evaluate embryo-larval development of *Xenopus laevis* embryos. Furthermore, adult frogs were kept in low boron water (<1 µg B/L) and on separate diets (one with 62.0 µg B/kg, one with boric acid-supplemented diet at 1851.8 µg B/Kg) for 28 days, then their reproduction performance and the resulting development of the embryos was studied. Premium-grade boric acid was used for the diet, boron concentrations were analyzed chemically. ASTM-grade FETAX solution was prepared to culture the Xenopus embryos. The result of the first FETAX was that concentrations of ≤ 3 µg B/L induced significant increases in the incidence of malformations, no significant lethal effects were noted here. In the test after the 28-day exposure of the adults to low boron environment and/or low boron diet, embryo necrosis and abnormal gastrulation were increased, viability rate was decreased significantly. Rates of necrosis and abnormal gastrulation were greater in embryos from frogs maintained on low boron diet, then from those maintained on the boric acid diet. Summed up, these studies demonstrate that insufficient boron leads to abnormal Xenopus development during organogenesis and substantially impairs normal reproductive function in adult frogs. The methods and statistics applied in the study are well described, and some of the procedures are done according to a guideline, so the study can be rated as Klimisch 2. No endpoint related for derivation of a PNEC can extracted.

Gersich, 1984

This study was designed to establish a procedure for conducting chronic daphnid static renewal tests with boric acid as the test substance. The proposed method aims to improve protocols by the OECD, USEPA and ASTM. In the study a 48-hr static acute toxicity test was used to find a range of boron concentrations for the 21-day static renewal chronic toxicity test, both conducted with *Daphnia magna Straus*. Carbon-filtered water from Lake Huron was used as dilution water, pH ranged from 7.9 – 8.2, conductivity was 290 µmhos/cm, hardness was 148 mg/L as $CaCO_3$. Test organism was *Daphnia magna*. The acute testing procedures were based on ASTM guidelines, the test duration was 48 hrs, the organisms were not fed during the test. For the chronic toxicity test, a static renewal procedure was applied. In this test the daphnids were fed with green alga, and medium was changed three times a week. Boric acid concentrations were verified using the carmine method. Statistical calculations performed on the data are described. In the acute toxicity test an 48-hr static acute LC50 value of 133 mg B/L was found, the no-kill level was <54 mg/L and the 100% kill concentration was 420 mg/L. The water pH ranged from 6.7 – 8.1 and temperatures ranged from 20.1 – 20.7 °C. With the chronic toxicity test a 21-day LC50 value of 52.2 mg B/L ("moving average") was found. The water temperature ranged from 19.5 – 20.5 °C. A significant effect on mean broods per daphnid, mean total young per daphnid, mean brood size per daphnid as well as mean size was each observed for 13.6 mg B/L. The MATC (maximum acceptable toxicant concentration) value was estimated to be 6.4 – 13.6 mg B/L. The authors compared their results with those from former publications carried out according to the guidelines mentioned above. They found similar toxicity results, but performance of the tests was less complicated, derivation of different endpoints from the same group of organisms, and the possibility to perform statistical and biological interpretation of critical endpoints. The study is only partly performed according to guidelines, but is sufficiently documented and can therefore be rated as Klimisch 2 – reliable with restriction.

Gersich and Milazzo, 1990

In this study a 14-day static renewal toxicity test with Daphnia magna Straus is performed to compare the results with 21-day test results, which are recommended by guidelines (ASTM 1987, USEPA 1982). Boric acid, reagent grade, is used as test substance (besides aniline and 2,4-dichlorophenol. Test procedures correspond to the guidelines (diet with green alga, static renewal procedure etc) except for the temperature which is held at approximately 24 °C. Tests were performed in Lake Huron water (hardness of about 170 mg /L as $CaCO_3$, pH 7.3 – 8.2, temperature 23 – 25.2 °C). Boron concentrations were analytically determined and within a range of 98.5 and 111.4 % of nominal. The test was performed in two replicates. Statistics are described; the toxicity value determined in this study was MATC (the maximum acceptable toxicant concentration).

The mean NOEL for both replicates was 2.46 mg B/L (14.1 mg Boric acid/L), the mean LOEL was 4.98 mg B/L (28.5 mg Boric acid/L). The MATC for Test I was between 2.41 – 4.91 mg B/L and for Test II between 2.5 – 5.05 mg B/L. When the authors compared the results from the 14-day tests to those from 21-day tests (Gersich 1984, Gersich and Milazzo 1988), they found similar MATC values (within a factor of 2). Also characteristics to confirm test acceptability (mean number of broods/adult, mean total young/adult, mean brood size and survival) were met by the 14-day tests. Therefore the authors concluded that the use of the 14-day test can be supported to reduce cost of these studies. The study is not performed according to a guideline, but the differences to guideline values are clearly documented and reasonable. The documentation is sufficient and thus the study can be rated as Klimisch 2 – reliable with restriction.

Note: In table 3, the concentrations are stated to be given as boric acid. Nevertheless there is an indication that these values could be related to boron, as the 21-day value of "9.3" from Gersich, 1984, is related to boron.

Guhl et al., 1991, unpublished report

The NOEC for the *Entosiphon sulcatum* was determined to occur after 72 hours at 18 mg B/L. The study is quoted as reliable with restriction, Klimisch "2".

Guhl et al., 2000

Viable and dead bacteria (*Pseudomonas putida*) were used as food for *Entosiphon sulcatum*. *Pseudomonas putida* were grown according to DIN 38412, part 8. Numbers of protozoa were determined after 24, 48 and 72 hours. The difference between live and dead protozoa was 7%. The NOEC/LOEC values were equivalent to 15/22 mg B/l. The EC_{50} value was 43 mg B/l, and the EC_{100} value was estimated as 65 mg B/l. The authors point out that this species is commonly found in wastewater treatment plants, with an annual average of 2.12 mg-B/L, suggesting that this species can be present at approx. 10-fold higher concentrations than suggested by Bringmann and Kühn, 1980. *Paramecium caudatum* was fed with viable *Pseudomonas putida*. The NOEC/LOEC (EC_{10}) value was equivalent to 20/25 mg B/l. The EC_{100} value was estimated as > 70 mg B/l. *Opercularia bimarginata* was fed with viable *Pseudomonas putida*. The NOEC value was equivalent to 10 mg B/l. The cell shape was changing at concentrations higher than 10 mg B/l and at concentrations higher than 20 mg

B/l zooids separated from their colony. Raw data and statistical analyses of the data are missing. Still the study description is acceptable, therefore a Klimisch-rating of 2 (reliable with restriction) is assigned.

Hamilton and Buhl, 1997

In this published study larval flannelmouth sucker (*Catostomus latipinnis*) were exposed to nine different inorganics and mixtures of them, among them was boron. The exposures were designed to reconstitute water of the San Juan River, New Mexico. Acute toxicity tests were performed according to the test procedures outlined by the American Society for Testing and Materials (Standard Guide E729-88a for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians, 1989). Additionally the testing procedures are well described and statistical analyses were performed. The fish were investigated in water simulating those in the Green River, Utah. The water used was deionized water substituted with major cations and anions to reconstitute the water of the San Juan River. Boron was added as boric acid either from aliquots of a stock solution or by directly adding to the test vessels, concentrations are nominal. The acute toxicity is given as a 24-hr/48-hr/72-hr/96-hr LC_{50}, 95 % CI in parentheses. Boron toxicity for 13 day old flannelmouth sucker larvae was found to be 1000 (746-3510) / 337 (276-434) / 225 (174-275) / 125 (102-162) mg boron /L. The study is done according to a guideline and well documented, still there are some data missing on boron purity and life conditions of the test animals and can thus be rated Klimisch 2 – reliable with restriction.

Hamilton, 1995

Hamilton tested in his study the toxicity of seven inorganics, among which boron, on the endangered species Colorado squawfish (*Ptychocheilus lucius*), razorback sucker (*Xyrauchen texanus*), and bonytail (*Gila elegans*). Acute toxicity tests closely followed those outlined by the American Society for Testing and Materials (Standard Guide E 729-88a for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians, 1989). Additionally the testing procedures are well described and statistical analyses were performed. The fish were investigated in water simulating those in the Green River, Utah. The water used was deionized water substituted with major cations and anions to reconstitute the water of the Green River. Boron was added as boric acid either from aliquots of a stock solution or by directly adding to the test vessels, concentrations are nominal. The acute toxicity is given as a 96-hr LC_{50}, 95 % CI in parentheses. Boron toxicity for Colorado squawfish was 279 (216-360) mg boron /L for swimup fry, > 100 mg/L for 0.4 – 1.1-g juvenile and 527 (430-667) mg/L for 1.7-g juvenile. Boron toxicity for razorback sucker was 233 (172-293) mg boron /L for swimup fry, 279 (216-360) mg/L for 0.9-g juvenile and >100 mg/L for 2.0-g juvenile. Boron toxicity for bonytail was 280 (226-347) mg boron/L for swimup fry, > 100 mg/L for 1.1-g juvenile and 552 (452-707) mg/L for 2.6-g juvenile. The calculated geometric mean was 337 (266-429) mg boron/L. The author describes boron as practically nontoxic, but still states that the natural concentration of boron in Ashley Creek (staging for the Green River) bears a moderate hazard. The study closely followed a guideline and is well documented, still there are some data missing on boron purity and life conditions of the test animals and can thus be rated Klimisch 2 – reliable with restriction.

Hamilton and Buhl, 1990

In this study the authors investigated the acute toxicity of boron, molybdenum, and selenium. Test organisms were Chinook salmon (*Oncorhynchus tshawytscha*) and coho salmon (*Oncorhynchus kisutch*). The water used resembled disposal of agricultural wastewaters into either fresh or brackish receiving water. Three different water conditions were used: two were designed to simulate water qualities for major anions and cations of standardized San Luis Drain water, which was then diluted tenfold in standardized fresh or 22.5-fold in standardized brackish water. The third condition used was water prepared as recommended by the US Environmental Protection Agency (USEPA) for use in acute toxicity tests with fish. Boron was added as boric acid (highest purity available), either from aliquots of a stock solution or by directly adding to the test vessels, concentrations are nominal. Acute toxicity tests were performed according to the test procedures outlined by the American Society for Testing and Materials (E729 Standard practice for conducting acute toxicity tests with fishes, macroinvertebrates, and amphibians, 1980) but in various dilution waters. The 96-hr LC_{50} values for boron in the various water qualities did not differ significantly. The CI is given in brackets. The LC_{50} values for boron toxicity on Chinook salmon was >1000 mg boron/L (24-hr), 725 (590-890) mg boron/L (96-hr) for San Luis Drain diluted in fresh water and >1000 mg boron/L (24-hr), 600 (511-706) mg boron/L (96-hr) for San Luis Drain diluted in brackish water. In soft water the acute toxicity of boron was >1000 mg boron/L for all 24-hr LC_{50}s for Chinook salmon eyed eggs, alevin and 0.31-g-fish. The 96-hr LC_{50}s were >1000 mg boron/L for Chinook salmon eyed eggs and alevin and 566 (482-664) mg boron/L for 0.31-g-fish. The LC_{50} values for boron toxicity on coho salmon was >1000 mg boron/L (24-hr), 447 (356-561) mg boron/L (96-hr) for San Luis Drain diluted in fresh water and >1000 mg boron/L (24-hr), 600 (511-705) mg boron/L (96-hr) for San Luis Drain diluted in brackish water. The study is well documented, still there are some data missing on boron purity and life conditions of the test animals and can thus be rated Klimisch 2 – reliable with restriction.

Hickey et al., 1991

This study aims to compare two toxicity end-point responses obtained by microtest procedures on the green alga *Selenastrum capricornutum*. 14 chemicals (9 metals, 5 organic compounds) are tested. The test parameters were intracellular ATP measured after 4-h exposure on one side, and cell counts comprising algal cell recovery after 96-h on the other side. In general the inorganic chemicals were by far more toxic than their organic counterparts, with the exception of B^{3+}, and the 96-h EC_{50} test proved to be more sensitive than the ATP and recovery test. All inorganic chemicals tested, with exception of boron (tested as $Na_2B_4O_7{\cdot}10H_2O$) showed toxic responses at concentrations of 5 mg/L or less. Boron had no significant effect on either ATP or cell recovery at exposures as high as 250 mg B/l. As an unbounded NOEC the value should not be used for PNEC-derivation. The study is not performed according to guidelines, but is sufficiently documented and can therefore be rated as Klimisch 2 – reliable with restriction.

Hickey, 1989

In this study the toxicity effects of a variety of substances, among them boron, were tested in four New Zealand cladoceran species (*Daphnia carinata, Simocephalus vetulus, Ceriodaphnia dubia,* and *Ceriodaphnia cf. pulchella*) in comparison to *Daphnia magna*. Test organisms were fed with nutrient solution (beef extract, glucose) and *Selenastrum capricornutum*. Acute and chronic tests were performed (procedures similar to those recommended by different guidelines for Daphnia magna tests). The dilution water (according to HMSO 1983) was prepared in ultrapure water. The pH was 7.9, hardness 250 mg/L as $CaCO_3$ and tests were performed at 20 °C in the dark. Test solutions were exchanged every 48 hrs. Boron was added as boric acid, AR grade. Calculations and statistics performed were described. S. vetulus and C. cf. pulchella showed poor survival characteristics in laboratory test conditions, therefore not all tests were carried out with these organisms. Differences between the species for the EC50 values were generally small, sensitivity differences were greater for the EC10 values. The acute results were EC50s of 319.8 mg B/L for D. magna, 267.7 mg B/L for D. carinata, 123.4 mg B/L for S. vetulus, 180.6 mg B/L for C. dubia, and 101.2 mg B/L for C.cf. pulchella. The EC10s were 250 mg B/L for D. magna, 138.8 mg B/L for D. carinata, 38.1 mg B/L for S. vetulus, 130.4 mg B/L for C. dubia, and 48.8 mg B/L for C.cf. pulchella. Chronic toxicity tests resulted in a LOEC of 32 mg B/L and a NOEC of 18 mg B/L for D. magna and a LOEC of 18 mg B/L and a NOEC of 10 mg B/L for C. dubia. The data were obtained using partly the recommendations from guidelines, but since also non-guidleline organisms were used, the test duration was only 24 hours and not all raw data are given, the study is classified as Klimisch 2 – reliable with restriction.

Lewis and Valentine, 1981

In this published study from the Procter & Gamble Company, the toxicity of boric acid to the commonly used test organism *Daphnia magna* Straus was investigated. A 48-hr static acute test and a 21-day static renewal chronic toxicity test were performed. The dilution water was carbon-filtered well water, in which analytical grade boric acid stocks in distilled water were diluted. Boron concentrations were verified using the curcumin method in chronic tests, in the acute tests, nominal boron concentrations are given. The test organisms were not fed during the acute test but during the chronic toxicity test. The diet consisted of Ralston Purina Trout Chow and dehydrated alfalfa in deionized water and was supplemented with alga suspension (*Selenastrum capricornutum* Printz). The acute toxicity test was performed according to the guidelines of the USEPA (1975).

The chronic toxicity test was performed using a static renewal procedure (test duration 21 days, test solutions were renewed three times weekly), young produced by adults in the tests were removed. The 21-day LC_{50} value was calculated from mortality data by probit analysis. The pH of the test water ranged from 7.1 – 8.7, mean temperature was 19.2 °C and water hardness averaged 166 mg /L as $CaCO_3$. The 48 hr LC_{50} determined in the acute test was 226 mg B/L, the no kill concentration was <200 mg/L. In the chronic toxicity test a 21-day LC_{50} (mortality) of 53.2 mg B/L was determined. Based upon mean length, the NOEC was 27 mg B/L and the LOEC was 53 mg B/L. Based upon mean brood sizes (the most sensitive parameter), the NOEC was 6 mg B/L and the LOEC was 13 mg B/L. The authors conclude that the effect concentrations of boron to daphnids are similar to those for algae and within the range for fish. The study is well documented and partly performed after guidelines (acute toxicity test), though some raw data are missing. Therefore the study is rated as reliable with restriction – Klimisch 2.

Maier and Knight, 1991

This study deals with the acute toxicity of waterborne sodium tetraborate on *Daphnia magna* and *Chironomus decorus*, as well as the sublethal toxicity on *Chironomus decurs*. Additionally the effects of water hardness and sulfate concentrations on boron toxicity to Daphnia magna are investigated. With *Daphnia magna* and *Chornomus decorus* two common aquatic invertebrates are used as test organisms. The acute toxicity test was performed using standardized methods (USEPA 1975). Boron was added as sodium tetraborate ($Na_2B_4O_7{\cdot}10\ H_2O$). Dilution water was reconstituted, moderately hard fresh water (according to USEPA 1975), with a hardness of 85 mg/L as $CaCO_3$, a temperature of 20 °C, and a pH of 9.1. The solution was replaced after 24 hr and boron concentrations were determined analytically. For the sublethal toxicity test, *Chironomus decorus* was incubated 96 hrs and the organisms were fed with cerophyll. The results of the acute toxicity tests were a 48-hr LC50 value of 141 mg B/L for neonate Daphnia magna and 1367 mg B/L for forth instar *Chironomus decorus*. Tests with different levels of water hardness or sulfate concentrations did not show significant differences. The sublethal test resulted in a siginificant inhibition of *Chironomus decorus* midge larval growth rate at 20 mg B/L (LOEC). Statistics and calculation methods used are described, but details on experimental setup and outcome are missing. For these reasons the study is rated as Klimisch 2 – reliable with restriction.

Rowe, Bouzan et al., 1998

The study by Rowe et al. evaluates the health effects of low and high boron concentrations on rainbow trout *Oncorhynchus mykiss* and zebrafish *Danio rerio*. Boron stimulated longitudinal growth of embryo-larval stage trout. Rainbow trout embryos showed stimulated growth in a dose-dependent manner. Exposures below 0.097 mg B/L (9 µM B/L) impaired growth and above 108.1 mg B/L (10 mmol B/L) caused death. For zebrafish the safe range of exposure to B was observed to be above 0.002 mg B/L (0.2 µmol B/L) and below 99.4 mg B/L (9.2 mmol B/L). The toxic effects of boron depended in the case of the rainbow trout on the origin of the embryos. While Mount Shasta strain (natural water B concentration in hatchery 0.038 mg B/L) embryos showed 95 % mortality at the hatch stage at 108.1 mg B/L (10 mmol/L), 85 % of the Hot Creek strain (natural water B concentration in hatchery 0.126 – 0.285 mg B/L) embryos survived. 88% of zebrafish embryos were killed at 99.4 mg B/L (92 mmol B/L). Thus the strain which came from water with the higher natural B concentration was more tolerant to higher B concentration. The LOAEL (Lowest-Observed-Adverse-Effect Level) at high exposure (toxicity range) was 108.1 mg B/L (10 mmol B/L) for rainbow trout and 99.4 mg B/L (9.2 mmol B/L) for zebrafish. The NOAEL (No-Observed-Adverse-Effect Level) at high exposure (toxicity range) was 86.5 mg B/L (8 mmol B/L) for rainbow trout and 13 mg B/L (1.2 mmol B/L) for zebrafish. At very low concentrations adverse effects due to deficiencies were observed. The data were not obtained according to a guideline, but the used experimental and statistical methods are well described and the conditions defined. Thus, the study is classified as Klimisch 2 – reliable with restriction.

Steber, 1991,

This summary of unpublished studies by Guhl was done for Henkel KGaA in 1991. By various methods the effect concentrations of Sodium tetraborate is assessed for bacteria, daphnia, algae, biocenosis and phragmites. An oxygen consumption inhibition test was conducted with *Pseudomonas putida*. The respiration inhibition was determined after 30 min reaction time. A mixture of bacteria, glucose and sodium tetraborate and dilution water was aerated for 30 min; the oxygen consumption was measured electrometrically. The EC_0 and EC_{10} were determined to be 110 and 340 mg B/l, respectively. The study was performed using DIN 38412, part 27 (refers to OECD guideline 209). A chronic growth inhibition test was performed using the DIN 38412, part 8 method. The growth inhibition of *Pseudomonas putida* during a period of 16 hours was investigated photometrically. The EC_0 and the EC_{10} values were 3.4 and 7.6 mg B/l. The toxicity values for *Photobakterium phosphoreum* in the luminous bacteria test (according to DIN 38412, part 34) was an EC_{20} of 18 mg B/L.

The chronic toxicity values for *Scenedesmus subspicatus* in the cell multiplication inhibition test (4 days, according to DIN 38412, part 9, referring to OECD guideline 201) were an EC_0 of 10 mg B/L, an EC_{10} of 24 mg B/L, an EC_{50} of 34 mg B/L and an EC_{100} of 100 mg B/L. The chronic toxicity values for *Daphnia magna* when reproduction and mortality and first appearance of offspring were tested (according to OECD guideline 202, part 2) gave the following results: the NOEC was 10 mg B/L and the FOEC (corresponding to the lowest observed effect concentration LOEC) was 30 mg B/L.

Tests on bacteria, algae and daphnia were stated to be done according to DIN or OECD guidelines, but no original data nor statistical analysis methods are given. Therefore, theses data can be classified as Klimisch 2 –reliable with restriction.

Thompson et al., 1976

Thompson et al., (1976) investigated effects of boron (as sodium metaborate) on salmon in sea and fresh water. For freshwater bioassays, coho alevins weighing 0.19 – 0.7g were used in groups of 20 fish per tank. The criterion for death was cessation of movement, including respiratory movement. After 283 hours an LC50 of 113 mg B/l could be determined. The publication meets basic scientific principles and is a peer-reviewed publication. However the procedures used differ from standard acute test methods; to use an LC_{50}-value is not current practice for such a long exposure. Consequently a Klimisch rating of “2” Reliable with restriction is suggested.

Klimisch 3

Bergmann et al., 1995

Boron toxicity was tested in *Phragmites australis* reed plants. Experiments were carried out on one side in soil substrate in the presence of free water (1992 – 1993) and on the other side in a gravel hydroculture (1992 – 1993). In both cases, boron was added discontinuously during the vegetation period. The endpoints were determined according to number of stems per pot, the average growth height of plants in one pot, the dry substance weight of stems and leaves, and the dry substance of the roots. Boron contents of water and plants were determined chemically. The results showed, that the test plants tolerated long-term concentrations of up to 4 mg B/l without effects and short-term concentrations up to 8 mg B/L. Long-term boron concentrations of $\geq$ 8 mg B/L lead to toxic effects. The authors therefore classify *Phragmites australis* as a particularly boron-tolerant plant. Since the test procedures are not standardized, the boron addition is discontinuously, the exposures not well characterized and the background-concentrations of boron (e.g. in soil) are not considered, the study is rated as not reliable – Klimisch 3.

Hamilton and Wiedmeyer, 1990

Chronic toxicity studies on young Chinook salmon *Oncorhynchus tshawytscha* were performed. The fish were exposed to a mixture of boron, molybdenum, selenate and selenite. The purpose of the study was to investigate the effect of agricultural drainage water in the basin of the San Joaquin Valley, California on fish. No detectable concentration of boron was found in fish, suggesting little accumulation of waterborne boron. The study is well documented but since only mixtures of boron with other substances are used in the tests, no toxicity data for boron can be derived. Therefore, the study is classified as Klimisch 3 – not reliable – as regards evaluating toxicity.

Mann, 1973

This study deals with toxic effects of boron species in conjunction with boron usage for bleaching in washing. Sodium perborate ($NaBO_2 . H_2O_2 . 2 H_2O$) is the sodium species used in bleaching, as testing compounds boric acid (H_2BO_3) and borax ($Na_2B_4O_7 . 10 H_2O$) and sodium perborate were used. Test animals were rainbow trout, guppies, eel spawn, *Gammarus tigrinus* and tubificides. Dilution water was Hamburg town water, in some conditions it was diluted with Helgoland sea water to obtain higher salt contents. Test procedures are described sufficiently although not very detailed. Results obtained with boric acid or borax were similar. The concentrations at which no harm was observed after 24 hrs (NOEC) obtained for boric acid were > 10000 mg/l (1748.14 mg B/L) for eel spawn, 10000 mg/l (1748.14 mg B/L) for rainbow trout, 5000 mg/l (875.07 mg B/L) for guppies, and 7500 mg/l (1311.11 mg B/L) for *Gammarus tigrinus* and for tubificides. Borax concentrations which showed no effect were 7500 mg/l (850.28 mg B/L) for eel spawn, 2500 mg/l (283.43 mg B/L) for rainbow trout and for guppies, 7500 mg/l (850.28 mg B/L) for *Gammarus tigrinus* and 750 mg/l (85.03 mg B/L) for tubificides. The second endpoint which was determined was an LD_{100} after 24 hrs. The LD_{100}s determined for boric acid were > 10000 mg/l (1748.14 mg B/L) for eel spawn, 7500 mg/l (1311.11 mg B/L) for rainbow trout and guppies and 10000 mg/l (1748.14 mg B/L) for *Gammarus tigrinus* and tubificides.. For borax LD_{100}s were determined to be > 10000 mg/l (1133.71 mg B/L) for eel spawn, 5000 mg/l (875.07 mg B/L) for rainbow trout and guppies, 10000 mg/l (1133.71 mg B/L) for *Gammarus tigrinus* and 2000 mg/L (226.74 mg B/L) for tubificides, The experiments are not done according to a guideline, the study description is insufficient, no raw data are presented and only a single value is presented, so the study is rated as not reliable – Klimisch 3.

Terhaar et al., 1972

This article describes the toxicity tests for "Simulated Ektaprint C color print process effluent" on fathead minnows *Pimephales promelas*. Kodak Park industrial water (Lake Ontario) is used to keep the fish (pH 7.6, hardness as $CaCO_3$ 82 mg /L). The authors calculated the time required to kill 50% of the fish (LT_{50}) by visually fitting a straight line on log-probability paper, to the observed data. Besides photographic processing chemicals also other chemicals, among them boric acid, were tested. The LT_{50} values for boric acid were 10 hrs at 10000 mg /L (1748.1 mg B/L) and 79 hrs at 1000 mg /L (174.8 mg B/L). After 96 hrs exposure of 100 mg/L (17.5 mg B/L) no mortality was observed. Since the documentation is poor, no usable endpoints are calculated and the statistic analysis were insufficient the study is rated as Klimisch 3 – not reliable.

Turnbull et al., 1954

This study mainly aimed to investigate the toxicity of industrial waters, but also some inorganic substances were tested. Dilutions of boron species were prepared with Philadelphia tap water filtered through a carbon filter; the dissolved oxygen content was maintained at 5 ppm or more during the entire test period. The test criterion was death of fish in 24 to 96 hours. The endpoint used is median tolerance limit (TL_m) which is the concentration of test substance at which 50 % of the test animals survive for a specified period of exposure. As test animals bluegill sunfish *Lepomis macrochirus* was used. Two boron species were tested: sodium tetraborate (results given as B_2O_3) and boron trifluoride which was prepared as 2.7% solution in sodium hydroxide. Test procedures are not described very detailed. No raw data are presented and only a single value (the median tolerance limits TLm) is presented. The 24 hr median tolerance limits observed for the boron species were 15 ppm (24 hr) for B_2O_3 (4.66 mg B/L) and 15 000 ppm for BF_3 (2391.45 mg B/L). The data for BF_3 cannot be used for a PNEC-derivation. The experiments are not done according to a guideline and the documentation is not sufficient, so the study is rated as not reliable – Klimisch 3.

Wallen et al., 1957

In this study the effects of chemicals in turbid waters on mosquitofish *Gambusia affinis* were tested to obtain data on the toxicity of turbid waste waters from refinery operations in Oklahoma. To obtain turbid water, clay (from different soils) was mixed in tap water. Boric acid was tested in water with a turbidity of 250 ppm (initial) and 210 ppm (final), the pH ranged from 5.4 – 7.3. The median tolerance limits (TL_m) were 18000 ppm (3147 mg B/L) after 24 hrs, 10500 ppm (1836 mg B/L) after 48 hrs, and 5600 ppm (979 mg B/L) after 96 hrs. Sodium borate (borax) was tested in water with a turbidity of 650 ppm (initial) and 410 ppm (final), the pH ranged from 8.6 – 9.1. The median tolerance limits (TL_m) were 12000 ppm (1361 mg B/L) after 24 hrs, 8200 ppm (930 mg B/L) after 48 hrs, 3600 ppm (408 mg B/L) after 96 hrs, and 1900 ppm (215 mg B/L) after 144 hrs. The documentation of the article is sufficient, but since the values observed in turbid water may not be representative for clear water, the study is rated as Klimisch 3 – not reliable.

Klimisch 4

Barnum, 1987

This article reviews the sources and uses of boron, the levels of boron in aquatic systems, the effects of boron on aquatic life and safe levels of boron in the aquatic environment. Studies reviewed for effects of boron on aquatic life contain Antia and Cheng (1975), Bingham (1982), Birge and Black (1977, 1981), Birge et al. (1979, 1983, 1984), Bringmann (1978) and Lewis and Valentine (1981). The author concludes from literature data that boron is not a concern for surface waters at current or anticipated usage levels. Since the articles does not present new data, it is classified as a review and therefore not assignable – Klimisch 4.

Bringmann and Kühn, 1979: Vergleich der toxischen Grenzwertkonzentrationen wassergefährdender Stoffe gegen Bakterien, Algen und Protozoen im Zellvermehrungstest & Bringmann and Kühn, 1980a: Comparison of the Toxicity Tresholds of Water Pollutants to Bacteria, Algae, and Protozoa in the Cell Multiplication Inhibition Test

These articles review data which were published before in the “Zeitschrift für Wasser- und Abwasser-Forschung“ (Bringmann and Kühn, 1977 and 1978) without referring to these data. Data on Pseudomonas putida and Scenedesmus quadricauda have already been published in Bringmann and Kühn, 1977: „Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Bakterien (Pseudomonas putida) und Grünalgen (Scenedesmus quadricauda)“, data on Entosiphon sulcatum in Bringmann and Kühn, 1978: „Bestimmung der biologischen Schadwirkung wassergefährdender Stoffe gegen Protozoen“. As these articles are reviews, they are rated as Klimisch 4 – not assignable.

Butterwick, de Oude et al., 1989

The article from Butterwick et al. from 1989 is a review on the effects of boron in the aquatic and terrestrial environments. It contains a rich collection of data points from various studies and for many species. These data are only reviewed and not re-evaluated. The authors concluded that generally, environmental concentrations of boron found in surface water are below levels identified as toxic to aquatic organisms. Since it is a review it is classified Klimisch 4 – not assignable.

Guhl, 1992b

This article origins from a talk given at a meeting in 1992. It reviews data from the literature. Therefore the article is to be classified as a review with Klimisch 4 – not assignable.

Loewengart, 2001

The article from Loewengart describes the data available for boron toxicity on rainbow trout *Oncorhynchus mykiss*. In a weight-of-the evidence assessment the data were reviewed. Additionally the review provides a valuable overview on original articles. Since no new data are reported, the article is classified as a review as Klimisch 4 – not assignable.

Meyer et al., 1998

This article reviews historical data about boron concentrations and trout in the Firehole River (Yellowstone National Park) and describes the start of a field study. The Firehole River contains naturally elevated concentrations of boron and is a known reservoir for rainbow trout *Oncorhynchus mykiss* and brown trout *Salmo trutta*. Boron concentrations in the Firehole River vary according to the different parts and tributaries of the river and its sidearms. They range from as high as 0.93 mg B/L (ca. 1.5 km above Firehole Falls), to 0.81 mg/L at the Lower Geyser Basin and a median concentration of 0.7 mg B/L at Madison Junction. Preliminary results of the field study indicate that 0.5 mg B/L did not appear to be avoided by rainbow trout or brown trout. Since no endpoint was determined and the data were preliminary, the study is classified as Klimisch 4 – not assignable.

Raymond and Butterwick, 1992

In this book chapter Raymond and Butterwick review characteristics, properties and effects of boron, especially effects on environment and its clinical toxicology. The conclusion of the review of fish toxicity data was that early life stages of rainbow trout are most sensitive to boron. Data on fish toxicity reviewed in the book chapter and here in this report are from: Turnbull (1954), Thompson et al. s(1976), Wallen et al. (1957), Birge and Black (1981), and Procter and Gamble Company (1987). There are additional datasets in the review which were not evaluated here: Procter and Gamble (1979), NAS (1973), McKee and Wolf (1963) and Wurtz (1945). In Procter and Gamble (1979) boric acid toxicity values for fathead minnow *(Pimephales promelas)* egg and fry are reported: a 30-day NOEC (reduction in growth) of 14 mg B/L and a 30-day LOEC (reduction in growth) of 24 mg B/L, respectively as well as a 60-day NOEC (reduction in fry survival) of 24 mg B/L and a 60-day LOEC (reduction in fry survival) of 88 mg B/L, respectively.

The NAS report from 1973 is cited to deliver a toxicity value for boric acid on minnow (not further defined) of 3145 – 3319 mg B/L as 6-h minimum lethal dose in distilled water. The 6-h minimum lethal dose for minnow as observed by McKee and Wolf (1963) was 3319-3407 mg B/L with boric acid as test substance, as well as minimum lethal doses of 370-374 mg B/L with borax as test substance in distilled water, and 793-850 mg B/L with borax as test substance in hard water. Wurtz (1945) is cited with an effect of darkening of skin at 874 mg B/L (in *Salmo gardieneri*) and an effect of immobilisation and loss of equilibrium at 13976 mg B/L caused by boric acid. The data Procter and Gamble data could possibly be used for PNEC derivation, but the other values do not present endpoint usable for further calculations. Since no new data are obtained by the authors, the article is classified as Klimisch 4 – not assignable.

Rowe and Eckhert, 1999

This report deals with the essentiality of boron. It was already known that boron is essential for plants. Here, the authors show that boron might be also essential for zebrafish *Danio rerio* embryogenesis. The test animals were obtained from Scientific Hatcheries (California, USA), these hatcheries rely on Los Angeles Metropolitan Water District for their water supply which contains 0.499 mg B/L (46.2 µmol B/L). Methods and applied statistics are described adequately. 92 % of embryos kept in low-boron environment (0.0011 mg B/L; 0.1 µmol/l) died until day 10 post-fertilization. Survival of zebrafish embryos was significantly reduced as soon as 4 hours after fertilization in low-boron conditions. If fertilized eggs from the low-boron conditions were immediately after fertilization transferred to boron-supplemented conditions (0.485 mg B/L (44.9 µmol B/L)), survival significantly improved. Since no toxicity endpoints are given in this study, it is not relevant to calculation of boron toxicity and can be rated Klimisch 4 – not assignable.

Schöberl and Huber, 1988

This article gives an overview on the ecotoxicity of non-surfactant components of detergents and cleaning agents. It refers to different studies (no references given), with LC_{50} values for borate ($Na_2B_4O_7$) of 807 mg/l for orfes *Leuciscus idus* and 3300 mg/l for minnows *Phoxinus phoxinus* (623 mg/l or 2546 mg/l respectively as $B_4O_7^{2-}$ and 173 mg/l or 709 mg/l respectively as B*)*. As only values are given without references the study is quoted as not assignable (Klimisch 4).

Unilever, 1994

This report reviews a project by SG Hambling and JHN Garland on boron levels in surface waters, and especially those containing young salmonid fish. They collected data on water from rivers and trout hatcheries in the UK. Boron concentrations in rivers varied greatly and ranged from 0.007 – 3.8 mg B/L. The samples from hatcheries contained 0.007 – 0.120 mg B/L. Additionally some, few data on boron levels in European surface waters are given in this report. Since no new data on boron toxicity are given in this report it is classified as review, Klimisch 4 – not assignable.

WHO, 1998

This report contains the views of an international group of experts on environmental health criteria of boron. It describes a wide range of aspects concerning boron toxicity: human and environmental exposure, to effects on laboratory mammals and in vitro test systems as well as on humans or other organisms in the laboratory and field. The risks and effects on human and environment are evaluated. In the chapter of effects on organisms in the laboratory and field also effects on aquatic organisms are evaluated. Acute and chronic toxicity data are cited. The risk of boron having adverse effects on the aquatic environment is considered low by the authors. Since no new data are presented, the report is rated as Klimisch 4 – not assignable.

Table 7.1 Freshwater organisms

Species	Endpoint Type	Test Duration (days)	Test Conditions	Tested Substance	Endpoint	Value	Reliability Statement	Limitations	Reference	Comments
Fish										
Zebrafish (Brachydanio rerio)	LC50 (mortality)	34	DSWL-E prepared from ground water (46.25 µmol B/L, pH 8.0-8.5, hardness as CaCO3 212 mg/l)	Boric acid	24	mg B/L	Reliable without restriction	Guideline study (OECD No. 210), GLP, well documented	Hooftman et al., 2000	usable for PNEC derivation
Zebrafish (Brachydanio rerio)	NOEC (mortality)	34	DSWL-E prepared from ground water (46.25 µmol B/L, pH 8.0-8.5, hardness as CaCO3 212 mg/l)	Boric acid	5.6	mg B/L	Reliable without restriction	Guideline study (OECD No. 210), GLP, well documented	Hooftman et al., 2000	usable for PNEC derivation
Zebrafish (Brachydanio rerio)	NOEC (growth-weight)	34	DSWL-E prepared from ground water (46.25 µmol B/L, pH 8.0-8.5, hardness as CaCO3 212 mg/l)	Boric acid	**1.8**	mg B/L	Reliable without restriction	Guideline study (OECD No. 210), GLP, well documented	Hooftman et al., 2000	usable for PNEC derivation
Zebrafish (Brachydanio rerio)	NOEC (growth-length)	34	DSWL-E prepared from ground water (46.25 µmol B/L, pH 8.0-8.5, hardness as CaCO3 212 mg/l)	Boric acid	5.6	mg B/L	Reliable without restriction	Guideline study (OECD No. 210), GLP, well documented	Hooftman et al., 2000	usable for PNEC derivation
Zebrafish (Brachydanio rerio)	NOEC (condition)	34	DSWL-E prepared from ground water (46.25 µmol B/L, pH 8.0-8.5, hardness as CaCO3 212 mg/l)	Boric acid	5.6	mg B/L	Reliable without restriction	Guideline study (OECD No. 210), GLP, well documented	Hooftman et al., 2000	usable for PNEC derivation
Zebrafish (Brachydanio rerio)	LOEC (mortality)	34	DSWL-E prepared from ground water (46.25 µmol B/L, pH 8.0-8.5, hardness as CaCO3 212 mg/l)	Boric acid	18	mg B/L	Reliable without restriction	Guideline study (OECD No. 210), GLP, well documented	Hooftman et al., 2000	usable for PNEC derivation
Zebrafish (Brachydanio	LOEC (growth-weight)	34	DSWL-E prepared from ground water (46.25	Boric acid	5.6	mg B/L	Reliable without	Guideline study (OECD No.	Hooftman et al., 2000	usable for PNEC derivation

rerio)			µmol B/L, pH 8.0-8.5, hardness as CaCO3 212 mg/l)				restriction	210), GLP, well documented		
Zebrafish (Brachydanio rerio)	LOEC (growth-length)	34	DSWL-E prepared from ground water (46.25 µmol B/L, pH 8.0-8.5, hardness as CaCO3 212 mg/l)	Boric acid	18	mg B/L	Reliable without restriction	Guideline study (OECD No. 210), GLP, well documented	Hooftman et al., 2000	usable for PNEC derivation
Zebrafish (Brachydanio rerio)	LOEC (condition)	34	DSWL-E prepared from ground water (46.25 µmol B/L, pH 8.0-8.5, hardness as CaCO3 212 mg/l)	Boric acid	18	mg B/L	Reliable without restriction	Guideline study (OECD No. 210), GLP, well documented	Hooftman et al., 2000	usable for PNEC derivation
Channel catfish (Ictalurus punctatus)	LC50	9	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Boric acid	22	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Channel catfish (Ictalurus punctatus)	LC50	9	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Borax	71	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Channel catfish (Ictalurus punctatus)	LC50	9	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	155	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Channel catfish (Ictalurus punctatus)	LC50	9	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Borax	155	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Goldfish (Carassius auratus)	LC50	7	"hard water": synthetic water prepared from distilled, double deionized water (300	Boric acid	75	mg B/L	Reliable with restriction - but use recalculated	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described

			µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)				data from Dyer 2001			
Goldfish (Carassius auratus)	LC50	7	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Borax	59	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Goldfish (Carassius auratus)	LC50	7	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	45	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Goldfish (Carassius auratus)	LC50	7	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Borax	65	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Rainbow trout (Oncorhynchus mykiss)	LC50	28	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Boric acid	79	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Rainbow trout (Oncorhynchus mykiss)	LC50	28	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Borax	54	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Rainbow trout (Oncorhynchus mykiss)	LC50	28	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	100	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Rainbow	LC50	28	"soft water": synthetic	Borax	27	mg	Reliable with	no guideline	Birge and	Teratogenesis of

trout (Oncorhynchus mykiss)			water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)			B/L	restriction - but use recalculated data from Dyer 2001	study, methodological limitations	Black, 1977	aquatic embryos is described
Channel catfish (Ictalurus punctatus)	LC1	9	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Boric acid	0.2	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Channel catfish (Ictalurus punctatus)	LC1	9	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Borax	1.7	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Channel catfish (Ictalurus punctatus)	LC1	9	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	0.5	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Channel catfish (Ictalurus punctatus)	LC1	9	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Borax	5.5	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Goldfish (Carassius auratus)	LC1	7	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Boric acid	0.2	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Goldfish (Carassius auratus)	LC1	7	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of	Borax	0.9	mg B/L	Reliable with restriction - but use recalculated data from	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described

			200 ppm as CaCO3, pH 7.9)				Dyer 2001			
Goldfish (Carassius auratus)	LC1	7	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	0.6	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Goldfish (Carassius auratus)	LC1	7	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Borax	1.4	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Rainbow trout (Oncorhynchus mykiss)	LC1	28	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Boric acid	0.001	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Rainbow trout (Oncorhynchus mykiss)	LC1	28	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Borax	0.07	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Rainbow trout (Oncorhynchus mykiss)	LC1	28	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	0.1	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Rainbow trout (Oncorhynchus mykiss)	LC1	28	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Borax	0.07	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Rainbow trout (Oncorhynch	LC50	24	reconstituted water (13.2 °C, hardness of 197 mg/l as CaCO3, pH	Boric acid	140	mg B/L	Reliable with restriction - but use	no guideline study, methodological	Birge and Black, 1981	Teratogenesis of aquatic embryos is described

us mykiss) embryo-larval stage (hatching)			7.4, conductivity 204 µmhos/cm)				recalculated data from Dyer 2001	limitations		
Rainbow trout (Oncorhynchus mykiss) embryo-larval stage (24 days hatching + 8 days posthatching)	LC50	32	reconstituted water (13.2 °C, hardness of 197 mg/l as CaCO3, pH 7.4, conductivity 204 µmhos/cm)	Boric acid	138	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1981	Teratogenesis of aquatic embryos is described
Largemouth bass (Micropterus salmoides) (embryo-larval stage) (hatching)	LC50	3	reconstituted water (20 °C, hardness of 204 mg/l as CaCO3, pH 7.5, conductivity 229 µmhos/cm)	Boric acid	485	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1981	Teratogenesis of aquatic embryos is described
Largemouth bass (Micropterus salmoides) (embryo-larval stage) (3 days hatching + 8 days posthatching)	LC50	11	reconstituted water (20 °C, hardness of 204 mg/l as CaCO3, pH 7.5, conductivity 229 µmhos/cm)	Boric acid	92	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1981	Teratogenesis of aquatic embryos is described
Rainbow trout (Oncorhynchus mykiss)	no endpoint, only frequencies of responses given	36	reconstituted water (13.7 °C, hardness of 188 mg/l as CaCO3, pH 7.7, conductivity 414 µmhos/cm)	boric acid			Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1984	
Rainbow trout (Oncorhynchus mykiss)	no endpoint, only frequencies of responses given	36	water from the Erwin National Fish Hatchery in Tennessee (14.1 °C, hardness of 88 mg/l as CaCO3, pH 7.8, conductivity 142 µmhos/cm)	boric acid			Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1984	

Rainbow trout (Oncorhynchus mykiss)	no endpoint, only frequencies of responses given	36	water from the Brookville Lake (12.8 °C, hardness of 209 mg/l as CaCO3, pH 8.1, conductivity 342 µmhos/cm)	boric acid			Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1984	
Rainbow trout (Oncorhynchus mykiss)	no endpoint, only frequencies of responses given	36	water from in the Firehole River (13.2 °C, hardness of 29 mg/l as CaCO3, pH 8.0, conductivity 327 µmhos/cm)	boric acid			Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1984	
Rainbow trout (Oncorhynchus mykiss)	LC50		soft water	Boric acid	125	mg B/L	Reliable with restriction although review – use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Rainbow trout (Oncorhynchus mykiss)	LC50		hard water	Boric acid	104	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Rainbow trout (Oncorhynchus mykiss)	LC50		hard water	Boric acid	97	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1981
Rainbow trout (Oncorhynchus mykiss)	LC50		hard water	Boric acid	3.63	mg B/L	Reliable with restriction although review - use	Review, re-evaluates data from Birge et al., calculation of	Dyer, 2001	original data from Birge et al, 1984

							data instead of original values from Birge and Black studies	endpoints from these data, methodological limitations *a*		
Rainbow trout (Oncorhynchus mykiss)	LC50		soft water	Borax	32	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Rainbow trout (Oncorhynchus mykiss)	LC50		hard water	Borax	53	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Channel catfish (Ictalurus punctatus)	LC50		soft water	Boric acid	108	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Channel catfish (Ictalurus punctatus)	LC50		hard water	Boric acid	33	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Channel catfish	LC50		soft water	Borax	118	mg B/L	Reliable with restriction	Review, re-evaluates data	Dyer, 2001	original data from Birge and Black,

(Ictalurus punctatus)							although review - use data instead of original values from Birge and Black studies	from Birge and Black, calculation of endpoints from these data, methodological limitations		1977
Channel catfish (Ictalurus punctatus)	LC50		hard water	Borax	79	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Largemouth bass (Micropterus salmoides)	LC50		hard water	Boric acid	121	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1981
Goldfish (Carassius auratus)	LC50		soft water	Boric acid	51	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Goldfish (Carassius auratus)	LC50		hard water	Boric acid	73	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977

Goldfish (Carassius auratus)	LC50		soft water	Borax	59	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Goldfish (Carassius auratus)	LC50		hard water	Borax	49	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Rainbow trout (Oncorhynchus mykiss)	LC20		soft water	Boric acid	44	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Rainbow trout (Oncorhynchus mykiss)	LC20		hard water	Boric acid	53	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1981
Rainbow trout (Oncorhynchus mykiss)	LC20		soft water	Borax	16	mg B/L	Reliable with restriction although review - use data instead of original values from	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data,	Dyer, 2001	original data from Birge and Black, 1977

							Birge and Black studies	methodological limitations		
Rainbow trout (Oncorhynchus mykiss)	LC20		hard water	Borax	28	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Channel catfish (Ictalurus punctatus)	LC20		soft water	Boric acid	41	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Channel catfish (Ictalurus punctatus)	LC20		hard water	Boric acid	9	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Channel catfish (Ictalurus punctatus)	LC20		soft water	Borax	62	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Channel catfish (Ictalurus punctatus)	LC20		hard water	Borax	38	mg B/L	Reliable with restriction although review - use data instead	Review, re-evaluates data from Birge and Black, calculation of	Dyer, 2001	original data from Birge and Black, 1977

							of original values from Birge and Black studies	endpoints from these data, methodological limitations		
Largemouth bass (Micropterus salmoides)	LC20		hard water	Boric acid	45	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1981
Goldfish (Carassius auratus)	LC20		soft water	Boric acid	28	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Goldfish (Carassius auratus)	LC20		hard water	Boric acid	35	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Goldfish (Carassius auratus)	LC20		soft water	Borax	33	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Goldfish (Carassius auratus)	LC20		hard water	Borax	27	mg B/L	Reliable with restriction although	Review, re-evaluates data from Birge and	Dyer, 2001	original data from Birge and Black, 1977

							review - use data instead of original values from Birge and Black studies	Black, calculation of endpoints from these data, methodological limitations		
Rainbow trout (Oncorhynchus mykiss)	LC10		soft water	Boric acid	2	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Rainbow trout (Oncorhynchus mykiss)	LC10		hard water	Boric acid	30	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1981
Rainbow trout (Oncorhynchus mykiss)	LC10		hard water	Boric acid	0.7	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge et al., calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge et al, 1984
Rainbow trout (Oncorhynchus mykiss)	LC10		soft water	Borax	8	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Rainbow	LC10		hard water	Borax	15	mg	Reliable with	Review, re-	Dyer, 2001	original data from

trout (Oncorhynchus mykiss)						B/L	restriction although review - use data instead of original values from Birge and Black studies	evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations		Birge and Black, 1977
Channel catfish (Ictalurus punctatus)	LC10		soft water	Boric acid	5	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Channel catfish (Ictalurus punctatus)	LC10		soft water	Borax	33	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Channel catfish (Ictalurus punctatus)	LC10		hard water	Borax	16	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Largemouth bass (Micropterus salmoides)	LC10		hard water	Boric acid	6	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological	Dyer, 2001	original data from Birge and Black, 1981

							Black studies	limitations		
Goldfish (Carassius auratus)	LC10		soft water	Boric acid	16	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Goldfish (Carassius auratus)	LC10		hard water	Boric acid	15	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Goldfish (Carassius auratus)	LC10		soft water	Borax	20	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Goldfish (Carassius auratus)	LC10		hard water	Borax	16	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Largemouth bass (Micopterus salmoides), embryo-larval stages	LC50	11	reconstituted water, conductivity 229 µmhos/cm at 20 °C, pH 7.5, hardness as $CaCO_3$ 204 mg/L	Boric acid	92 (84-100)	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	reconstituted water used

Largemouth bass (Micopterus salmoides), embryo-larval stages	LOEC (mortality plus teratogenesis)	11	reconstituted water, conductivity 229 µmhos/cm at 20 °C, pH 7.5, hardness as CaCO3 204 mg/L	Boric acid	12.17	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	reconstituted water used
Largemouth bass (Micopterus salmoides), embryo-larval stages	NOEC (mortality plus teratogenesis)	11	reconstituted water, conductivity 229 µmhos/cm at 20 °C, pH 7.5, hardness as CaCO3 204 mg/L	Boric acid	1.39	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	reconstituted water used
Rainbow trout (Oncorhynchus mykiss) embryo-larval stage; Soap Lake strain	LC50	32	reconstituted water, conductivity 204 µmhos/cm at 13.2 °C, pH 7.4, hardness as CaCO3 197 mg/L	Boric acid	138 (126-150)	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	reconstituted water used
Rainbow trout (Oncorhynchus mykiss) embryo-larval stage; Soap Lake strain	LOEC (mortality plus teratogenesis)	32	reconstituted water, conductivity 204 µmhos/cm at 13.2 °C, pH 7.4, hardness as CaCO3 197 mg/L	Boric acid	0.1	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	reconstituted water used
Rainbow trout (Oncorhynchus mykiss) embryo-larval stage; Soap Lake strain	NOEC (mortality plus teratogenesis)	32	reconstituted water, conductivity 204 µmhos/cm at 13.2 °C, pH 7.4, hardness as CaCO3 197 mg/L	Boric acid	0.009	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	reconstituted water used
Rainbow trout (Oncorhynchus mykiss) embryo-larval stage; Soap Lake strain	NOEC (mortality)	32	reconstituted water, conductivity 204 µmhos/cm at 13.2 °C, pH 7.4, hardness as CaCO3 197 mg/L	Boric acid	0.1	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	reconstituted water used

Rainbow trout (Oncorhynchus mykiss) embryo-larval stage; Soap Lake strain	LOEC (mortality)	32	reconstituted water, conductivity 204 µmhos/cm at 13.2 °C, pH 7.4, hardness as CaCO3 197 mg/L	Boric acid	0.009	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	reconstituted water used
Rainbow trout (Oncorhynchus mykiss) Hildebrand strain; 20-day old embryos were used for highest test concentration of 18	NOEC (adverse effects including mean embryo viability, survival of embryos at hatching and survival, total length, weight of larvae)	87	well water, conductivity 90-150 µmhos/cm at 12 °C, pH 6.8-7.1, hardness as CaCO3 24-39 mg/L	Boric acid	18	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	Unbounded NOEC
Rainbow trout (Oncorhynchus mykiss) Hildebrand strain; freshly fertilized eggs were used	NOEC (adverse effects including mean embryo viability, survival of embryos at hatching and survival, total length, weight of larvae)	87	well water, conductivity 90-150 µmhos/cm at 12 °C, pH 6.8-7.1, hardness as CaCO3 24-39 mg/L	Boric acid	2.1	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	Unbounded NOEC
Rainbow trout (Oncorhynchus mykiss) Wytheville strain	LOEC (Teratogenesis plus mortality at 8 days posthatching)	32	reconstituted water, conductivity 414 µmhos/cm at 13.2 °C, pH 7.7, hardness as CaCO3 188 mg/L	Boric acid	1.34	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	reconstituted water used
Rainbow trout (Oncorhynchus mykiss) Wytheville strain	NOEC (Teratogenesis plus mortality at 8 days posthatching)	32	reconstituted water, conductivity 414 µmhos/cm at 13.2 °C, pH 7.7, hardness as CaCO3 188 mg/L	Boric acid	0.103	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	reconstituted water used
Rainbow trout (Oncorhynch	LOEC (Teratogenesis plus mortality at 8 days	32	natural water from the Erwin National Fish Hatchery in Tennessee,	Boric acid	1.1	mg B/L	Reliable with restriction	no guideline study, methodological	Black et al, 1993	Unbounded LOEC

us mykiss) Wytheville strain	posthatching)		ambient boron concentration 0.023 mg /l, conductivity 142 µmhos/cm at 14.1 °C, pH 7.8, hardness as CaCO3 88 mg/L					limitations might apply		
Rainbow trout (Oncorhynchus mykiss) Wytheville strain	LOEC (Teratogenesis plus mortality at 8 days posthatching)	32	natural water from the Brookville Lake in Indiana, ambient boron concentration 0.091 mg/l, conductivity 342 µmhos/cm at 12.8 °C, pH 8.1, hardness as CaCO3 209 mg/L	Boric acid	1.24	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	Unbounded LOEC
Rainbow trout (Oncorhynchus mykiss) Wytheville strain	LOEC (Teratogenesis plus mortality at 8 days posthatching)	32	natural water from the Firehole River in Yellowstone National Park, ambient boron concentration 0.75 mg/l, conductivity 327 µmhos/cm at 13.2 °C, pH 8.0, hardness as CaCO3 29 mg/L	Boric acid	1.73	mg B/L	Reliable with restriction	no guideline study, methodological limitations might apply	Black et al, 1993	Unbounded LOEC
Rainbow trout (Oncorhynchus mykiss)	NOEC (morphological or swimming defects in embryos or hatched larvae)	5 wks until hatching + ev. 2 wks posthatch	Type 1 ASTM ultrapure grade water supplemented with boric acid, Ca, Na and Mg salts were added	Boric acid	10.12	mg B/L	Reliable with restriction	No guideline study, but well documented; study design did not aim to derive toxicity data	Eckhert, 1998	Unbounded NOEC
Rainbow trout (Oncorhynchus mykiss)	NOEC (survival at eye and hatch stage and as embryonic and larval trout length)	5 wks until hatching + ev. 2 wks posthatch	ultrapure water supplemented with boric acid	Boric acid	0.98	mg B/L	Reliable with restriction	No guideline study, but well documented; study design did not aim to derive toxicity data	Eckhert, 1998	Unbounded NOEC
Chinook salmon (Oncorhynchus tshawytscha)	LC50	4	San Luis Drain water/fresh:	Boric acid	725 (590-890)	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton and Buhl, 1990	

Chinook salmon (Oncorhynchus tshawytscha)	LC50	1	San Luis Drain water/fresh:	Boric acid	>1000	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton and Buhl, 1990	
Chinook salmon (Oncorhynchus tshawytscha)	LC50	4	San Luis Drain water/brackish:	Boric acid	600 (511-706)	mg B/L	Reliable with restriction	published guideline study, some information missing (boron acid purity, living conditions of fish)	Hamilton and Buhl, 1990	
Chinook salmon (Oncorhynchus tshawytscha)	LC50	1	Saint Luis Drain water/brackish:	Boric acid	>1000	mg B/L	Reliable with restriction	published guideline study, some information missing (boron acid purity, living conditions of fish)	Hamilton and Buhl, 1990	
Chinook salmon (Oncorhynchus tshawytscha) fish	LC50	4	soft water (USEPA):	Boric acid	566 (482-664)	mg B/L	Reliable with restriction	published guideline study, some information missing (boron acid purity, living conditions of fish)	Hamilton and Buhl, 1990	
Chinook salmon (Oncorhynchus tshawytscha) fish	LC50	1	soft water (USEPA):	Boric acid	>1000	mg B/L	Reliable with restriction	published guideline study, some information missing (boron acid purity, living conditions of fish)	Hamilton and Buhl, 1990	
Chinook salmon (Oncorhynch	LC50	4	soft water (USEPA):	Boric acid	>1000	mg B/L	Reliable with restriction	published guideline study, some	Hamilton and Buhl, 1990	

us tshawytscha) eyed eggs, alevin								information missing (boron acid purity, living conditions of fish)		
Chinook salmon (Oncorhynchus tshawytscha) eyed eggs, alevin	LC50	1	soft water (USEPA):	Boric acid	>1000	mg B/L	Reliable with restriction	published guideline study, some information missing (boron acid purity, living conditions of fish)	Hamilton and Buhl, 1990	
Coho salmon (Oncorhynchus kisutch)	LC50	4	San Luis Drain water/fresh:	Boric acid	447 (356-561)	mg B/L	Reliable with restriction	published guideline study, some information missing (boron acid purity, living conditions of fish)	Hamilton and Buhl, 1990	
Coho salmon (Oncorhynchus kisutch)	LC50	1	San Luis Drain water/fresh:	Boric acid	>1000	mg B/L	Reliable with restriction	published guideline study, some information missing (boron acid purity, living conditions of fish)	Hamilton and Buhl, 1990	
Coho salmon (Oncorhynchus kisutch)	LC50	4	San Luis Drain water/brackish:	Boric acid	600 (511-705)	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton and Buhl, 1990	
Coho salmon (Oncorhynchus kisutch)	LC50	1	San Luis Drain water/brackish:	Boric acid	>1000	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity,	Hamilton and Buhl, 1990	

								living conditions of fish)		
Flannelmouth sucker (Catostomus latipinnis)	LC50	4	Reconstitute water of San Juan River, New Mexico	Boric acid	125 (102-162)	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton and Buhl, 1997	
Flannelmouth sucker (Catostomus latipinnis)	LC50	3	Reconstitute water of San Juan River, New Mexico	Boric acid	225 (174-275)	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton and Buhl, 1997	
Flannelmouth sucker (Catostomus latipinnis)	LC50	2	Reconstitute water of San Juan River, New Mexico	Boric acid	337 (276-434)	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton and Buhl, 1997	
Flannelmouth sucker (Catostomus latipinnis)	LC50	1	Reconstitute water of San Juan River, New Mexico	Boric acid	1000 (746-3510)	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton and Buhl, 1997	
Colorado squawfish (Ptychocheilus lucius) swimup fry	LC50	4	Reconstituted water simulating the middle part of the Green River of Utah	Boric acid	279 (216-360)	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton, 1995	
Colorado	LC50	4	conductivity 610	Boric acid	>100	mg	Reliable with	published	Hamilton, 1995	

squawfish (Ptychocheilus lucius) 0.4-1.1-g juvenile			Reconstituted water simulating the middle part of the Green River of Utah			B/L	restriction	guideline study, some information missing (boric acid purity, living conditions of fish)		
Colorado squawfish (Ptychocheilus lucius) 1.7-g juvenile	LC50	4	Reconstituted water simulating the middle part of the Green River of Utah	Boric acid	527 (430-667)	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton, 1995	
Razorback sucker (Xyrauchen texanus) swimup fry	LC50	4	Reconstituted water simulating the middle part of the Green River of Utah	Boric acid	233 (172-293)	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton, 1995	
Razorback sucker (Xyrauchen texanus) 0.9-g juvenile	LC50	4	Reconstituted water simulating the middle part of the Green River of Utah	Boric acid	279 (216-360)	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton, 1995	
Razorback sucker (Xyrauchen texanus) 2.0-g juvenile	LC50	4	Reconstituted water simulating the middle part of the Green River of Utah	Boric acid	>100	mg B/L	Reliable with restriction	published guideline study, some information missing (boron acid purity, living conditions of fish)	Hamilton, 1995	
Bonytail (Gila elegans) swimup fry	LC50	4	Reconstituted water simulating the middle part of the Green River of Utah	Boric acid	280 (226-347)	mg B/L	Reliable with restriction	published guideline study, some information	Hamilton, 1995	

								missing (boric acid purity, living conditions of fish)		
Bonytail (Gila elegans) 1.1-g juvenile	LC50	4	Reconstituted water simulating the middle part of the Green River of Utah	Boric acid	>100	mg B/L	Reliable with restriction	published guideline study, some information missing (boric acid purity, living conditions of fish)	Hamilton, 1995	
Bonytail (Gila elegans) 2.6-g juvenile	LC50	4	Reconstituted water simulating the middle part of the Green River of Utah	Boric acid	552 (452-707)	mg B/L	Reliable with restriction	published guideline study, some information missing (boron acid purity, living conditions of fish)	Hamilton, 1995	
Rainbow trout (Oncorhynchus mykiss)	LOAEL (embryonic death)	fertilization until 2 wk posthatch	Solution that approximated the quality of the Merced River	Boric acid	108,1	mg B/L	Reliable with restriction	no guideline study, but methods well documented	Rowe et al, 1998	
Rainbow trout (Oncorhynchus mykiss)	NOAEL (embryonic death)	fertilization until 2 wk posthatch	Solution that approximated the quality of the Merced River	Boric acid	86.5	mg B/L	Reliable with restriction	no guideline study, but methods well documented	Rowe et al, 1998	
Zebrafish (Danio rerio)	LOAEL (embryonic death)	4	Solution containing 79.9 mmol/l $CaCl_2$ $2H_2O$; 20 mmol/l $MgSO_4$ $7H_2O$, 3 mmol/l KCL and 30 mmol/l $NaHCO_3$	Boric acid	99,4	mg B/L	Reliable with restriction	no guideline study, but methods well documented	Rowe et al, 1998	
Zebrafish (Danio rerio)	NOAEL (embryonic death)	4	Solution containing 79.9 mmol/l $CaCl_2$ $2H_2O$; 20 mmol/l $MgSO_4$ $7H_2O$, 3 mmol/l KCL and 30 mmol/l $NaHCO_3$	Boric acid	13	mg B/L	Reliable with restriction	no guideline study, but methods well documented	Rowe et al, 1998	
Coho salmon (Oncorhynchus kisutch)	LC50	11,8	Fresh water		113	mg B/L	Reliable with restriction	no guideline study, but peer-reviewed	Thompson, Davis et al., 1976	

alevins								publication use of LC_{50}no current practise for such a long exposure.		
Eel spawn (anguilla)	LD100	1	Hamburg town water	Boric acid	1748,14	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Eel spawn (anguilla)	LD100	1	Hamburg town water	Borax	1133,71	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Rainbow trout (Oncorhynchus mykiss)	LD100	1	Hamburg town water	Boric acid	1311,11	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Rainbow trout (Oncorhynchus mykiss)	LD100	1	Hamburg town water	Borax	566,85	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Guppies (Poecilia reticulate)	LD100	1	Hamburg town water	Boric acid	1311,11	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Guppies (Poecilia reticulate)	LD100	1	Hamburg town water	Borax	566,85	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Eel spawn (anguilla)	NOEC	1	Hamburg town water	Boric acid	>1748.14	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Eel spawn (anguilla)	NOEC	1	Hamburg town water	Borax	850,28	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Rainbow trout (Oncorhynchus mykiss)	NOEC	1	Hamburg town water	Boric acid	1748,14	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Rainbow trout	NOEC	1	Hamburg town water	Borax	283,43	mg B/L	Not reliable	poor study description; no	Mann, 1973	

(Oncorhynchus mykiss)								raw data provided		
Guppies (Poecilia reticulate)	NOEC	1	Hamburg town water	Boric acid	874,07	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Guppies (Poecilia reticulate)	NOEC	1	Hamburg town water	Borax	283,43	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Fathead minnow (Pimeohales promelas)	LT50 (time required to kill 50% of the fish)	10 hrs	Kodak Park industrial water	boric acid	1748	mg B/L	Not reliable	no endpoints, statistics and documentation not sufficient	Terhaar et al., 1972	
Fathead minnow (Pimeohales promelas)	LT50 (time required to kill 50% of the fish)	3,29166667	Kodak Park industrial water	boric acid	174,81	mg B/L	Not reliable	no endpoints, statistics and documentation not sufficient	Terhaar et al., 1972	
Fathead minnow (Pimeohales promelas)	LT50 (time required to kill 50% of the fish)	>96 hrs	Kodak Park industrial water	boric acid	17,48	mg B/L	Not reliable	no endpoints, statistics and documentation not sufficient	Terhaar et al., 1972	
Bluegill sunfish (Lepomis macrochirus)	TLm (median tolerance limit)	1	Philadelphia tap water)	Sodium tetraborate	4,66	mg B/L	Not reliable	published study, no guidelines, no sufficient study decription	Turnbull et al, 1954	
Bluegill sunfish (Lepomis macrochirus)	TLm (median tolerance limit)	1	Philadelphia tap water	Boron trifluoride	2391,45	mg B/L	Not reliable	published study, no guidelines, no sufficient study decription	Turnbull et al, 1954	
Mosquitofish (Gambusia affinis)	median tolerance limit (TLm)	1	turbid water	boric acid	3146,66	mg B/L	Not reliable	data collected in turbid water	Wallen et al., 1957	
Mosquitofish (Gambusia affinis)	median tolerance limit (TLm)	2	turbid water	boric acid	1835,55	mg B/L	Not reliable	data collected in turbid water	Wallen et al., 1957	
Mosquitofish (Gambusia affinis)	median tolerance limit (TLm)	4	turbid water	boric acid	978,96	mg B/L	Not reliable	data collected in turbid water	Wallen et al., 1957	
Mosquitofish (Gambusia affinis)	median tolerance limit (TLm)	1	turbid water	sodium perborate (borax	1360,45	mg B/L	Not reliable	data collected in turbid water	Wallen et al., 1957	

Mosquitofish (Gambusia affinis)	median tolerance limit (TLm)	2	turbid water	sodium perborate (borax	929,64	mg B/L	Not reliable	data collected in turbid water	Wallen et al., 1957	
Mosquitofish (Gambusia affinis)	median tolerance limit (TLm)	4	turbid water	sodium perborate (borax	408,13	mg B/L	Not reliable	data collected in turbid water	Wallen et al., 1957	
Mosquitofish (Gambusia affinis)	median tolerance limit (TLm)	6	turbid water	sodium perborate (borax	215,4	mg B/L	Not reliable	data collected in turbid water	Wallen et al., 1957	
Zebrafish (Danio rerio)	LC50	4			14,2	mg B/L	Not assignable	Review	Loewengart, 2001	
Mosquitofish (Gambusia affinis)	LC50	4			978	mg B/L	Not assignable	Review	Loewengart, 2001	
Fish generally	LC50	4			>200	mg B/L	Not assignable	Review	Loewengart, 2001	
Rainbow trout (Oncorhynchus mykiss)	LOEC				0.001 - 0.008	mg B/L	Not assignable	Review	Loewengart, 2001	
Channel catfish (Ictalurus punctatus)	LC1				0.2 - 5.5	mg B/L	Not assignable	Review	Loewengart, 2001	
Rainbow trout (Oncorhynchus mykiss)	LC1				0.2 - 1.4	mg B/L	Not assignable	Review	Loewengart, 2001	
Rainbow trout (Oncorhynchus mykiss)				Boron	0,5	mg B/L	Not assignable	preliminary data, no endpoint (0.5 mg B/L does not disturb fish population)	Meyer et al, 1998	
Rainbow trout (Oncorhynchus mykiss)				Boron	0,5	mg B/L	Not assignable	preliminary data, no endpoint (0.5 mg B/L does not disturb fish population)	Meyer et al, 1998	
Fathead minnow (Pimeohales promelas) egg and fry	NOEC (reduction in growth	30	well water, 25 °C, pH 7.1 - 7.9, hardness 38-36 mg/L	boric acid	24	mg B/L	Not assignable	Review	Raymond and Butterwick, 1992	original data from Procter and Gamble, 1979

Fathead minnow (Pimeohales promelas) egg and fry	NOEC (reduction in fry survival	60	well water, 25 °C, pH 7.1 - 7.9, hardness 38-36 mg/L	boric acid	88	mg B/L	Not assignable	Review	Raymond and Butterwick, 1992	original data from Procter and Gamble, 1979
Fathead minnow (Pimeohales promelas) egg and fry	LOEC (reduction in growth	30	well water, 25 °C, pH 7.1 - 7.9, hardness 38-36 mg/L	boric acid	14	mg B/L	Not assignable	Review	Raymond and Butterwick, 1992	original data from Procter and Gamble, 1979
Fathead minnow (Pimeohales promelas) egg and fry	LOEC (reduction in fry survival)	60	well water, 25 °C, pH 7.1 - 7.9, hardness 38-36 mg/L	boric acid	24	mg B/L	Not assignable	Review	Raymond and Butterwick, 1992	original data from Procter and Gamble, 1979
Minnows (Phoxinus phoxinus)	minimum lethal dose		19 °C, distilled water	boric acid	340-374	mg B/L	Not assignable	Review	Raymond and Butterwick, 1992	original data from McKee and Wolf, 1963
Minnows (Phoxinus phoxinus)	minimum lethal dose		17 °C, hard water	boric acid	793-850	mg B/L	Not assignable	Review	Raymond and Butterwick, 1992	original data from McKee and Wolf, 1963
Rainbow trout (Salmo gairdneri)	immobilisation and loss of equilibrium			boric acid	13976	mg B/L	Not assignable	Review	Raymond and Butterwick, 1992	original data from Wurtz, 1945
Rainbow trout (Salmo gairdneri)	Darkening of skin			boric acid	874	mg B/L	Not assignable	Review	Raymond and Butterwick, 1992	original data from Wurtz, 1945
Rainbow trout (Salmo gairdneri), fingerling	80 % mortality			sodium perborate	23,7	mg B/L	Not assignable	Review	Raymond and Butterwick, 1992	original data from McKee and Wolf, 1963
Minnows (Phoxinus phoxinus)	6-h minimum lethal dose		20 °C, distilled water	boric acid	3145-3319	mg B/L	Not assignable	Review	Raymond and Butterwick, 1992	original data from NAS, 1973
Minnows (Phoxinus phoxinus)	6-h minimum lethal dose		20 °C, hard water	boric acid	3319-3407	mg B/L	Not assignable	Review	Raymond and Butterwick, 1992	original data from McKee and Wolf, 1963
Minnows (Phoxinus phoxinus)	LC-50			Borate	709	mg B/L	Not assignable	Review	Schöberl, 1988	no references given
Orfes (Leuciscus idus)	LC-50	2		Borate	173	mg B/L	Not assignable	Review	Schöberl, 1988	no references given

Amphibia										
Leopard frog Rana pipiens	LC1 LC1 LC50 LC50	7.5	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Boric acid Borax Boric acid Borax	22 3 135 54	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Leopard frog Rana pipiens	LC1 LC1 LC50 LC50	7.5	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid Borax Boric acid Borax	13 5 130 47	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Fowler's Toad Bufo fowleri	LC1 LC1 LC50 LC50	7.5	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Boric acid Borax Boric acid Borax	5 - 123 -	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Fowler's Toad Bufo fowleri	LC1 LC1 LC50 LC50	7.5	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid Borax Boric acid Borax	25 - 145 -	mg B/L	Reliable with restriction - but use recalculated data from Dyer 2001	no guideline study, methodological limitations	Birge and Black, 1977	Teratogenesis of aquatic embryos is described
Fowler's Toad Bufo fowleri	LC10		"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Boric acid	30	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Fowler's Toad Bufo fowleri	LC20		"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH	Boric acid	53	mg B/L	Reliable with restriction although review - use data instead of original	Review, re-evaluates data from Birge and Black, calculation of endpoints from	Dyer, 2001	original data from Birge and Black, 1977

			7.9)				values from Birge and Black studies	these data, methodological limitations		
Fowler's Toad Bufo fowleri	LC50		"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Boric acid	97	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Fowler's Toad Bufo fowleri	LC10		"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	55	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Fowler's Toad Bufo fowleri	LC20		"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	75	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Fowler's Toad Bufo fowleri	LC50		"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	112	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977

Leopard frog Rana pipiens	LC10		"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	48	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Leopard frog Rana pipiens	LC20		"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	76	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Leopard frog Rana pipiens	LC50	4 days posthatching	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as CaCO3, pH 7.9)	Boric acid	130	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Leopard frog Rana pipiens	LC10	4 days posthatching	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Boric acid	56	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Leopard frog Rana pipiens	LC20	4 days posthatching	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Boric acid	83	mg B/L	Reliable with restriction although review - use data instead of original values from	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data,	Dyer, 2001	original data from Birge and Black, 1977

							Birge and Black studies	methodological limitations		
Leopard frog Rana pipiens	LC50	4 days posthatching	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as $CaCO_3$, pH 7.9)	Boric acid	134	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Leopard frog Rana pipiens	LC10	4 days posthatching	"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as $CaCO_3$, pH 7.9)	Borax	18	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Leopard frog Rana pipiens	LC20		"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as $CaCO_3$, pH 7.9)	Borax	29	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Leopard frog Rana pipiens	LC50		"soft water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 50 ppm as $CaCO_3$, pH 7.9)	Borax	50	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977

Leopard frog Rana pipiens	LC10		"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Borax	15	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Leopard frog Rana pipiens	LC20		"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Borax	31	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Leopard frog Rana pipiens	LC50	4 days posthatching	"hard water": synthetic water prepared from distilled, double deionized water (300 µhos/cm, hardness of 200 ppm as CaCO3, pH 7.9)	Borax	62	mg B/L	Reliable with restriction although review - use data instead of original values from Birge and Black studies	Review, re-evaluates data from Birge and Black, calculation of endpoints from these data, methodological limitations	Dyer, 2001	original data from Birge and Black, 1977
Toad (Bufo vulgaris formosus)	Teratogenic defects and reduced survival	24 hrs at various embryonic stages and then unti 14 days past fertilization	static, tap water	Boric acid	1747	mg B/L	Not assignable	Review	Butterwick et al., 1989	original data from Takeuchi (1958)
Crustacea										

Daphnia magna	EC50 (reproduction)	21	DSWL-E prepared from ground water	Boric acid	22	mg B/L	Reliable without restriction	guideline study (OECD No. 211), GLP, well documented	Hooftman, 2000	
Daphnia magna	NOEC (reproduction)	21	DSWL-E prepared from ground water	Boric acid	10	mg B/L	Reliable without restriction	guideline study (OECD No. 211), GLP, well documented	Hooftman, 2000	
Daphnia magna	LOEC (reproduction)	21	DSWL-E prepared from ground water	Boric acid	18	mg B/L	Reliable without restriction	guideline study (OECD No. 211), GLP, well documented	Hooftman, 2000	
Daphnia magna	NOEC (condition)	21	DSWL-E prepared from ground water	Boric acid	18	mg B/L	Reliable without restriction	guideline study (OECD No. 211), GLP, well documented	Hooftman, 2000	
Daphnia magna	LOEC (condition)	21	DSWL-E prepared from ground water	Boric acid	32	mg B/L	Reliable without restriction	guideline study (OECD No. 211), GLP, well documented	Hooftman, 2000	
Daphnia magna	LC50 (mortality)	21	DSWL-E prepared from ground water	Boric acid	34	mg B/L	Reliable without restriction	guideline study (OECD No. 211), GLP, well documented	Hooftman, 2000	
Daphnia magna	LC50 (mortality)	14	DSWL-E prepared from ground water	Boric acid	54	mg B/L	Reliable without restriction	guideline study (OECD No. 211), GLP, well documented	Hooftman, 2000	
Daphnia magna	LC50 (mortality)	7	DSWL-E prepared from ground water	Boric acid	60	mg B/L	Reliable without restriction	guideline study (OECD No. 211), GLP, well documented	Hooftman, 2000	

Daphnia magna	NOEC (mortality)	21	DSWL-E prepared from ground water	Boric acid	32	mg B/L	Reliable without restriction	guideline study (OECD No. 211), GLP, well documented	Hooftman, 2000	
Daphnia magna	LOEC (mortality)	21	DSWL-E prepared from ground water	Boric acid	56	mg B/L	Reliable without restriction	guideline study (OECD No. 211), GLP, well documented	Hooftman, 2000	
Daphnia magna	LC0	2	tap water	Disodiumte traborate (Na2B4O7)	17	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, short test duration, no raw data presented, some data on test substance missing	Bringmann and Kühn, 1977	Disodium tetraborate concentration referring to acting ion B4O7-
Daphnia magna	LC100	2	tap water	Disodiumte traborate (Na2B4O7)	538	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, short test duration, no raw data presented, some data on test substance missing	Bringmann and Kühn, 1977	Disodium tetraborate concentration referring to acting ion B4O7
Daphnia magna	LC50	2	tap water	Disodiumte traborate (Na2B4O7)	95	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, short test duration, no raw data presented, some data on test substance missing	Bringmann and Kühn, 1977	Disodium tetraborate concentration referring to acting ion B4O7

Daphnia magna	LC50	2	Lake Huron water	Boric acid	133	mg B/L	Reliable with restriction	Testing procedures based on ASTM, but only limited presentation of raw data	Gersich, 1984	
Daphnia magna	no-kill level	2	Lake Huron water	Boric acid	<54	mg B/L	Reliable with restriction	Testing procedures based on ASTM, but only limited presentation of raw data d	Gersich, 1984	
Daphnia magna	100% kill concentration	2	Lake Huron water	Boric acid	420	mg B/L	Reliable with restriction	Testing procedures based on ASTM, but only limited presentation of raw data	Gersich, 1984	
Daphnia magna	LC50 (mortality)	21	Lake Huron water	Boric acid	52.2	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented	Gersich, 1984	
Daphnia magna	LOEL (mean broods per daphnid), t	21	Lake Huron water	Boric acid	13.6	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented	Gersich, 1984	
Daphnia magna	LOEL (mean total young per daphnid)	21	Lake Huron water	Boric acid	13.6	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented	Gersich, 1984	
Daphnia magna	LOEL (mean brood size per daphnid)	21	Lake Huron water	Boric acid	13.6	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented	Gersich, 1984	

Daphnia magna	LOEL (mean size)	21	Lake Huron water	Boric acid	13.6	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented	Gersich, 1984	
Daphnia magna	MATC (Maximum acceptable toxicant concentration) based on mean total young per replicate, mean brood size and mean size	21	Lake Huron water	Boric acid	Between 6.4 and 13.6 (geometric mean: 9.3)	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented	Gersich, 1984	
Daphnia magna Straus	NOEL (survival); as mean of two replicates	14	Lake Huron water	Boric acid	2,46 (14.1 as boric acid)	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, clarification needed, whether concentration refers to boric acid or boron	Gersich and Milazzo, 1990	In Gersich,1984, the stated concentrations are referring to boron. The MATC-value of 9.3 in table 3 of this publication most probably also refers to boron. This indicates, that the boric acid concentrations stated in this publication also already refer to boron concentrations. In this case no calculation of Boron /L would be necessary and the value 14.1 (given in brackets) would already refer to the boron
Daphnia magna Straus	NOEL (mean total young/adult); as mean of two replicates	14	Lake Huron water	Boric acid	2,46 (14.1 as boric acid)	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, clarification needed, whether concentration refers to boric acid or boron	Gersich and Milazzo, 1990	
Daphnia magna Straus	NOEL (mean brood size/adult) as mean of two replicates	14	Lake Huron water	Boric acid	2,46 (14.1 as boric acid)	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, clarification needed, whether concentration refers to boric acid or boron	Gersich and Milazzo, 1990	

Daphnia magna Straus	NOEL (mean dry weight/adult) as mean of two replicates	14	Lake Huron water	Boric acid	2,46 (14.1 as boric acid)	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, clarification needed, whether concentration refers to boric acid or boron	Gersich and Milazzo, 1990	concentration
Daphnia magna Straus	LOEL (survival) as mean of two replicates	14	Lake Huron water	Boric acid	4,98 (28.5 as boric acid)	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, clarification needed, whether concentration refers to boric acid or boron	Gersich and Milazzo, 1990	In Gersich,1984, the stated concentrations are referring to boron. The MATC-value of 9.3 in table 3 of this publication most probably also refers to boron. This indicates, that the boric acid concentrations stated in this publication also already refer to boron concentrations. In this case no calculation of Boron /L would be necessary and the value 28.5 (given in brackets) would already refer to the boron concentration
Daphnia magna Straus	LOEL (mean total young/adult) as mean of two replicates	14	Lake Huron water	Boric acid	4,98 (28.5 as boric acid)	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, clarification needed, whether concentration refers to boric acid or boron	Gersich and Milazzo, 1990	
Daphnia magna Straus	LOEL (mean brood size/adult) as mean of two replicates	14	Lake Huron water	Boric acid	4,98 (28.5 as boric acid)	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, clarification needed, whether concentration refers to boric acid or boron	Gersich and Milazzo, 1990	
Daphnia magna Straus	LOEL (mean dry weight/adult) as mean of two replicates	14	Lake Huron water	Boric acid	4,98 (28.5 as boric acid)	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, clarification needed, whether concentration	Gersich and Milazzo, 1990	

								refers to boric acid or boron		
Daphnia magna	EC50	1	dilution waster (according to HMSO 1983)	Boric acid	319,8	mg B/L	Reliable with restriction	no guideline study, but published and sufficiently documented; short test duration	Hickey, 1989	
Daphnia carinata	EC50	1	dilution waster (according to HMSO 1983)	Boric acid	267,7	mg B/L	Reliable with restriction	no guideline study, but published and sufficiently documented; short test duration	Hickey, 1989	
Simocephalus vetulus	EC50	1	dilution waster (according to HMSO 1983)	Boric acid	123,4	mg B/L	Reliable with restriction	no guideline study, but published and sufficiently documented; short test duration	Hickey, 1989	
Ceriodaphnia dubia	EC50	1	dilution waster (according to HMSO 1983)	Boric acid	180,6	mg B/L	Reliable with restriction	no guideline study but sufficiently documented; short test duration	Hickey, 1989	
Ceriodaphnia cf. Pluchella	EC50	1	dilution waster (according to HMSO 1983)	Boric acid	101,2	mg B/L	Reliable with restriction	no guideline study and sufficiently documented; short test duration	Hickey, 1989	
Daphnia magna	EC10	1	dilution waster (according to HMSO 1983)	Boric acid	250	mg B/L	Reliable with restriction	no guideline study but sufficiently documented; short test	Hickey, 1989	

								duration		
Daphnia carinata	EC10	1	dilution waster (according to HMSO 1983)	Boric acid	138,8	mg B/L	Reliable with restriction	no guideline study but sufficiently documented; short test duration	Hickey, 1989	
Simocephalus vetulus	EC10	1	dilution waster (according to HMSO 1983)	Boric acid	38,1	mg B/L	Reliable with restriction	no guideline study but sufficiently documented; short test duration	Hickey, 1989	
Ceriodaphnia dubia	EC10	1	dilution waster (according to HMSO 1983)	Boric acid	130,4	mg B/L	Reliable with restriction	no guideline study but sufficiently documented; short test duration	Hickey, 1989	
Ceriodaphnia cf. Pluchella	EC10	1	dilution waster (according to HMSO 1983)	Boric acid	48,8	mg B/L	Reliable with restriction	no guideline study but sufficiently documented; short test duration	Hickey, 1989	
Daphnia magna	LOEC	14	dilution waster (according to HMSO 1983)	Boric acid	32	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented; no raw data presented	Hickey, 1989	
Daphnia magna	NOEC	14	dilution waster (according to HMSO 1983)	Boric acid	18	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented; no raw data presented	Hickey, 1989	

Ceriodaphnia dubia	LOEC	14	dilution waster (according to HMSO 1983)	Boric acid	18	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented; no raw data presented	Hickey, 1989	
Ceriodaphnia dubia	NOEC	14	dilution waster (according to HMSO 1983)	Boric acid	10	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented; no raw data presented	Hickey, 1989	
Daphnia magna Straus	LC50	2	well water	Boric acid	226	mg B/L	Reliable with restriction	Followed USEPA guidelines, no raw data presented	Lewis and Valentine, 1981	
Daphnia magna Straus	no kill concentration	2	well water	Boric acid	<200	mg B/L	Reliable with restriction	Followed USEPA guidelines, no raw data presented	Lewis and Valentine, 1981	
Daphnia magna Straus	LC50 (mortality)	21	well water	Boric acid	53,2	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented; pH ranged from 7.1 to 8.7	Lewis and Valentine, 1981	
Daphnia magna Straus	NOEC (mean length)	21	well water	Boric acid	27	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented; pH ranged from 7.1 to 8.7	Lewis and Valentine, 1981	
Daphnia magna Straus	LOEC (mean length)	21	well water	Boric acid	53	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented; pH ranged from 7.1 to 8.7	Lewis and Valentine, 1981	

Daphnia magna Straus	NOEC (brood size)	21	well water	Boric acid	6	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented; pH ranged from 7.1 to 8.7	Lewis and Valentine, 1981	
Daphnia magna Straus	LOEC (brood size)	21	well water	Boric acid	13	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented; pH ranged from 7.1 to 8.7	Lewis and Valentine, 1981	
Daphnia magna (neonate)	LC50 (mortality)	2	reconstituted USEPA water	Borax	141	mg B/L	Reliable with restriction	Standardized USEPA methologies used, outcome details missing, PH in treatment groups 9.1	Maier and Knight, 1991	
Daphnia magna	NOEC (mortality, rate of reproduction, time at which adverse effects set in)	21 days		Sodium tetraborate	10	mg B/L	Reliable with restriction	Guideline study (OEC-Guideline 202, part 2) but no raw data presented	Steber, 1991	
Daphnia magna	FOEC (LOEC) (mortality, rate of reproduction, time at which adverse effects set in)	21 days		Sodium tetraborate	30	mg B/L	Reliable with restriction	Guideline study (OEC-Guideline 202, part 2) but no raw data presented	Steber, 1991	
Gammarus tigrinus	LD100	1	Hamburg town water	Boric acid	1748,14	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Gammarus tigrinus	LD100	1	Hamburg town water	Borax	1133,71	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	

Gammarus tigrinus	NOEC	1	Hamburg town water	Boric acid	1311,11	mg B/L	Not reliable	poor study description; no raw data provided t	Mann, 1973	
Gammarus tigrinus	NOEC	1	Hamburg town water	Borax	56,69	mg B/L	Not reliable	poor study description; no raw data provided	Mann, 1973	
Daphnia	EC-50	24 h		Borate	240,66	mg B/L	Not assignable	Rewiev	Schöberl, 1988	no references given
Daphnia magna	Threshold concentration for immobilization		Lake Erie water, 25 °C	Sodium perborate	≤ 0.38 (estimated: 0.19)	mg B/L	Not assignable	Review	Butterwick et al., 1989	original data from McKee and Wolf (1963)
Daphnia magna	Threshold concentration for immobilization		Lake Erie water, 25 °C	Sodium tetraborate	≤ 27.2 (estimated: 13.6)	mg B/L	Not assignable	Review	Butterwick et al., 1989	original data from McKee and Wolf (1963)
Daphnia magna	EC50	2			>100	mg B/L	Not assignable	Review	Loewengart, 2001	
Insecta										
Chironomus decorus (fourth instar)	LC50	2	reconstituted USEPA water	Borax	1376	mg B/L	Reliable with restriction	Standardized USEPA methologies used, outcome details missing, PH in treatment groups 9.1	Maier and Knight, 1991	

Chironomus decorus (fourth instar)	LOEC (midge larval growth rate)	4	reconstituted USEPA water	Borax	20	mg B/L	Reliable with restriction	no guideline study, but published and sufficiently documented; PH in treatment groups 9.1	Maier and Knight, 1991	
Mosquito larvae (Anopheles quadrimaculatus)	LC100	1		Boric acid	125	mg B/L	Not assignable	Review	Butterwick et al., 1989	original data from Fay (1959)
Mosquito larvae (Anopheles quadrimaculatus)	LC92	2		Boric acid	25	mg B/L	Not assignable	Review	Butterwick et al., 1989	original data from Fay (1959)
Annelida										
Tubificides	NOEC	1	Hamburg town water	Boric acid	1311,1	mg B/L	not reliable	poor study description; no raw data provided	Mann, 1973	
Tubificides	NOEC	1	Hamburg town water	Borax	85,03	mg B/L	not reliable	poor study description; no raw data provided	Mann, 1973	
Tubificides	LD100	1	Hamburg town water	Boric acid	1748,14	mg B/L	not reliable	poor study description; no raw data provided	Mann, 1973	
Tubificides	LD100	1	Hamburg town water	Borax	226,74	mg B/L	not reliable	poor study description; no raw data provided	Mann, 1973	
Algae										

Selenastrum capricornutum	NOEC	3	growth inhibition test, ultrapure water (185 µg/L boric acid, hardness as CaCO3 24.2 mg/L, pH 7.5 - 8.3)	Boric acid	17,5	mg B/L	Reliable without restriction	guideline study, well documented	Hanstveit, 2000	
Selenastrum capricornutum	ErC50	3	growth inhibition test, ultrapure water (185 µg/L boric acid, hardness as CaCO3 24.2 mg/L, pH 7.5 - 8.3)	Boric acid	52,5	mg B/L	Reliable without restriction	guideline study, well documented	Hanstveit, 2000	
Selenastrum capricornutum	EbC50	3	growth inhibition test, ultrapure water (185 µg/L boric acid, hardness as CaCO3 24.2 mg/L, pH 7.5 - 8.3)	Boric acid	40,3	mg B/L	Reliable without restriction	guideline study, well documented	Hanstveit, 2000	
Scenedesmus quadricauda	Toxicity threshold (Growth inhibition test); 3 % change from neg. control	8	cell multiplication inhibition test, sterile bi-distelled water, pH 7	Disodium tetraborate	0,16	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, no raw data presented, some data on test substance missing, TT-Endpoint no longer used	Bringmann and Kühn, 1977	same data as in Bringmann and Kühn 1978 and 1980; Disodium tetraborate concentration referring to acting ion B4O7
Scenedesmus subspicatus	EC0 (cell multiplication inhibition)	4	Defined nutrient solution	Sodium tetraborate	10	mg B/L	Reliable with restriction	Guideline study (DIN 38412 part 9; referring to OECD guideline 201) but raw data missing	Steber, 1991	
Scenedesmus subspicatus	EC10 (cell multiplication inhibition)	4	Defined nutrient solution	Sodium tetraborate	24	mg B/L	Reliable with restriction	Guideline study (DIN 38412 part 9; referring to OECD guideline 201) but raw data missing	Steber, 1991	
Scenedesmus subspicatus	EC50 (cell multiplication inhibition)	4	Defined nutrient solution	Sodium tetraborate	34	mg B/L	Reliable with restriction	Guideline study (DIN 38412 part 9; referring to OECD guideline 201) but raw	Steber, 1991	

								data missing		
Scenedesmus subspicatus	EC100 (cell multiplication inhibition)	4	Defined nutrient solution	Sodium tetraborate	100	mg B/L	Reliable with restriction	Guideline study (DIN 38412 part 9; referring to OECD guideline 201) but raw data missing	Steber, 1991	
Selenastrum capricornutum	NOEC (cell recovery)	4	AAP (algal assay procedure4) medium with Na2EDTA	Na2B4O7 10 H2O	250	mg B/L	Reliable with restriction	No guideline study, but sufficiently documented	Hickey et al., 1991	As unbounded NOEC not usable for derivation of PNEC
Selenastrum capricornutum	NOEC (intracellular ATP)	4 hours	AAP (algal assay procedure4) medium with Na2EDTA	Na2B4O7 10 H2O	250	mg B/L	Not reliable	No guideline study, but sufficiently documented	Hickey et al., 1991	As unbounded NOEC and not used endpoint not usable for derivation of PNEC
Chlorella algae (C. vulgaris)	Toxic				50	mg B/L	Not assignable	Review	Butterwick et al., 1989	original data from Bowen and Gauch (1966)
Chlorella algae (C. Protothicoides and C. emersanii)	Toxic				100	mg B/L	Not assignable	Review	Butterwick et al., 1989	original data from Bowen and Gauch (1966)
Protozoa										
Entosiphon sulcatum	Toxicity threshold (Growth inhibition test); 5 % change from neg. control	72 hours	Nutrient media	Sodium tetraborate	0.28	mg/l	Reliable with restriction	no guideline study, but sufficiently documented, no raw data presented, some data on test substance	Bringmann and Kühn , 1978	Endpoint reported as 1 mg B/L of Disodium tetraborate (concentration referring to acting ion B4O7-)

								missing, TT-endpoint no longer used		
Entosiphon sulcatum	NOEC	72 hours	Nutrient media	Sodium tetraborate	18	mg-B/L	Reliable with restriction		Guhl, 1991; Unpublished;Henkel KGaA, Berichts Nr. 1991/3090, Oct. 1992	
Entosiphon sulcatum	NOEC/LOEC EC50/EC100 (Growth inhibition test)	72 hours	Fresh water (culture medium)	only boron equivalents are given	15/22 43/65	mg-B/L	Reliable with restriction	Peer-reviewed technical publication. Raw data not presented.	Guhl, 2000	
Paramecium caudatum	NOEC/ LOEC(EC10) EC100 (Growth inhibition test)	72 hours	Fresh water (culture media)	not indicated	20/25 >70	mg-B/L	Reliable with restriction	Peer-reviewed technical publication. Raw data not presented.	Guhl 2000	
Opercularia bimarginata	NOEC (Growth inhibition test)	72 hours	Fresh water	not indicated	10	mg-B/L	Reliable with restriction	Peer-reviewed technical publication. Raw data not presented.	Guhl 2000	
Uronema pardaczi	Toxicity Treshold (EC5) (growth inhibition test) 5% change from neg. control	20hrs	Fresh water	Disodium tetraborate	30.3	mg-B/L	Reliable with restriction	no guideline study, but sufficiently documented, no raw data presented, some data on test substance missing, TT-endpoint no longer used	Bringmann & Kuhn, 1980b	Disodium tetraborate (concentration referring to acting ion)
Bacteria										

Pseudomonas putida (microbe)	EC0 (acute toxicity: oxygen consumption inhibition test)	30 min	media	Sodium tetraborate	110	mg-B/L	Reliable with restriction	Guidline study (DIN 38412, part 27 referring to OECD 209), but no raw data	Steber, 1991	
Pseudomonas putida (microbe)	EC10 (acute toxicity oxygen consumption inhibition test)	30 min	media	Sodium tetraborate	340	mg-B/L	Reliable with restriction	Guidline study (DIN 38412, part 27 referring to OECD 209), but no raw data	Steber, 1991	
Pseudomonas putida (microbe)	EC0 (chronic toxicity: growth inhibition test)	16 hours	media	Sodium tetraborate	3.4	mg-B/L	Reliable with restriction	Guideline study according to DIN 38412, part 8, but no raw data	Steber, 1991	
Pseudomonas putida (microbe)	EC10 (chronic toxicity: growth inhibition test)	16 hours	media	Sodium tetraborate	7.6	mg-B/L	Reliable with restriction: no raw data	DIN 38412, part 8	Steber, 1991	
Pseudomonas putida (microbe)	Toxicity threshold (Growth inhibition test)	16 hrs	Fresh water (culture medium)	Disodium tetraborate	290	mg-B/L	reliable with restriction	No data reported; non-standard endpoint; exposure estimates ignore background sources; conc not measured	Bringman and Kühn, 1977	Endpoint reported as 1040 mg/L of Disodium tetraborate (concentration referring to acting ion)
Photobacterium phosphorum	EC20 (inhibiton of luminescence)				18	mg-B/L	Reliable with restriction	Data from unpublished study using DIN 38412 Part 34 method. Raw data not provided.	Steber, 1991	
Cyanobacteria										
Microcystis aeruginosa	Toxicity threshold (Growth inhibition test); 3% change from negative control	8	cell multiplication inhibition test	Disodium tetraborate	20.4	mg B/L	Reliable with restriction	no guideline study, but sufficiently documented, no raw data	Bringmann and Kühn, 1978	same data as in Bringmann and Kühn 1979 and 1980; Disodium tetraborate

								presented, some data on test substance missing, TT-Endpoint no longer used		concentration referring to acting ion B4O7
Higher plants										
Duckweed Spirodella polyrrhiza	EC50 (frond production)	10	static renewal test, pH stabilized nutrient media	Boric acid	14,3	mg B/l	Reliable with restriction	partly done according to guidelines, well documented	Davis et al., 2002	
Duckweed Spirodella polyrrhiza	LOEC (frond production)	10	static renewal test, pH stabilized nutrient media	Boric acid	3,5	mg B/l	Reliable with restriction	partly done according to guidelines, well documented	Davis et al., 2002	LOEC unbounded
Duckweed Spirodella polyrrhiza	EC50 (growth rate)	10	static renewal test, pH stabilized nutrient media	Boric acid	11,7	mg B/l	Reliable with restriction	partly done according to guidelines, well documented	Davis et al., 2002	
Duckweed Spirodella polyrrhiza	NOEC (growth rate)	10	static renewal test, pH stabilized nutrient media	Boric acid	6,1	mg B/l	Reliable with restriction	partly done according to guidelines, well documented	Davis et al., 2002	
Duckweed Spirodella polyrrhiza	LOEC (growth rate)	10	static renewal test, pH stabilized nutrient media	Boric acid	18,9	mg B/l	Reliable with restriction	partly done according to guidelines, well documented	Davis et al., 2002	
Duckweed Spirodella polyrrhiza	EC50 (abnormal fronds)	10	static renewal test, pH stabilized nutrient media	Boric acid	17,7	mg B/l	Reliable with restriction	partly done according to guidelines, well documented	Davis et al., 2002	
Duckweed Spirodella polyrrhiza	NOEC (abnormal fronds)	10	static renewal test, pH stabilized nutrient media	Boric acid	18,9	mg B/l	Reliable with restriction	partly done according to guidelines, well documented	Davis et al., 2002	

Duckweed Spirodella polyrrhiza	LOEC (abnormal fronds)	10	static renewal test, pH stabilized nutrient media	Boric acid	22,4	mg B/l	Reliable with restriction	partly done according to guidelines, well documented	Davis et al., 2002	
Phragmites australis	NOEC	vegetation period (one year)	graduated additions of boron	Boric acid	>4	mg B/l	Not reliable	No standardized test procedures, boron addition discontinuously, exposures not well characterized, background-concentrations not considered	Bergmann et al., 1995	
Phragmites australis	LOEC	vegetation period (one year)	graduated additions of boron	Boric acid	≥8	mg B/l	Not reliable	No standardized test procedures, boron addition discontinuously, exposures not well characterized, background-concentrations not considered	Bergmann et al., 1995	
Spiked or Eurasian watermillfoil (Myriophyllum spcatum)	50 % inhibition of roots weight	32	Freshwater	Tetraborate salt (B4O72-)	40,3	mg B/L	Not assignable	Review	Butterwick et al., 1989	original data from Stanley (1974)
Crops				Boron	0.3 - 1	mg B/l	Not assignable	Review	Schöberl, 1988	no references given; in sprinkling water

7.1.1.2 Calculation of PNEC$_{freshwater}$

According to the REACH Guidance Document (2008) the PNEC for freshwater (PNECfreshwater) can be calculated using assessment factors or statistical extrapolation techniques.

For the following PNEC-derivation the first approach was chosen: The PNEC was estimated by division of the lowest value for the toxicity with the relevant assessment factor.

The lowest value for toxicity was a 34-day-NOEC for growth (dry weight) of 1.8 mg B/L for Brachydanio rerio (Hooftman et al., 2000b). The study was done according OECD Guideline no. 210 (ELS) and is rated as reliable without restriction (Klimisch 1).

According to the REACH Guidance Document an assessment factor of 10 will be applied when long-term toxicity NOECs are available from at least three species across three trophic levels (e.g. fish, Daphnia, and algae or a non-standard organism instead of a standard organism). As 3 long-term toxicity NOECs from at least three trophic levels are available an assessment factor of 10 is applied to the lowest NOEC added, water of 1.8 mg B/l, resulting in a PNEC added, water of 0.18 mg B/l.

As freshwater data for several taxonomic groups are available, also the approach using a species sensitivity distribution (SSD) was considered. Therefore a thorough screening to use these data for a species sensitivity distribution was performed. The main issue, why this approach cannot be considered applicable, was the lack of long term studies on insect species. This taxonomic group is included in the minimum species requirements of chapter R.10 of Guidance on IR and CSA, when using the Species Sensitivity Distribution method for the freshwater compartment. Only a 96h-growth test with Chironomus decorus (Maier and Knight, 1991) is available, which cannot be considered a chronic or long-term test. Therefore an inclusion of these data into a SSD is not possible. Agreement about this was reached during evaluation of the Biocides report on Boric Acid and Disodium tetraborates under Council directive 98/8/EC. The 96h-growth-test with Chironomus decorus (Maier and Knight, 1991) was excluded from a preliminary SSD because it is no long-term-study. The SSD approach is not used in the final version of the biocide report on boric acid – also due to lack of reliable long-term data.

The deficiency of quality long-term tests for insects is especially problematic as boric acid is used as an insecticide: Insects of the freshwater compartment might be sensitive for boric acid. This is even more important as the mode of the insecticidal action is fairly known. Boric acid can act as an stomach poison in ants, cockroaches, silverfish and termites and as abrasive to the insects exoskeleton (see EPA R.E.D., 1993). Further investigations to clarify the underlying mechanism have to be conducted.

It has to be stated that the SSD-approach is principally considered a valuable method because it better addresses the toxicity towards organisms of a specific compartment than the key-study-approach which focuses on the most sensitive species. The studies summarized in this dossier have been carefully reviewed. Many of them are of good quality and reliability (Klimisch 1 and 2) and can be used for a later application of the SSD-approach for a PNEC-derivation. However potentially sensitive taxonomic groups as well as enough NOECs from 8 taxonomic groups are necessary.

Data from field studies stating that a specific organism can live in an environment with a high boron concentration are of limited value, as these organisms might reflect less sensitive ecotypes of a species.

7.1.2 Marine Compartment

For the marine assessment single-species toxicity data for the marine environment can be based only on a few standardised marine species protocols available (Chapter R.7, Guidance on IRs and CSA) and the database for boron effects on marine species is small. Due to the high natural boron background of ~5mg B/L in the marine environment, it is likely that marine species are less sensitive than freshwater species, thereby reducing the usefulness of extrapolating toxicity data from freshwater organisms to marine organisms. For borates, like for other ions, it is also difficult to evaluate toxic effects in saline waters due to the multitude of possible interactions with other ions. This is most important for the estuarine environment with its frequent changes in salinities. Special attention needs to be paid to the fact that the toxicity of boric acid and borates might depend on salinity (Pillard et al., 2002), concluding that data on estuarine species and the resulting risk should be interpreted carefully. Effect data for boric acid and tetraborates for marine organisms are summarised in Table 7-7.: Marine organisms. The quality of the studies was assessed according to Klimisch *et* al., 1997 and is indicated in Table 7-7.

Effect data

Crustacean

Li et al., 2008

Little information is available regarding the toxic effects of boron to crustacean. The study determined the LC_{50} value of boron to juvenile white shrimp, *Litopenaeus vannamei* at two different salinities (3‰, 20‰,). Boric acid was diluted to final concentrations of 0, 30, 60, 120, 240, 480, 960 mg/l at 20‰ salinity and 0, 20, 40, 80, 460, 320, 640 mg/l at 3‰, salinity. Animals were initially cultured at a salinity of 15‰ for 1 week, then divided randomly into two groups and acclimated to the target salinities by changing 2‰ per day. After reaching the targeted salinity, each tank was acclimated an additional week. The number of individuals tested in each group was 20. The test was performed for 24h, 48h, 72h and 96h without feeding. Test solution was renewed every 24h. All treatments were done in triplicates. Actual concentrations of boron in test solutions are nominal concentrations. Results were significantly different (T-test) at $P<0.05$. The mean LC_{50} values of boron at 24, 48, 72 and 96h were 552.6, 153.4, 50.1, 25.1 at 3‰ and 598.1, 219.5, 147.8, 80.1 at 20‰,. The mean 96h LC_{50} values for boron were 25.1 at 3‰,and 80.1 at 20‰, indicating that the white shrimp is more susceptible to boron than most fish, when kept at sub-optimal salinity (optimal salinity for growth of *L. vannamei* is at around 20‰). The susceptibility is even increasing at lower salinity. Aquaculture might be affected by high boron concentrations, especially in brackish water aquaculture. The study did not follow an OECD or national guideline, although it follows accepted scientific principles. The acclimation procedure was described, but no information was presented that the procedure did not affect test results by imposing additional stress. It was reported that postlarvae of *L. vannamei* tolerate wide ranges of salinities (Wickins, 1976; reviewed in Bückle et al., 2006). However, since the age or instar of the test organisms was not specified, the results at 3‰ cannot be clearly interpreted as ecologically relevant. The study is quoted as reliable with restrictions, Klimisch “2”.

Pillard et al., 2002

Salinity was described to influence toxicity of major ions. Pillard et al., (2002) conducted this study to evaluate the toxicity of six major seawater ions, one of which was borate ($B_4O_7^{2-}$). Toxicity was tested in the mysid shrimp (*Americamysis bahia*) at salinities of 10 and 20‰. This species was chosen because it is the most common marine invertebrate required in whole effluent toxicity (WET) tests (US EPA, 1991) and it has been proven to be more sensitive to ion toxicity than other WET organisms. Mysid shrimp were 4 – 5 days old and acclimatised to artificial seawater per US EPA procedures for WET tests. The exposure time was 48h without renewal. Concentration of the major ions in the stock solution was determined analytically, however, no raw data on the actually tested concentrations were given in the report. NOAECs were calculated using either parametric or nonparametric (as appropriate) methods using Toxstat ® 3.5 (Gulley, 1996). LC50 values were calculated using the trimmed Spearman-Karber method (US EPA, 1994). At the salinity of 10‰ a NOAEC of 257mg B/L and an LC50 of 310mg B/L were derived. At 20‰ the NOAEC and LC50 were 170 and 291mgB/L, respectively. The authors concluded that the salinity had no distinct impact on tolerance of mysid shrimp to the toxicity of boron, although the NOAEC and LC_{50} at 20‰ were higher as compared to the values at 10‰. The identity and purity of the test substance is not indicated within the study but the referenced standard method and related work by this group (Pillard et al., 1999) suggests that borax (sodium borate decahydrate) was used. Note that the NOAEC values have been calculated and are therefore no NOAECs in the strict sense. No OECD guideline was used, but the WET protocol was followed. AS no raw data were presented in the study it is quoted as reliable with restrictions, Klimisch "2".

Pillard et al., 2000

Pillard et al. 2000 evaluated the toxicity of major ions in seawater while keeping a constant salinity of 31‰, using Mysidopsis bahia (syn Americamysis bahia). Salinity was maintained by changing sodium and chloride concentrations while varying Ca^{+2}, Mg^{+2}, K^{+}, Sr^{+2}, HCO_3^{-}, $B_4O_7^{-2}$, SO_4^{-2} and Br^{-}. This design was intended to identify toxicities associated with elevated concentrations of specific ions without changing overall salinity. Toxicity was expressed as the function of both the ion molar concentration and the ion activity. Modified artificial seawaters were prepared following the US EPA procedures for whole effluent testing (WET) (US EPA, 1991). Species were cultured in a salinity of 25‰ at 24 to 25°C. At test initiation, mysid shrimp were from 2 to 5 days old. Young were fed nauplii of Artemia until test initiation. Reference toxicant tests indicated that organism sensitivity was within historical ranges. Over the course of the study test treatments were typically duplicated, although in most individual tests, a single chamber of 50ml solution with five individuals was tested. Concentrations of cations and anions were measured in each stock solution. Ion concentrations were reported based on chemical equilibrium modelling of the ion levels, and ion activity values were calculated using the Debye-Huckel equation. Data sets are reported separately, but an LC_{50} of 380 mg $B_4O_7^{-2}$/L was reported for 31‰ (0.00244 M). The study should be considered as reliable with restrictions, Klimisch "2": it is a peer-reviewed publication following accepted scientific principles. However, the WET design is not the same as the OECD method and no raw data were presented in the study.

Fish

Furuta T., *et.* al 2007

The acute toxicities of boron (boric acid) were examined for two common marine finfish, the Japanese flounder (*Paralichthys olivaceus*) and the red sea bream (*Pagrus major*). Both fish are found throughout the costal waters in Japan. Boron toxicity decreased with fish size, but increased with water temperature in a linear way. The acute toxicity test was performed with boric acid (special grade) under semi-static conditions according to OECD guideline 203. Every 24 h fish were transferred into a new tank with fresh testing water. The Japanese flounders were exposed to boron between 103 and 367 mg B/L and the red sea bream were exposed between 60 and 257 mg B/L. No mortality was observed in the control group for Japanese flounder. The mortality in the control group for red rea bream was less than 5%. LC_{50} values are listed in Table 7.2. The fish loadings exceeded the OECD guideline value of 4g fish/L. For Japanese flounder, loadings were up to 8g fish/L and for red sea bream, loadings were up to 3,5g fish/L. Raw data were not presented. The red sea bream appeared more sensitive the Japanese flounder. The study was performed in order to evaluate the relation between boron toxicity and temperature or fish weight. Therefore the number of replicates if often not sufficient, fish loadings exceeded the guideline values and the values generated at temperatures at temperatures ≥ 20°C appear to high for non-tropical fish species. The study is rated Klimisch "3"

Pillard et al., 2000

The methods of this study of major ion toxicity in seawater are described above for the invertebrate mysid shrimp. For the sheepshead minnow (*Cyprinodon variegatus*) an LC50 of 450 mg $B_4O_7^{-2}$/L was reported for 31‰ (0.00293 M). For the sheepshead minnow (*Menidia beryllina*) an LC50 of 320 mg $B_4O_7^{-2}$/L was reported for 31‰ (0.00206 M). The study is peer-reviewed following accepted scientific principles. However, the WET design is not the same as the OECD method and raw data were not included. It is judged reliable with restrictions, Klimisch "2".

Taylor et al., 1985 and Hugman & Mance, 1983 (unpublished study)

The acute toxicity of (sodium metaborate $Na_2B_4O_7$) boron has been studied with a common British marine fish, the dab (*Limanda limanda*). This fish is commonly found in British estuarine and costal waters. The LC_{50} value was calculated after 96-h exposure under semi-static test conditions. Test animals were not fed during acclimatisation or exposure. The seawater (salinity = 34.5‰) was pre-filtered before use. The variation of pH over the course of the study was as follows: pH 7.7 ± 0.8, T = 12 ± 1, DO 7.9 ± 0.6 mg/l, S 34.62 ± 0.2‰. At 24 h intervals mortility was recorded. The 96 h LC_{50} value was found to be 74 mg B/l (95% CI: 66.4 – 83.0). The study predates the OECD guidelines, but was conducted following general scientific standards. The study is considered reliable with restrictions, Klimisch “2”.

Thompson et al., 1976

Thompson et al., (1976) investigated effects of boron (as sodium metaborate) on salmon in sea and fresh water. For freshwater bioassays, coho alevins weighing 0.19 – 0.7g were used in groups of 20 fish per tank. The criterion for death was cessation of movement, including respiratory movement. After 283 hours an LC_{50} of 113 mg B/l could be determined. For saltwater bioassays, coho underyearlings of 1.8 – 3.8g were acclimated to seawater during three weeks of gradual increase of salinity. Due to the larger size of the fish only 6 fish could be inserted per tank. The saltwater bioassay resulted in an LC_{50} value of 12.2 mg B/l after 283 hours, indicating a sensitivity 1 order of magnitude higher compared to the freshwater experiment. The authors stated that differences in fish age, test temperature and available boron levels (due to background levels of boron in sea water) may account in part for the difference in apparent toxicity in fresh and salt water. They also mentioned that it seemed unlikely that these results can be explained in terms of salinity stress to the salt-water adapted group as they were adapted gradually in a carful adaptation process.

Though the coho underyearlings were gradually adapted to saline conditions, it is still possible that salinity stress influenced the results of this test. Under natural conditions cohos of that age remain in freshwaters and might not have developed the physiological capacities to adapt to higher salinities. The publication meets basic scientific principles and is a peer-reviewed publication. However, due to the above stated deficiencies and differences in procedures from standard acute test methods the study is related not reliable, Klimisch “3”.

Hamilton & Buhl, 1990

Acute toxicity of boric acid (highest purity) was determined for swim-up fry and advanced fry of chinook salmon (*Oncorhynchus tshawytscha*) and coho salmon (*O. kisutch*) using the ASTM standard method. The 96 h LC_{50} value was found to be > 100 mg B/L to both life stages of both species. Static acute toxicity tests were conducted in standardized fresh water (Chloride: 59.2 mg/L), brackish water (Chloride: 726 mg/L) and soft water (Chloride: < 1 mg/L, recommended by US EPA). Nominal concentrations were used and expressed as the total element added. Organism’s number for each test is missing in the method section. Young coho salmon were less tolerant than older fish tested in brackish water and Chinook salmon in either dilution water. The 96h LC50 value was found to be 600mg B/l (95% CI: 511 – 706) for Chinook salmon in brackish water, or coho salmon held in brackish water this value was also 600 mg B/l (95% CI: 511 – 705). The procedures followed a standard procedure, but the dilution waters mimicked San Joaquin River water. A Klimisch rating of “2” is suggested, reliable with restrictions based on use of scientific procedures in a peer-reviewed study.

Algae

Antia & Cheng, 1975

The autotrophic growth of 19 species of marine phytoplankters was tested on axenic cultures with boric acid additions of 0 – 100 mg B/L (0, 10, 50 and 100 mg B/L). Growth measurements (22 – 24°C) were made at intervals of 2 – 4 days by determining the optical density at 600 nm. The growth media contained endogenous 3.65 mg B/L. In addition to the growth rate also the pre-exponential lag period was taken into account. 5 – 10 mg B/L had no inhibitory effect on growth of any of the species. 50 mg B/L inhibited the growth rate about half the total number of species to the extent of 30 – 70%. At a concentration of 100 mg B/L 63% of the species were inhibited and it appeared to be lethal. *Skeletonema costatum*, *Rhodomonas lens* and *Anacystis marina* showed an increased growth at 10 mg B/L. The most sensitive alga was *Monallantus salina* and *Emiliania huxleyi*. The study is rated reliable with restrictions, Klimisch “2”.

Subba Rao et al., 1980

Subba Rao (1980) investigated the effects of boron (as boric acid) on natural populations of nanoplankton. While addition of 30mg/ml boron increased photosynthesis compared to untreated samples collected during November to May, the addition of the same amount of boron had the opposite effect on samples collected during June to October. It is interesting to mention that from November to May nutrient concentrations (nitrate, phosphate and silicates) are high and temperatures low, the opposite is the case during the rest of the year. These findings support the study of Antia and Cheng (1975) who concluded that marine phytoplankton from eutrophic waters readily tolerates boron concentrations up to 10mg/l.

Next to natural populations, Subba Rao (1980) also investigated the effect 30mg/l boron on isolated algal species. In cultures grown for 5 days, boron treatment inhibited photosynthesis at a significant level in *Chaetoceros septentrionalis*, centric diatom 10, *chrysomonad A*, and *Cachoninaniei*. Inhibition was not significant in *Skeletonema costatum*. In 14-days-old cultures, boron treatment enhanced photosynthesis of *S. costatum*, centric diatom 10, and chrsomonad A, and it was significant in S. costatum, Photosynthesis of *C. septentrionalis* and *C. niei* was inhibited by boron, which was siginificant only in the latter. The study is not applicable as only one concentration was tested.

Sea urchin

Kobayashi et al., 1971

Kobayashi et al. (1971) investigated effects of boric acid on the development of fertilized sea urchin eggs. The study is well performed and reported, with the exception that the concentrations tested cannot be derived from the report. It can therefore not be used for PNEC derivation.

PNEC derivation for the marine environment

In general there exist only few experiments on acute and chronic toxicity of boron to marine organisms. In total the marine effects database contains two reliable 96- hours LC_{50}-values for crustacean (25.1 – 80.1 mgB/L), four LC_{50} values (40 – 108 mg/L) for fish and 19 NOECs for marine algae (4 x 5mg; 10 x 10 mg; 4 x 50 mg; and 1x 100mg B/L). The boron toxicity to algae seemed to be species specific and dependent on nutrient conditions. Since boron is an essential element for plants hormesis abates the applicability of algal NOECs for PNEC-derivation. Specific evaluations for hormetic effects on the available marine test have not been conducted per Guidance on IR and CSA, chapter R.7b.

Though there exists a huge amount of freshwater data their use for deriving a $PNEC_{marine}$ is limited by observed differences in sensitivity between marine and freshwater biota (Li et al., 2007; Pillard et al., 2002; Thompson et al., 1976). No detailed investigation of the relation between marine and freshwater toxicity of boron has been carried, however, the available data support that boron toxicity might depend on salinity.

The high natural boron background of ~5mg B/L in the open sea indicates that truly marine species are likely to be less sensitive to boron toxicity than estuarine or freshwater organisms. Based on the lowest $NOEC_{freshwater}$ of 1,8 for Brachydanio rerio and an assessment factor of 10 a $PNEC_{add,freshwater}$ of 0,18 mg/L can be derived. It can be assumed that the $PNEC_{freshwater}$ also protects the marine environment (open sea). This PNEC has to be re-evaluated once information on marine PEC values is available. This might also include further testing with marine species. Industry has a detailed plan for the collection of marine boron data and the re-evaluation of this PNEC value (see ANNEX II).

In contrast to the open sea it cannot be anticipated that the $PNEC_{add,freshwater}$ would also protect estuarine species. Therefore industry will collect data on boron concentrations in the estuarine areas and will assess the necessity for further toxicity tests. An intermittent PNEC might also be considered for this specific environmental department based on the outcome of the exposure evaluation. See ANNEX II for planned actions.

Table 7-2. Marine Organisms

Species	Endpoint Type	Test Duration	Test Conditions	Tested Substance	Endpoint	Value	Reliability Statement	Limitations	Reference	Comments
Crustaceans										
Litopenaeus vannamei	LC$_{50}$	24h, 48h, 72h, 96h	Salt water (3% salinity)	Boric acid	552.6; 153.4; 50.1; 25.1	mg-B/L	Reliable with restrictions	Peer-reviewed study	Li et al, 2008	Usable for PNEC derivation (estuaries)
Litopenaeus vannamei	LC$_{50}$	24h, 48h, 72h, 96h	Salt water (20% salinity)	Boric acid	598.1; 219.5; 147.8; 80.1	mg B/L	Reliable with restriction	Peer-reviewed study	Li et al, 2008	Usable for PNEC derivation (estuaries)
Americamysis bahia	NOAEL/LC$_{50}$	48h	Salt water 10 ppt	Borax*	275/310	mg B/L	Reliable with restriction	Peer-reviewed study	Pillard et al., 2002	No description of the used chemical is given; no raw data; no guideline study. Unclear spacing of test concentration.
Americamysis bahia	NOAEL/LC$_{50}$	48h	Salt water 20 ppt	Borax*	170/291	mg B/L	Reliable with restriction	Peer-reviewed study	Pillard et al., 2002	No description of the used chemical is given; no raw data; no guideline study.
Fish										
Limanda limanda (Dab)	LC$_{50}$	96h; 72h; 24h;	Sea water 34.8‰	Sodium metaborate (Na$_2$B$_4$O$_7$)	74; 75.7; 88.3;	mg-B/L	Reliable with restriction	Peer-reviewed study, GLP, (OECD, 1982)	Taylor et al., 1985 and Hugman & Mance,1983 (unpublished)	*L. limanda*: 16.9 g, at 12°C
Paralichthys olivaceus (Japanese flounder)	LC$_{50}$	96h	Sea water	Boric acid	108, 178, 178, 206,	mg-B/L	Not reliable	Peer-reviewed study, OECD 203	Furuta et al., 2007	Different weight group (g): 0.1, 0.6, 1.5, 1.8,

					153, 151, 190 252					2.4, 2.6, 6.7, 70.0
Pagrus major (Red sea bream)	LC_{50}	96h	Sea water	Boric acid	97, 113, 147, 156, 169, 145, 172	mg-B/L	Not reliable	Peer-reviewed study, OECD 203	Furuta et al., 2007	Different weight group (g): 0.6, 0.7, 2.9, 3.1, 3.2 7.4, 20.3
Paralichthys olivaceus (Japanese flounder)	LC_{50}	96h	Sea water	Boric acid	299, >259, 178, 108, 350, 207, 206, **113**	mg-B/L	Not reliable	Peer-reviewed study, OECD 203	Furuta et al., 2007	Different temperature (°C) & weight group (g): 10 °C, 0.5 g 15 °C, 0.5 g 20 °C 0.6 g 25 °C,0.6 g 10 °C, 1.5 g 15 °C, 1.7 g 20 °C 1.8 g **25 °C,1.6 g**
Pagrus major (Red sea bream)	LC_{50}	96h	Sea water	Boric acid	<110, 127, 113, 75, 220, 193, 147, 129	mg-B/L	Not reliable	Peer-reviewed study, OECD 203	Furuta et al., 2007	Different temperature (°C) & weight group (g): 12 °C, 0.6 g 15 °C, 0.6 g 20 °C 0.7 g 25 °C,0.6 g 12 °C, 2.1 g 15 °C, 2.3 g 20 °C 2.9 g 25 °C,1.6 g

Oncorhynchus kisutch (Coho salmon)	LC_{50}	96h	well water 8°C	Sodium metaborate ($Na_2B_4O_7$)	113	mg-B/L	Not reliable	Peer-reviewed study, predates OECD	Thompson et al., 1976	Fish 1.8 – 3.8 g Cited in Taylor et al., 1985; Butterwick et al., 1989; and Furuta et al., 2007;
Oncorhynchus kisutch (Coho salmon)	LC_{50}	283h	Sea water 8°C, salinity 28 ‰	Sodium metaborate ($Na_2B_4O_7$)	12.2	mg-B/L	Not reliable	No raw data; no background conc. Measured	Thompson *et* al., 1976	Under yearlings, Fish 1.8 – 3.8 g
Oncorhynchus kisutch (Coho salmon)	LC_{50}	283h	Fresh water,	Sodium metaborate ($Na_2B_4O_7$)	113	mg-B/L	Not reliable	No raw data, no information on concentrations is given	Thompson *et* al., 1976	0.19 – 0.7 g
Oncorhynchus tshawytscha (Chinook salmon)	LC_{50}	96 h	Brackish water (Chloride: 726 mg/L)	Boric acid	600	mg-B/L	Reliable with restriction	Non-standard species, raw data not reported, brackish water, number of test organisms is missing	Hamilton and Buhl, 1990	
Oncorhynchus kisutch (Coho salmon)	LC_{50}	96 h	Brackish water (Chloride: 726 mg/L)	Boric acid	600	mg-B/L	Reliable with restriction	Non-standard species, raw data not reported, brackish water, number of test organisms is missing	Hamilton and Buhl, 1990	

Algae										
Agmenellum quadruplicatum	NOEC LOEC	10 d	Sea water media	Boric acid	50 100	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC are based on the prolonged lag period in comparison to control; growth rate was not effected
Amphidinium carteri	NOEC LOEC	10 d	Sea water media	Boric acid	10 50	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC are both based on the prolonged lag period and the effect on growth rate.
Anacystis marina	NOEC	10 d	Sea water media	Boric acid	?	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	No LOEC, growth rate was stimulated at 10 and 50 mg B/L; NOEC might be at 5 or 100 mg/L → high uncertainty. The lag period has nearly doubled at 5 and 100 mg B/L.
Bellerochea polymorpha (diatom)	NOEC LOEC	10 d	Sea water media	Boric acid	50 100	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC are both based on the prolonged lag period and the effect on growth rate.
Chroomonas salina	NOEC LOEC	10 d	Sea water media	Boric acid	10 50	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets	Antia & Chang 1975	NOEC and LOEC are both based on the prolonged lag period and the effect on growth rate.

								basic scientific principles.		
Cyclotella cryptica (diatom)	NOEC LOEC	10 d	Sea water media	Boric acid	10 50	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC are both based on the prolonged lag period and the effect on growth rate.
Dunaliella tertiolecta	NOEC LOEC	10 d	Sea water media	Boric acid	50 100	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC are both based on the prolonged lag period and the effect on growth rate.
Emiliania huxleyi	NOEC	10 d	Sea water media	Boric acid	5	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC is based on on the prolonged lag period and the effect on growth rate.Results of the 10 mg B/L test conc. Is missing.
Isochrysis galbana	NOEC LOEC	10 d	Sea water media	Boric acid	10 50	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC are both based on the prolonged lag period and the effect on growth rate.

Monallantus salina	NOEC LOEC	10 d	Sea water media	Boric acid	5 10	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	.NOEC and LOEC is based on growth rate.
Monochrysis lutheri	NOEC LOEC	10 d	Sea water media	Boric acid	10 50	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC are both based on the prolonged lag period and the effect on growth rate.
Nannochloris oculata	NOEC LOEC	10 d	Sea water media	Boric acid	10 50	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC are both based on the prolonged lag period and the effect on growth rate.
Phaeodactylum tricornutum (diatom)	NOEC LOEC	10 d	Sea water media	Boric acid	10 50	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC based on the effect on growth rate.
Porphyridium cruentum	NOEC LOEC	10 d	Sea water media	Boric acid	50 100	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific	Antia & Chang 1975	NOEC and LOEC are both based on the prolonged lag period and the effect on growth rate.

								principles.		
Rhodomonas lens	NOEC LOEC	10 d	Sea water media	Boric acid	5 50	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	Growth rate increased at 10 mg B/L, NOEC and LOEC based on the effect on growth rate.
Skeletonema costatum (diatom)	NOEC LOEC	40 d	Sea water media	Boric acid	5 50	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	Growth rate increased at 10 mg B/L; LOEC is based on growth rate.
Tetraselmis maculata	NOEC LOEC	10 d	Sea water media	Boric acid	10 50	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC are based on growth rate.
Thalassiosira fluviatilis (diatom)	NOEC LOEC	10 d	Sea water media	Boric acid	50 100	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC are both based on the prolonged lag period and the effect on growth rate.
Thalassiosira pseudonana	NOEC	10 d	Sea water media	Boric acid	100	mg-B/L	Reliable with restriction	Peer-reviewed technical publication	Antia & Chang 1975	No LOEC

								that meets basic scientific principles.		
Cyclotella cryptica	NOEC LOEC	10 d	Sea water media	Boric acid	10 50	mg-B/L	Reliable with restriction	Peer-reviewed technical publication that meets basic scientific principles.	Antia & Chang 1975	NOEC and LOEC are based on growth rate.

* The identity and purity of the test substance is not indicated within the study but the referenced standard method (US EPA, 1991) and related work by this group (Pillard et al., 1999) suggests that borax (sodium borate decahydrate) was used.

7.1.3 Freshwater Sediment

Relevance of ecotoxicological data for sediment

The toxicity data on benthic organisms are from ecotoxicity tests that study relevant ecotoxicological parameters such as survival, growth, reproduction, emergence, sediment avoidance and burrowing activity.

B-only exposures are considered relevant for the effects assessment. Studies should be rejected if indications exist that impurities or other substances might have an effect on the toxic properties of the substance under investigation. Studies are rejected in case atypical trace element concentrations (mixed pollution) are observed in the control sediment.

Toxicity test results for sediment organisms

One high quality chronic single-species toxicity test is available for the assessment of the hazard regarding freshwater sediment organisms:

Hooftman et al., 2000

Test species: *Chironomus riparius*

Test protocol: Draft OECD document, May 1998 (Chironomid testing using spiked sediments)

Test medium: The sediment/water system used in the test was prepared from artificial sediment and a standard water. Four replicate batches of sediment were prepared by mixing portions of clay, sand and sphagnum peat. The sediment was mixed thoroughly to obtain a homogenous distribution, before being placed in the exposure vessels (600 ml beakers, with a diameter of ca. 8 cm) and the overlying water was added.

Physico-chemical characteristics: of the artificial sediment: pH-KCl of artificial sediment: 7.8; TOC content of artificial sediment: 2.73 g C/100 g dry weight. In overlying water: pH value range 7.1-8.1, lowest measured oxygen concentration: 5.9 mg/l; temperature range: 20.2-20.5°C; The test was carried out under a 16h light/8h dark regime.

Medium preparation: The sediments were spiked in the test beakers based on the dry weight. For each exposure concentration a number of four replicate containers were separately filled with a layer of ca 1.5 cm spiked sediment or control sediment. For chemical analytical purposes two extra test vessels were prepared for the control, the 32, 100 and 320 mg/kg exposure concentration. Standard water was added to obtain a ratio between sediment layer and water column in the range 1:4. At the start of the test, a number of 20 first instar larvae were randomly added to each test substance concentration (using a random table); the larvae were transferred in groups of five to each test vessel.

Test concentrations: 0-18-32-56-100-180-320 mg B/kg d.w. 4 replicates were used.

Equilibration period: 2 days.

Test duration: 28 days, the time needed for emergence of the adults in the control.

Endpoints: mortality, emergence

Analytics: The samples (from the exposure concentrations 0, 32, 100 and 320 mg/kg for overlying water, sediment extract and pore water) were analysed for boron directly or after dilution using ICP-AES.

Statistics: The LC50 values and their interval were calculated by means of a parametric model (Kooiman, 1981). Emergence data are arcsin transformed, and the Dunnett test (significance at level 99%) was used to detect significant differences with the control.

Control: According to the OECD 218 validity criteria, the emergence in the controls must be at least 70% at the end of the test. The results show that the emergence in the control was 95%.

Toxicity data: The 28d LC50 is 278 mg B/kg dw (nominal concentration), the 28d LOEC for mortality and emergence is 320 mg B/kg dw and the 28d NOEC for mortality and emergence is 180 mg B/kg dw. In all concentrations up to 180 mg/kg at least 91% of the larvae added to the vessels emerged. At 320 mg/kg only 2 out of the 80 larvae emerged.

Reliability: 1, the test was carried out according to the Draft OECD document, May 1998 (Chironomid testing using spiked sediments) and the OECD Principles of Good Laboratory Practice.

Toxicity data from this test are summarised in table 7.3. All toxicity values in this table are presented as nominal values. Values selected for the effects assessment are put in bold. Two individual high quality NOEC values (for 1 species) are selected of 180 mg B/kg (nominal concentration) for both endpoints (mortality and emergence).

Table 7.3: Overview of the sediment based toxicity values: (mg B/kg d.w.) for *Chironomus riparius* from Hooftman et al., 2000 (values selected for the effect assessment are put in bold)

Klimish							**NOEC and ECx**			
	Test subst.	**Organism**	**Medium**	**Equil.Period**	**Duration**	**Endpoint**	NOEC	EC10	LOEC/ECx (with x > 10%)	L(E)C50
				d	**d**		**mg B/kg d.w.**	**mg B/kg d.w.**		
1	H_3BO_3	*Chironomus riparius* (sediment-dwelling larvae)	Artificial sediment	2	28	mortality				278
1	H_3BO_3	*Chironomus riparius* (sediment-dwelling larvae)	Artificial sediment	2	28	mortality	**180**			
1	H_3BO_3	*Chironomus riparius* (sediment-dwelling larvae)	Artificial sediment	2	28	mortality			320 (LOEC)	
1	H_3BO_3	*Chironomus riparius* (sediment-dwelling larvae)	Artificial sediment	2	28	emergence	**180**			
1	H_3BO_3	*Chironomus riparius* (sediment-dwelling larvae)	Artificial sediment	2	28	emergence			320 (LOEC)	

Calculation of the PNEC$_{\text{freshwater sediment}}$

According to chapter R.10 of the Guidance on IR and CSA the PNEC for freshwater sediment (PNEC$_{\text{freshwater sediment}}$) should be derived from sediment toxicity data from freshwater benthic organisms (sediment-dwelling organisms). In the absence of toxicity data for benthic organisms, the PNEC for sediment may provisionally be calculated using the equilibrium partitioning (EP) method. In this report chronic toxicity data for only 1 benthic organism are available, i.e. with the midge *Chironomus riparius. C. riparius* is a burrowing species with a combined surface and subsurface feeding behavior. The toxicity data from that species will preferably be used for the derivation of the PNEC for the freshwater sediment. As recommended by chapter R.10 of the Guidance on IR and CSA no PNEC will be derived using the equilibrium partitioning method as sediment data are available.

There is only 1 chronic sediment toxicity test available that can be used for the derivation of the PNEC for the freshwater sediment compartment. The study of Hooftman et al. (2000) reported the effects of boric acid on the larvae of the dipteran *C. riparius*. The toxicity test generated 28 d NOEC values for 2 different endpoints, i.e. mortality and emergence. According to the REACH Guidance Document (2008) the PNEC should be derived from the lowest available NOEC/EC10 obtained in chronic tests by application of the appropriate assessment factor. The lowest chronic NOEC for the tested freshwater benthic organism is 180 mg B/kg dry weight (for both endpoints). Applying an assessment factor of 100 on the total B concentration results in a PNEC$_{\text{freshwater sediment}}$ of 1.8 mg B/kg dry sediment. The assessment factor of 100 is in accordance with the REACH Guidance Document (2008).

It is noted that there are insufficient data for benthic organisms to apply the statistical extrapolation method.

Overall conclusion on PNEC$_{\text{freshwater sediment}}$:

A PNEC$_{\text{freshwater sediment}}$ added of 1.8 mg B/kg dry sediment **is proposed (as added concentrations not corrected for bioavailability).**

7.1.4 Marine Sediment

Toxicity test results for marine sediment organisms

No toxicity data on marine sediment organisms are available.

Calculation of PNEC for marine sediment

According to chapter R.10 of the Guidance on IR and CSA the PNEC for marine sediment (PNECmarine sediment) can be derived from long-term sediment toxicity data from freshwater benthic organisms using an assessment factor.

Hooftman et al., 2000, tested the midge Chironomus riparius, a burrowing species with a combined surface and subsurface feeding behavior. The test was performed according to an OECD draft version and is rated Klimisch 1. The lowest chronic NOEC for this tested freshwater benthic organism is 180 mg B/kg dry weight (see section on freshwater sediment, chapter 7.2.)

An assessment factor of 1000 should be applied, if one long-tem freshwater sediment test is available (see chapter R.10 of the Guidance on IR and CSA). If there is convincing evidence that the sensitivity of marine organisms is adequately covered by that available from freshwater species, the assessment factors used for freshwater sediment data may be applied. Such evidence may include data from long-term testing of freshwater and marine aquatic organisms, and must include data on specific marine taxa. Such data are available in the freshwater and marine compartment section (see chapter 7.1. and 7.3.).

Moreover, the high natural boron background of ~5mg B/L in the open sea indicates that marine species are likely to be less sensitive to boron toxicity than freshwater organisms.

Additionally Hooftman et al, 2000, showed in the test with the freshwater sediment organism Chironomus riparius that at the beginning of the test, the boron concentrations in the pore water of the freshly spiked sediment were higher than at the end of the test period (28 days), when concentrations of boron were similar in pore water and overlying water. This indicates that an equilibrium between boron concentrations in pore water and overlying water is eventually achieved. Therefore it can be assumed that Boron concentrations in the sediment are rather constant and no accumulation of Boron in sediment takes place.

This evidence suggests that the assessment factor of 100, which is used for freshwater sediment data, can also be applied for the marine sediment:

Applying an assessment factor of 100 on the NOEC of 180 mg B/kg dry weight (derived from a long-term test on the freshwater benthic organism Chironomus riparius) a $\text{PNEC}_{\text{marine sediment added}}$ of 1.8 mg B/kg dry weight is proposed.

7.1.5 Micro organisms in sewage treatment plants (STP)

A PNEC for sewage treatment plants (STPs) can be based on the result of various microbial tests (e.g. respiration inhibition, nitrification inhibition, ready biodegradability test), with a corresponding assessment factor stated in Table 10-6 of chapter R.10 from the guidance on information requirements and chemical safety assessment. More information and guidance about information on toxicity to STP micro-organisms is available in Sections R.7.8.14 to R.7.8.20.

Effects of boric acid and sodium tetraborates on micro-organisms (STP) are summarised in Table 7.4.: Aquatic micro-organisms (STP). The quality of the studies was assessed according to Klimisch et al., 1997 and is indicated in Table 7-6. Although the form of boron tested varies in different studies, the predominant species of boron in the aquatic systems, regardless of its initial formulation, is undissociated boric acid. Several abiotic factors may influence the toxicity of boron (e.g. hardness, type of test water). Boron adsorption to activated sludge in wastewater treatment plants is rather limited (Fujita et al., 2005). Most of the boron stays in the liquid phase of activated sludge.

Effects on the respiration of activated sludge

Hansveit and Schoonmade, unpublished report, 2002

The inhibition of respiratory activity of activated sludge using boric acid (manufacturing grade) was investigated by Hanstveit and Schoonmade (unpublished, 2002). The tests were performed by adding activated sludge (collected from an oxidation ditch receiving domestic sewage, Hazerswoude Dorp, Netherlands) to a series of vessels with synthetic sewage according to OECD guideline No. 209 and different concentrations of boric acid (0; 0.56; 1.75; 5.6; 17.5; 56 and 175 mg B/L) were tested. The respiratory activity (i.e. oxygen uptake) was measured after 3 hours contact time between sludge and boric acid. The control values were recorded before and after the incubation time of 3 hours (according to the guideline protocol).

The authors stated an EC_{50} value of > 175 mg B/L, and the EC_{20} value was estimated as 112 mg B/L (95% C.I: 87 – 144 mg B/L). The NOEC was stated to be 17,5 mg B/L, with an inhibition of 4%, whereas the LOEC was at 56 mg B/L (inhibition of 17%). In an attempt to further evaluate the data, a statistical evaluation was carried out for the present dossier. The OECD guideline 209 does not define a NOEC. The study authors defined the NOEC as less than 10% inhibition relative to control average. Since there were no replicate units it was not possible to statistically determine which exposure group was different from controls (LOEC). A log-logistic model can be calculated from the original data (Figure 7.1.) which provides a statistically based EC_{10} estimate of 35 mg B/L. The model also estimates an EC_{50} of 826 mg B/l, a value which lies outside the tested range of concentrations.

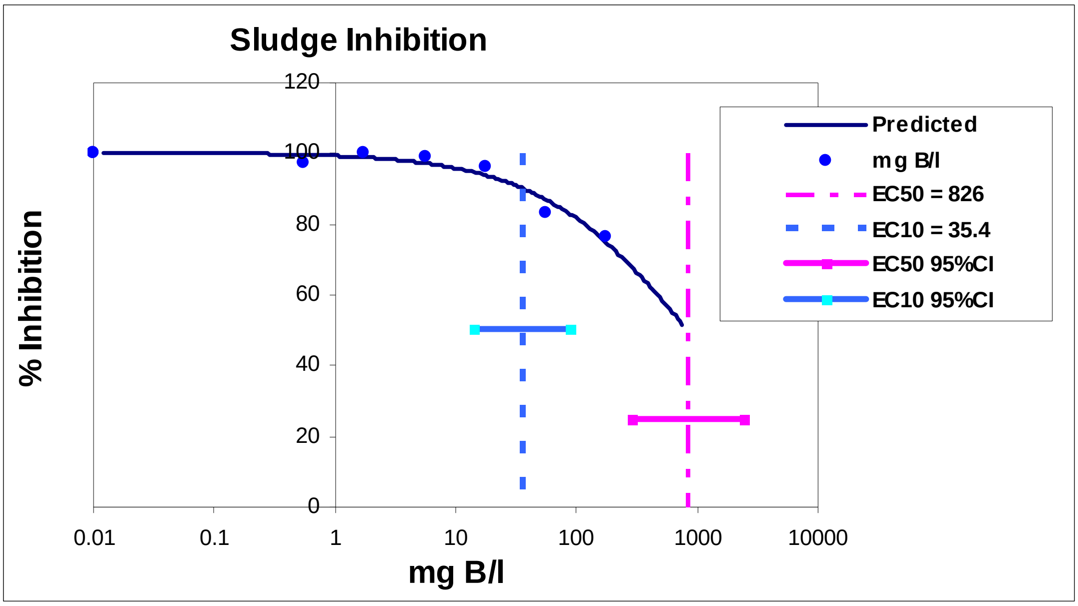


Figure 7.1.: Derivation of EC_{10} for Sludge Respiration Inhibition.

The OECD 209 guideline does not prescribe to estimate an EC_{10}. An EC_{50} value should be derived, and if possible, also EC_{20} and EC_{80}. It also states that the achieved EC_{50} value should be regarded merely as a guide to the likely toxicity of the test substance either to activated sludge sewage treatment or waste-water micro-organisms, since the complex interactions occurring in the environment cannot be accurately simulated in a laboratory test. The purpose of the method is to provide a rapid screening method whereby substances which may adversely affect aerobic microbial treatment plants can be identified and to indicate suitable non-inhibitory concentrations of test substances to be used in biodegradability tests.

The NOEC in this study was equivalent to 17,5 mg B/L. At this concentration an inhibition of respiratory activity of 4% was detected (initial and final control: ± 3%). A clear inhibition of 17% could be detected at the concentration of 56 mg B/L, which was concluded to be the LOEC from this study. At the highest dose, 175 mg B/L, the inhibition was 24%. The study is quoted as reliable without restriction, Klimisch “1”.

Gerike et al., 1976

Gerike *et* al. (1976), used an earlier version OECD activated sludge method. 20 mg B/L (sodium-perborate: $NaBO_2.H_2O_2.3H_2O$) have shown no effect on activated sludge which had been adapted for 2 weeks. The measured parameters were chemical oxygen demand (COD) reduction, and reduction of MBAS (degradation parameter: % reduction of Methylenblue Activity). Perborate was heated for 25 min at 95°C. Approximately half of the perborate was decomposed. At 10 mg B/L MBAS influent and effluent concentration did not differ significantly, but COD in the effluent differed significantly. At higher concentrations this inhibition was not observed. The authors stated, that inhibition started at a concentration of 40 mg B/L. After adapting the sludge a strong inhibition was observed at a concentration of 120 mg B/L. The value 120 mg B/L was cited within the review of Butterwick et al., 1989, Guhl 1992a and 2000. This study cannot be used to derive a $PNEC_{add,STP}$ value, because adapted sewage sludge was used. The study is quoted as reliable with restriction (according to Klimisch et al, 1997).

Guhl, 2000

Effects of boron on activated sludge (containing e.g. *Entosiphon sulcatum*, *Paramecium caudatum*, *Opercularia bimarginata* and *coarctata*) were investigated using different concentrations of boron (0, 10, 15, 20, 50 and 110 mg B/L). After 72 hours contact time activated sludge samples were taken and examined by light-microscope. The NOEC value was determined at 20 mg B/L. At 50 mg B/L the abundance of *Opercularia bimarginata* was reduced. In activated sludge the number and abundance of specific species is difficult to determine on a scientific basis. Raw data and statistical analyses of the data are missing. Therefore the study is quoted as reliable with restrictions (Klimisch 2). The results on species abundance can only be used in a qualitative approach, the values derived cannot be used for PNEC derivation.

Effects on nitrification

Buchheister et al., 2003

No NOEC or LOEC values can be derived from this study, but it might be of interest that nitrification might adapt to increasing boron concentrations. The effect of boric acid (128 – 1026 mg/l) on nitrification was investigated in a study conducted by Buchheister et al., 2003. Activated sludge from a nitrifying wastewater treatment plant (Pfintztal-Berghausen, Germany) was used in batch experiments to study the inhibition of nitrification and in fixed bed reactors with continuous flow to study the adaptation to boric acid. Results showed that the first step of the nitrification, the ammonia oxidation was uncompetitvely inhibited, whereas the oxidation of nitrite to nitrate was stimulated. It took 14 days to establish full nitrification (fed only with ammonium) and 27 days with 100 mg B/L in the fixed bed reactors. After establishing the nitrification, the concentration of boric acid in the influent was raised continuously up to 500 mg B/L without loss of the nitrification rate. An adaptation time of 13 weeks was necessary to establish full nitrification at 400 mg B/L. At concentrations of 600 and 700 mg B/L the nitrification rate dropped to 55%. After 5-7 weeks a full recovery of the nitrification was achieved. No stable nitrification could be established at 800 mg B/L. For a stable nitrification an adaptation time of several weeks is necessary. The study cannot be used for PNEC derivation, nevertheless it was included into Table 7.6 and rated reliable with restriction, Klimisch “2”.

Effect on anaerobic sludge digestion

Speece, 1988

Anaerobic sludge digestion at boron levels below 200 mg B/L showed no inhibition (Speece, 1988). The document could not be reviewed and has to be rated as Klimisch “4”, not assignable.

Effects on Bacteria (*Pseudomonas putida & Photobacterium phosphoreum*)

In general, results of the cell multiplication inhibition test with *P. putida* (Bringmann and Kuehn, 1980a) should be used for calculations of the $\text{PNEC}_{\text{micro-organisms}}$ only in cases where no other test results are available (Chapter R.7B of the guidance on IRs and CSA). Other information from tests with individual bacterial species is presented below. Effect concentrations for the bacterium *Pseudomonas putida* range widely (Steber, 1991, Schöberl and Huber, 1989**,** and Bringmann & Kühn, 1980a).

Steber, 1991 unpublished report

This summary of unpublished studies by Guhl was done for Henkel KGaA in 1991. By various methods the effect concentrations of Sodium tetraborate is assessed for bacteria, daphnia, algae, biocenosis and phragmites.

An oxygen consumption inhibition test was conducted with *Pseudomonas putida*. The respiration inhibition was determined after 30 min reaction time. A mixture of bacteria, glucose and sodium tetraborate and dilution water was aerated for 30 min; the oxygen consumption was measured electrometrically. The EC_0 and EC_{10} were determined to be 110 and 340 mg B/L, respectively. The study was performed using DIN 38412, part 27 (refers to OECD guideline 209). In addition a chronic growth inhibition test was performed using the DIN 38412, part 8 method. The growth inhibition of *Pseudomonas putida* during a period of 16 hours was investigated photometrically. The EC_0 and the EC_{10} values were 3.4 and 7.6 mg B/L.

In the luminous bacteria test (according to DIN 38412, part 34) effect concentrations (EC_{20} - light loss) for the *Photobacterium phosphoreum* was determined to occur after 30 min at 18 mg B/L.

Tests were stated to be done according to DIN or OECD guidelines, but no original data or statistical analysis methods are given. Therefore, theses data can be classified as Klimisch "2" –reliable with restrictions.

Bringmann and Kühn, 1977b: Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Bakterien (Pseudomonas putida) und Grünalgen (Scenedesmus quadricauda)

Toxicity tests (cell multiplication inhibition test) for 190 substances potentially hazardous to water were performed. Test animals were the bacteria *Pseudomonas putida* and the green alga *Scenedesmus quadricauda*. Pseudomonas tests were performed over 16 hrs. Test medium was bi-distilled water, the boron species tested was Disodiumtetraborate ($Na_2B_4O_7$). The concentration of sodium tetraborate at which an inhibitory action of a substance starts is determined at the extinction value ≥ 3% below the value for negative control. The growth inhibition of *Pseudomonas putida* was measured turbidimetrically. The media (test media and control media) for preliminary cultures (100 ml) contains 5 ml trace element solution including 0.614 g H_3BO_3 (= 0.1 g B/L) a.r. per litre. So each flask (100ml) contains 0.025 mg B/L. The TT_{ps} value for sodium tetraborate is 1040 mg/l (290 mg B/L). The study was not performed according to a guideline, some data on the test substance are missing, no data are presented besides a single endpoint and the TTs are no longer used. Still, the documentation is sufficient and methods scientifically acceptable. Thus, the study is rated as Klimisch "2" – reliable with restrictions.

Bringmann and Kühn, 1979: Vergleich der toxischen Grenzwertkonzentrationen wassergefährdender Stoffe gegen Bakterien, Algen und Protozoen im Zellvermehrungstest & Bringmann and Kühn, 1980a: Comparison of the Toxicity Tresholds of Water Pollutants to Bacteria, Algae, and Protozoa in the Cell Multiplication Inhibition Test

These articles review data which were published before in the journal "Zeitschrift für Wasser- und Abwasser-Forschung“ (Bringmann and Kühn, 1977 and 1978) without referring to these data. Data on *Pseudomonas putida* have already been published in Bringmann and Kühn, 1977: „Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Bakterien (*Pseudomonas putida*) und Grünalgen (*Scenedesmus quadricauda*)“. As these articles are reviews, they are rated as Klimisch 4 – not assignable.

Schöberl and Huber, 1988

This article gives an overview on the ecotoxicity of non-surfactant components of detergents and cleaning agents including toxicity data on *Pseudomonas putida*. As only values are given without references, the study is quoted as not assignable (Klimisch "4").

Effects on Protozoa

Guhl et al., 1991 unpublished report

The NOEC for the *Entosiphon sulcatum* was determined to occur after 72 hours at 18 mg B/L. The study is quoted as reliable with restriction, Klimisch "2".

Guhl, 2000

Viable and dead bacteria (*Pseudomonas putida*) were used as food for *Entosiphon sulcatum*. *Pseudomonas putida* were grown according to DIN 38412, part 8. Numbers of protozoa were determined after 24, 48 and 72 hours. The difference between live and dead protozoa was 7%. The NOEC/LOEC values were equivalent to 15/22 mg B/L. The EC_{50} value was 43 mg B/L, and the EC_{100} value was estimated as 65 mg B/L. The authors point out that this species is commonly found in wastewater treatment plants, with an annual average of 2.12 mg-B/L, suggesting that this species can be present at approx. 10-fold higher concentrations than suggested by Bringmann and Kühn, 1980. *Paramecium caudatum* was fed with viable *Pseudomonas putida*. The NOEC/LOEC(EC_{10}) value was equivalent to 20/25 mg B/L. The EC_{100} value was estimated as > 70 mg B/L. *Opercularia bimarginata* was fed with viable *Pseudomonas putida*. The NOEC value was equivalent to 10 mg B/L. The cell shape was changing at concentrations higher than 10 mg B/L and at concentrations higher than 20 mg B/L zooids separated from their colony. Raw data and statistical analyses of the data are missing. Still the study description is acceptable, therefore a Klimisch-rating of 2 (reliable with restrictions) is assigned.

Bringmann & Kühn, 1980b

Bringmann *et* al., 1980 determined a 72 hours NOEC > 10 mg B/L *for Entosiphon sulcatum*. *Paramecium caudatum* showed growth inhibition EC_{100} < 70 mg B/L. The study is quoted as reliable with restriction (according to Klimisch *et* al, 1997).

Sprague, 1972

The following data were generated by Ambartsumyan (1965) and reviewed by Sprague et al., 1972. The original report was not available for evaluation. *Paramecium caudatum* 72 hours NOEC 18 mg B/L. Boric acid (400 ppm) caused *Paramecium caudatum* to cease to divide and begin to die after 3 days. Upon removal from the boric acid solution after one day exposure they recovered, but exposures for as long as two days caused irreversible damage. A concentration of 100 ppm boric acid, however stimulated cell division. The study is quoted as not assignable, Klimisch "4".

Bringmann, 1978: Bestimmung der biologischen Schadwirkung wassergefährdender Stoffe gegen Protozoen

Cell multiplication inhibition tests for 171 substances potentially hazardous to water organisms were performed. Test organism was the flagellate *Entosiphon sulculatum*. These protozoans feed on aquatic bacteria from water. In the tests they were fed with *Escherichia coli*. Tests were performed over 72 hrs. Cell multiplication was observed with an electronic cell counter. Test medium was sterile bi-distilled water (pH 6.9), the boron species tested was Disodiumtetraborate ($Na_2B_4O_7$). The TT for Entosiphon was 0.28 mg B/L (1 mg $Na_2B_4O_7$/L, concentration referring to acting ion). The study was not performed according to a guideline, some data on the test substance are missing, no data are presented besides a single endpoint and the TTs are no longer used. Some concerns about the feeding with dead bacteria and consequently suboptimal test conditions are raised by Guhl, 2002. Still the documentation is sufficient and methods scientifically acceptable. Thus, the study is rated as Klimisch "2" – reliable with restrictions.

Bringmann and Kühn, 1980b: Bestimmung der biologischen Schadwirkung wassergefährdender Stoffe gegen Protozoen II. Bakterienfressende Ciliaten

Cell multiplication inhibition tests which were established for Entosiphon sulcatum were used for the protozoan Uronema parduczi. These protozoans take up bacteria from water and so help to clean the water. 169 substances potentially hazardous to water organisms were tested. The test animals were fed with *Escherichia coli*. Tests were performed over 20 hrs. Cell multiplication was observed with an electronic cell counter. Test medium was sterile bi-distilled water (pH 6.9), the boron species tested was Disodiumtetraborate ($Na_2B_4O_7$). The TT (based on 5% change) for Uronema parduczi was 30.3 mg B/L (109 mg $Na_2B_4O_7$/L, concentration referring to acting ion). The study was not performed according to a guideline, some data on the test substance are missing, no data are presented besides a single endpoint and the TTs are no longer used. Still the documentation is sufficient and methods scientifically acceptable. Thus, the study is rated as Klimisch 2 – reliable with restrictions.

Bringmann and Kühn, 1979: Vergleich der toxischen Grenzkonzentrationen wassergefährdender Stoffe gegen Bakterien, Algen und Protozoen im Zellvermehrungstest & Brongmann and Kühn, 1980: Comparison of the Toxicity Thresholds of Water Pollutants to Bacteris, Algae, and Protozoa in the Cell Multiplication Inhibition Test.

These articles review data which were published before in the journal "Zeitschrift für Wasser- und Abwasser-Forschung" (Bringmann and Kühn, 1977 and 1978) without referring to these data. Data on Entosiphon sulcatum in Bringmann and Kühn, 1978: Bestimmung der biologischen Schadwirkung wassergefährdender Stoffe gegen Protozoen. As these articles are reviews, they are rate das Klimisch „4“, not assignable.

$\mathrm{PNEC_{STP}}$ derivation

For the evaluation of the potential toxicity of a substance to sewage treatment plants (STPs), the preferred biological material should be activated sludge. Functional endpoints (i.e. good and stable functioning) should take precedence over structural endpoints (Guidance on IRs and CSA, chapters R.7.8.14 to R.7.8.20). Several test approaches are available for the assessment of effects on sludge micro-organisms. A good indicator for the combined activity of the waste-water biocoenosis is the respiration inhibition test. As whole sludge samples are investigated with this method the effect on single species is not assessed. The measured endpoint, i.e. O_2-consumption, is also no measure for possible inhibition of specific processes like nitrification. STPs can adapt to high boron concentrations, as indicated by the results obtained for nitrification rates by Buchheister et al. (2003), but a certain time lag can be anticipated. Pulses of high boron concentrations might be problematic for the biocoenoses in STPs. Toxicity data of boron to micro-organisms are presented in **Table 7.4**.

Two tests on the effect of boric acid or sodium-perborate on sludge respiration were found (Hansvelt and Schoonmade, 2002 and Gerike et al., 1976). One test was performed according to the OECD 209-guidelines (respiration inhibition test), the other was conducted using an older OECD (1971) guideline method. The NOEC values were equivalent to 1.75 and 2 mg B/L, respectively.

Effect concentrations of boron for *Pseudomonas putida* fluctuated widely (Steber, 1991, and Bringmann & Kühn, 1977). The lowest EC_0 and the EC_{10} values were 3.4 and 7.6 mg B/L, respectively (Guhl et al., 1991). Due to the observed variability of boron toxicity for *P. putida*, none of the tests with bacterial cultures have been selected for deriving a $\mathrm{PNEC_{STP}}$.

Some toxicity data were also obtained for various protozoa (Guhl et al., 2000, Bringmann & Kühn, 1978, 1980, Sprague et al., 1972). The lowest NOEC (72 hours) was equivalent to 0.28 mg B/L obtained for *Entosiphon sulcatum* (Bringmann & Kühn, 1980). But a different study revealed a NOEC value of 18 mg B/L for the same species (Guhl et al., 1991).

The respiration inhibition study (OECD 209) of Hansveit and Schoonmade, 2002 is used as key study to derive a $\mathrm{PNEC_{add,STP}}$ value. The OECD 209 guideline states that EC_{50} values should be derived from this method, and these should be seen as guide to the likely toxicity of the test substance either to activated sludge sewage treatment or waste-water micro-organisms. The purpose of this guideline is to provide a rapid screening method, which is not designed to derive EC_{10} values. It was therefore decided that the derived EC_{10} value should not be used and in accordance with the Biocides report on Boric Acid and Disodium tetraborates under Council directive 98/8/EC the NOEC of 17,5 mg B/L was divided by an assessment factor of 10 to derive a $\mathrm{PNEC_{add,\ STP}}$ of 1,75 mg B/L. This PNEC is a precautionary value which also considers the NOEC achieved in single species tests of lower quality (Klimisch ”2”).

Monitoring data from studies on a pilot-scale plant indicate that once microorganisms have been adapted to the presence of boron they might tolerate boron up to a concentration of 3 mg B/L (Umweltbundesamt BE121, 2000), which exceeds the derived $\mathrm{PNEC_{add,\ STP}}$. The measured arithmetic average influent concentrations were 3.0 mg B/L (min. 1.6; max. 4.9 mg B/L) in unfiltered samples collected after primary treatment. The function (nitrogen and carbon - removal) of the pilot-scale plant was not affected. This observation indicates that the $\mathrm{PNEC_{add,\ STP}}$ derived above may be overprotective for STPs that regularly receive high boron concentrations, and are therefore acclimated to boron in the influent. Unfortunately, boron data of full-scale plants which include good performance data are missing. Zessner et al. 2003 monitored average boron concentrations in the effluent of two Austrian full-scale STPs. The average concentration was 1.31 mg B/L for STP1 and 0.78 mg B/L for STP2. But both values were beneath the $\mathrm{PNEC_{add,\ STP}}$ concentration. ECETOC (1997) reported influent and effluent concentrations between 0,27-0,78 and 0,39 -0,75 mg B/L.

The boron discharge of specific industrial sectors, landfills or power plants might be higher compared to municipal STPs. These STPs need to be considered separately. STP monitoring data will need to be collected and toxicity assessments for industrial STPs will have to be included within Industry's registration dossier. For a detailed program see ANNEX II.

Table 7-4.Aquatic micro-organisms (STP)										
Species	**Endpoint Type**	**Test Duration (days)**	**Test Conditions**	**Tested Substance**	**Endpoint**	**Value**	**Reliability Statement**	**Limitations**	**Reference**	**Comments**
Activated Sludge/Sludge Digestion										
Activated sludge	NOEC	3 hour	Sewage treatment plant	Boric acid	17.5	mg B/L	Reliable without restriction	*Guideline study (OECD 209, GLP)*	Hanstveit and Schoonmade, 2000	Used to derive PNEC-stp
Activated sludge	EC_{20} (Inhibition of respiration)	3 hour	Sewage treatment plant	Boric acid	112	mg-B/L	Reliable without restriction	*Guideline study (OECD 209, GLP) Confidence Interval 95% (87 – 144 mg B/L))*	Hanstveit and Schoonmade, 2000	
Activated sludge	EC_{50} (Inhibition of respiration)	3 hour	Sewage treatment plant	Boric acid	>175	mg-B/L	Reliable without restriction	*Guideline study (OECD 209, GLP)*	Hanstveit and Schoonmade, 2000	
Activated sludge	NOEC (treatment plant performance)	3 hr	OECD (1971)	(sodium-perborate: $NaBO_2.H_2O_2.3H_2O$)	20	mg-B/L	Reliable with restriction	*Peer-reviewed technical publication. Method based on OECD method for COD. Acclimation period included in standard method*	Gerike et al, 1976	Not usable for PNEC-stp derivation, but can be used as a supportive argument for PNEC derivation.
Activated sludge	LOEC (treatment plant performance)	3 hr	OECD (1971)	(sodium-perborate: $NaBO_2.H_2O_2.3H_2O$)	40	mg-B/L	Reliable with restriction	*Peer-reviewed technical publication. Method based on OECD method for COD. Acclimation period included in standard method*	Gerike et al, 1976	Only for 10 and 20 mg B/L data present, no data and statistics are available for 40 and 120 mg B/L; nominal boron concentrations retrieved by cooking of perborates for 5 min.
Activated sludge	NOEC/LOEC (microscopic investigation)	72 hours	No guideline	only boron equivalents are given	20/50	mg-B/L	Reliable with restriction,	*Peer-reviewed technical publication. Raw*	Guhl et al., 2000	Abundance of *Opercularia bimarginata* decreased. No quantitative data are available.

							but not applicable for PNEC-derivation	*data not presented.*		
Activated sludge	Nitrification, No determination of NOEC/LOEC	Up to 28 weeks	Non standard method, synthetic waste water	Boric acid			Reliable with restriction	*Peer-reviewed publication.*	Buchheister et al., 2003	Adaption of nitrification to high concentrations of boron.
Bacteria										
Pseudomonas putida (microbe)	EC_0 (acute toxicity: oxygen consumption inhibition test)	30 min	media	Sodium tetraborate	110	mg-B/L	Reliable with restriction: no raw data	*Guidline study (OECD 209), DIN 38412, part 27*	Steber, 1991	
Pseudomonas putida (microbe)	EC_{10} (acute toxicity oxygen consumption inhibition test)	30 min	media	Sodium tetraborate	340	mg-B/L	Reliable with restriction: no raw data	*Guidline study (OECD 209), DIN 38412, part 27*	Steber, 1991	
Pseudomonas putida (microbe)	EC_0 (chronic toxicity: growth inhibition test)	16 hours	media	Sodium tetraborate	3.4	mg-B/L	Reliable with restriction: no raw data	*DIN 38412, part 8*	Steber, 1991	Cited in ECETOC (1997) and Guhl 1992a
Pseudomonas putida (microbe)	EC_{10} (chronic toxicity: growth inhibition test)	16 hours	media	Sodium tetraborate	7.6	mg-B/L	Reliable with restriction: no raw data	*DIN 38412, part 8*	Steber, 1991	Cited in ECETOC (1997) and Guhl 1992a

Pseudomonas putida (microbe)	Toxicity threshold (Growth inhibition test)	16 hrs	Fresh water (culture medium)	Disodium tetraborate	290	mg-B/L	reliable with restriction	*No data reported; non-standard endpoint; exposure estimates ignore background sources; conc not measured*	Bringman and Kühn, 1977	Endpoint reported as 1040 mg/L of Disodium tetraborate (concentration referring to acting ion)
Photobacterium phosphorum	EC20 (inhibiton of luminescence)				18	mg-B/L	Reliable with restriction	*Data from unpublished study using DIN 38412 Part 34 method. Raw data not provided.*	Steber, 1991	Endpoint not relevant for $PNEC_{STP}$ derivation (according TGD, p 109)
Protozoa										
Entosiphon sulcatum (protozoan)	Toxicity threshold (Growth inhibition test	72 hours	Nutrient media	Sodium tetraborate	0.28	mg B/L	Reliable with restriction	No Guideline method; well described method	Bringmann and Kühn, 1978	Endpoint reported as 1 mg B/L of Disodium tetraborate (concentration referring to acting ion)
Entosiphon sulcatum (protozoan)	NOEC/LOEC $EC50/EC_{100}$ (Growth inhibition test)	72 hours	Fresh water (culture medium)	only boron equivalents are given	15/22 43/65	mg-B/L	Reliable with restriction	*Peer-reviewed technical publication. Raw data not presented.*	Guhl, 2000	
Entosiphon sulcatum (protozoan)	NOEC	72 hours	Nutrient media	Sodium tetraborate	18	mg-B/L	Reliable with restriction		Unpublished;Henkel KGaA, Berichts Nr. 1991/3090, Oct. 1992	

Paramecium caudatum (protozoan)	NOEC/ LOEC(EC_{10}) EC_{100} (Growth inhibition test)	72 hours	Fresh water (culture media)	not indicated	20/25 >70	mg-B/L	Reliable with restriction	*Peer-reviewed technical publication. Raw data not presented.*	Guhl, 2000	
Opercularia bimarginata (protozoan)	NOEC (Growth inhibition test)	72 hours	Fresh water	not indicated	10	mg-B/L	Reliable with restriction	*Peer-reviewed technical publication. Raw data not presented.*	Guhl, 2000	
Uronema pardaczi	EC5 (growth inhibition test)	20 hours	Fresh water	Disodium tetraborate	30	mg-B/L	Reliable with restriction	*Peer-reviewed technical publication. Only endpoint (Toxicity Threshold) is reported, set at 5% reduction in population growth. EC5 more stringent than currently accepted EC10, may be within normal variability.*	Bringmann & Kuhn, 1980	Endpoint reported as 109 mg B/L of Disodium tetraborate (concentration referring to acting ion).

7.2 Terrestrial compartment

7.2.1 Background information

Sources of ecotoxicological data

The ecotoxicological data in this report are derived from original papers on the subject, gathered from the industry, environmental agencies or published in international journals.

Selection of ecotoxicological data

The toxicity data on invertebrates and plants are from single-species tests that study common ecotoxicological parameters such as survival, growth and/or reproduction. The toxicity data on micro-organisms are from tests in which microbe-mediated soil processes, such as C- and N- mineralisation were studied. These microbial toxicity tests are multiple species tests because these microbe-mediated processes reflect the action of many species in soil microbial communities.

All data are screened for their relevancy and reliability. Relevancy points to the appropriatness of the data for a particular hazard identification or risk caharacterisation, while reliability is based on the inherent quality of the test method and report. Reliability is addressed through Klimisch criteria.

Only data that are considered reliable (Klimisch scores 1 and 2) AND relevant will be used for HC_{5-50} and PNEC derivation.

Relevance

Biological relevancy

The toxicity data on terrestrial organisms are from ecotoxicity tests that study relevant ecotoxicological parameters such as survival, growth, reproduction, and emergence. Relevant endpoints for soil micro-organisms focused on functional parameters (such as respiration, nitrification, mineralization) and microbial growth. Enzymatic processes are considered not relevant for this risk assessment and the available information –presented in Annex IV- is proposed to be used as supporting information.

Relevancy of the test media

Only data from observations in natural and artificial standard (OECD) soil media have been used in this report for the derivation of the PNECs, tests performed in substrates that were judged as not representative for soils (e.g. nutrient solution, agar, pure quartz sand and farmyard manure) were included in this effects assessment as part of the weight of evidence approach (Annex IV).

The data used in the effect assessment should ideally be based on organisms and exposure conditions relevant for Europe. This would, however, considerably reduce the amount of data that can be used. Therefore, also data based on soils collected outside Europe have been used, if having properties relevant for the EU conditions. Therefore only the toxicity data performed using soils with physico-chemical properties, within the point-based 10th and 90th percentiles of the EU soils were retained for the PNEC derivation (for a description of these parameters see below). The dataset used for the derivation of these boundaries for the EU soils has been already discussed and agreed at the TC NES for the EU risk assessments of Ni and Cu. Based on that dataset (see Annex V) only the ecotoxicity data were retained in case they were within the following bounderies: pH (0.01M $CaCl_2$): 3.8 – 7.4 or pH (H_2O): 4.6 – 7.8; organic matter: 1.7 – 20.6% and clay: 3.7 – 31.2%. Ecotoxicity data derived from soils with properties outside these boundaries were presented as supporting information in Annex IV, as this data can be used to derive PNEC values for soil types outside the 10th to 90th percentile of EU soils (e.g. very sandy soils). It should be noted, however, that even though this approach was accepted for the copper risk assessment, it should be taken into account that especially those soils with more “extreme” characteristics often represent especially vulnerable ecosystems.

Furthermore, for certain OECD guidelines (e.g. OECD guideline 216) the use of "extreme" soils is recommended, as there the availability of the substance is especially high. According to the parameters listed above, those results would have to be excluded, even though they were performed according to an OECD guideline.

The exclusion of the soils outside the 10th and 90th percentile has to be reconsidered when the GEMAS project is finalised and ecoregions have been refined, thus this approach should be reconsidered for the industry's registration dossier under REACH.

As boron is a naturally occurring substance, a natural background concentration of boron will be present in the soils used for toxicity testing. Boron being an essential nutrient for terrestrial plants (see chapter 3.2.5.2.1), data derived from toxicity tests will have to be interpreted carefully.

Relevancy of the test substance

Studies on the ecotoxicity of boron have been performed with various compounds, such as boric acid (H_3BO_3), anhydrous sodium tetraborate ($Na_2B_4O_7$), and hydrated sodium tetraborates ($Na_2B_4O_7.xH_2O$). For the purpose of this evaluation, all endpoints are converted to concentrations of elemental boron (B) using the relative molar mass.

Test duration

What comprises "chronic exposure" is a function of the life cycle of the test organisms. A priori fixed exposure durations are therefore not relevant. The duration should be related to the typical life cycle and should ideally encompass the entire life cycle or, for longer-lived species the most sensitive life stage. Retained exposure durations should also be related to recommendations from standard ecotoxicity (e.g. ISO, OECD, ASTM) protocols.

Typically chronic test durations for the higher plants are within the range of 4 (e.g. the root elongation test based on ISO 11269-1 (1995)) and 21 days (e.g. the shoot yield test based on ISO 11269-2 (1995)). OECD n° 208 (plant seedling emergence and growth test, 1984) recommended a test duration of at least 14 days after emergence of the seedlings. Testing with soil invertebrates have a typical acute exposure duration of 7 to 14 days for the oligochaetes *Eisenia fetida/Eisenia andrei*. Assessment of the chronic effects of substances on sub-lethal endpoints such as reproduction on oligochaetes has a typical exposure duration of 3 to 6 weeks for the standard organism *Enchytraeus albidus* (OECD, 2000; ISO 16387). For another standard species *Folsomia candida* survival and reproduction is typically assessed after 28 days of exposure (ISO 11267, 1999). Reported test duration using soil micro-organisms vary and last 28 days for the carbon transformation test (OECD n° 217) and for the nitrogen transformation test (OECD n° 216).

Reliability

Scoring system

Evaluations of study reliability were made for the studies discussed in this report following the Klimisch et al. (1997) codes. These evaluations follow the TGD guidelines regarding reliability and relevancy.

Klimisch 1: The studies most closely following accepted standard protocols were rated "*Reliable without restriction*".

Klimisch 2: High quality studies that did not strictly follow standard protocols were rated "*Reliable with restriction*".

Klimisch 3: Studies with significant deviations from current scientific standards or protocol practices were rated "*Not reliable*".

Klimisch 4: Some reported test results could not be evaluated because the studies do not give sufficient experimental details or the data are only listed in short abstracts or secondary literature (books, reviews, etc.) and therefore these studies were rated "Not assignable".

Only the toxicity data that received a Klimisch score of 1 or 2 and that are considered relevant will be used as the basis for the derivation of the HC5-50 and PNEC value.

Type of test

Both standard test organisms and non-standard species can be used in the framework of a risk assessment. In general, toxicity data generated from standardised tests, as prescribed by organizations such as OECD and USEPA will need less scrutiny than non-standardised test data, which will require a more thorough check on their compliance with reliability criteria before being used. GLP and non-GLP tests can be used provided that the latter fulfill the stipulated requirements.

For terrestrial soil ecotoxicity testing, adequate time should elapse between mixing trace element compounds into the test medium and introducing biota (plants or soil invertebrates). However, as few details on the equilibration time may be available, it might be difficult to consider this criterion in this exercise.

Concentration-effect relationships

Because effect concentrations include statistically derived values, information concerning the statistics should be used as a criterion for data selection. Data from studies with insufficiently described methodology or data derivation were considered unreliable. Effect levels derived from toxicity tests using only 1 test concentration were thus considered unreliable, and only data from toxicity test using at least 2 boron concentrations and 1 control group were retained.

Chemical analysis

There is a strong preference for using measured data. The data used in the effect assessment should therefore ideally be based on measured concentrations. This would however considerably reduce the amount of data to be used. Therefore, in this effects assessment, both nominal and actual (measured) effect concentrations were selected for PNEC derivation. If it is not mentioned whether the NOEC/L(E)C_{10} values are based on measured or nominal concentrations, they were considered as nominal concentrations.

Tests that do not comply with the above-mentioned stipulations are rated as not reliable and are not recommended for use in the risk assessment exercise.

Unmeasured background concentrations

Boron is naturally present in soil at average levels of between 10-20 ppm although there are geographical areas with a higher background concentration (ECETOC, 1997). For many studies the background B concentration (Cb, concentration in the control) of the test soil used was not reported in the original studies. Estimating the missing background of boron concentrations in the test media will need to be investigated when applying the total risk approach.

Derivation of NOEC/L(E)Cx values

Test reports of acceptable quality are anticipated to provide statistically derived endpoints, such as EC50 or NOEC or EC10 values and these will be reported as calculated by the study authors.

Following regulatory guidance and current practice, the preferred value for acute effect endpoints (such as mortality) are EC50 values. The preferred values for chronic effect endpoints (such as growth) are NOEC or EC10 values. (For simplicity, endpoints calculated from a concentration-response model will be called ECx values, although they are also referred to as LCx or ICx values.)

In some standard test methods, statistical analysis is prescribed, e.g., an ANOVA should be used to evaluate the presences of a significant difference from control response, and a pairwise procedure, such as Dunnett's test, can be used to identify test groups differing from controls. It is important to evaluate the nature of the concentration-response pattern to use such statistics, or to justify the use of alternative statistics.

The variability in ecotoxicity tests has been a matter of extensive discussion. For many standardized tests, inherent variability is considered to be about 10%, e.g., a change in response of 10% or less cannot be reliably distinguished from typical control responses. Consequently, 10% inhibition is often used as a surrogate estimate for a maximally acceptable response (e.g., LOECs are determined if they exhibit an inhibition of the control response of > 10%). Similarly, for ECx calculations, the value of x is usually taken as 10%. However, some test guidelines acknowledge that the inherent variability of the test exceeds 10% and may recommend an alternative threshold, e.g., x = 20%.

In some tests, the lowest (non-control) test group showed a significant response. This results in the lowest group being identified as the LOEC, termed an "unbounded" LOEC and the value will be indicated by "<". According to Guidance on IR and CSA Chapter R.10 (2008), the NOEC could be derived in specific cases from the LOEC. Indeed, if the EC10 or the NOEC is not reported and cannot be calculated due to lack of suitable effect concentrations, the NOEC is derived from the LOEC using the following extrapolation factors:

(a) NOEC = LOEC/2, in case inhibition is >10% but ≤20%. Following that reasoning, NOEC values could also be calculated from EC20 values, i.e. NOEC = EC20/2. Estimation of EC20 values outside the measured concentration range introduces a great deal of uncertainty (i.e. extrapolation outside the range of the data) and should therefore be avoided. Indeed, if EC20 is below the lowest dose tested (meaning that there is >20% effect at the LOEC), no NOEC is derived.

(b) If the percentage inhibition at the LOEC is >20% or in the case that the percentage inhibition is not known, no NOEC is derived.

In a related manner, the highest test group may show no significant response, resulting in an unbounded NOEC, indicated by "≥". Unbounded NOEC values are not further used for the PNEC derivation but could be used as supportive information in the weight of evidence approach.

If the EC50 or EC10 is outside the range of tested concentrations, the accuracy of the underlying model should be questioned, and the result expressed as an unbounded result. For example, if the EC50 exceeds the highest tested concentration, the results are difficult to use quantitatively. Similarly, if the EC10 is below the lowest test concentration, the precision of the result may be questioned.

Approach for PNEC derivation

Averaging thresholds for same process/species

The geometric mean of the retained quality screened toxicity data for higher plants, invertebrates and microbial processes was calculated to avoid over-representation of ecotoxicological data from one particular species or function. The approach used is outlined hereunder:

If for one process/species several chronic NOEC or EC10 values based on the same toxicological endpoint are available, these values are averaged by calculating the geometric mean, resulting in the "species mean" NOEC or EC10.

If for one species several chronic NOEC or EC10 values based on different toxicological endpoints are available, the value for the most sensitive endpoint is selected. This value is determined on the basis of the geometric mean if more than one value for the same endpoint is available.

After a thorough evaluation of the database it was concluded that the SSD approach is not applicable due to the following reasons:

According to Guidance on IR and CSA chapter R.10, it is required to include data on at least 8 taxonomic groups. Despite the large amount of data available, it only covers plants and 3 invertebrates. 9 days before the deadline for submission of this transitional dossier, industry recovered a study from the year 2001 on soil microorganisms (Klimisch 1) performed according to OECD guideline 216. Unfortunately there was not enough time to fully evaluate the EC10 calculated by industry and to discuss some discrepancies in the data derivation. This included, for example, the fact that it is not clear whether the results derived after 102 days test duration were used, which is not in compliance with the recommended 28 days for chemicals other than agrochemicals. The NOEC from this study on a soil with characteristics outside the 10th to 90th percentile after 28 days was 3 mg/kg soil, which would have been the smallest NOEC derived from a study. OECD guideline 216 suggests the use of soils representing a "worst case situation", i.e. adsorption of the test chemical is minimum and its availability to the microflora is maximum. As time was too short to discuss these values, they were taken out and put into Annex III.

The term "taxonomic group" set out in the Guidance Document leaves room for interpretation; however, due to the complex nature of soils, we consider the use of taxonomic groups based mostly on plants insufficient for the SSD approach. We suggest further studies including organisms covering more trophic levels. These should include several reliable studies on micro-organisms, and invertebrate species, as Borates are known for their fungicidal, bacteriocidal, and insecticidal properties. Thus, the inclusion of toxicity tests on species of these groups is of paramount importance for a SSD approach, as species of the mentioned taxa could be the most sensitive. The essentiality of B for plants and their different B optima renders SSD application more difficult, and requires a careful consideration of B background concentrations.

Since SSD is not applicable, PNEC is derived following the key study approach.

Boron specific considerations

Because boron is a necessary plant micronutrient, it is intentionally added in some instances where required by crop plants and limited in the natural soil. Typical applied doses are 1-2 kg B/ha/yr (Shorrocks, 1997). This may be in the form of formulated fertilizers broadcast to agricultural soils or sprays applied directly to the plant or vicinity of the plants. In these instances, it might be appropriate to use a PNEC for agricultural soil that protects the agricultural uses of the soil, rather than a PNEC derived to protect non-agricultural or non-industrial soil. This is consistent with the REACH Guidance Document (2008) distinctions in developing PEC for agricultural, natural/grassland, and industrial soil.

A potential approach would therefore be to derive a PNEC for agricultural soil based on toxicity, but also with consideration of the risk of deficiency. For natural soils, the presumption is that locally-adapted species will not be adversely affected by boron deficiency, so only boron toxicity is relevant for deriving a PNEC.

Bioavailability of boron in soils

Essentiality

Boron is a naturally occurring element that is essential to a variety of organisms. In plants, it is necessary for a variety of metabolic processes (e.g. nitrogen metabolism, nucleic acid metabolism and membrane integrity and stability) and has been known to be an essential micronutrient for terrestrial plants for several decades (Butterwick et al., 1989, Eisler, 2000). Shorrocks (1997) documented the use of boron applications for 132 crops in over 80 countries, demonstrating the widespread nature of agricultural use of boron.

Evidence exists that it is essential for nitrogen fixation in some species of algae (Smyth and Dugger, 1981), fungi and bacteria (Saiki et al., 1993, Fernandez et al., 1984), some diatoms and algae and macrophytes (Eisler, 2000). Required levels may vary, especially among plants, such that essential levels for one species may be toxic to another (Eisler, 1990).

The concentration-response curve for boron is likely to be U-shaped for most species, with adverse effects observed at high and low concentrations, while no adverse effects are observed at the intermediate concentrations (Lowengart, 2001). Figure 1 illustrates such a pattern for plants (Gupta et al., 1985) although the response has been normalized to 100%, making the curve an inverted-U shape.

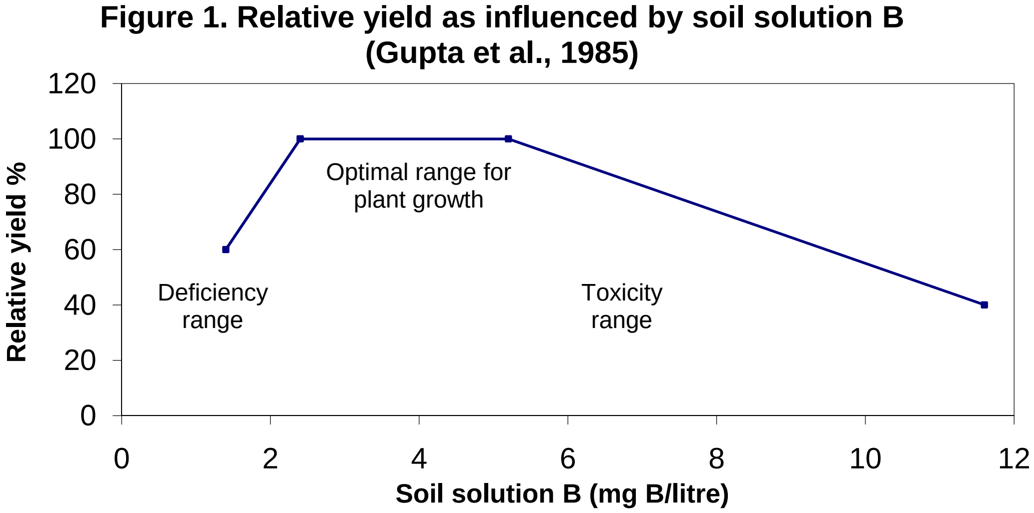


Figure 7.2.: U-Shaped Toxicity Pattern: Plant yield as influenced by soil boron concentrations (Gupta et al., 1985)

Plant and animal species vary in the concentrations associated with deficiency and toxicity. Monocotyledons (e.g., corn and grasses) require about one-quarter as much boron as dicotyledons (e.g., tomatoes, carrots, clovers, beets) (Butterwick et al., 1989). The mobility of boron within the plant may help explain the observed deficiency and toxicity patterns. Boron is more mobile in plants that produce the simple sugars known as polyols (e.g., sorbitol and mannitol) than in species that do not produce polyols. In polyol-producing species, boron is translocated from one part of the plant to another and so may reach the meristem and affect growth. In the absence of polyols, boron is relatively immobile within the plant (Brown et al., 2002). A polyol-producing plant may be both more tolerant of boron deficiency and more sensitive to higher boron concentrations because of the mobility of boron within the plant. This is important in agricultural applications of boron, which may be applied as a soil treatment or as foliar spray.

Agricultural application of boron depends on the plant and cultivar, as well as the local soil. Recommended application rates range from 0.5 to 7.6 kg-B/ha (Borax, 2002), but typically are in the range of 1 to 2 kg-B/ha (Shorrocks, 1997). If one assumes typical soil densities of 1700 kg/m³ and a mixing depth of 20 cm (default values used in the EUSES model), an application rate of 1 to 2 kg-B/ha results in an estimated soil concentration of 0.3 to 0.6 mg-B/kg-soil. Mortvedt et al. (1992) estimated soil concentrations of 0.16 to 2.0 mg-B/kg-soil for several crops with application rates of 0.45 to 5.7 kg/ha. The intentional application of borates to achieve such soil concentrations for agricultural crops should be acknowledged in the risk assessment process.

Chemistry of B in soils

Boron may be considered a typical metalloid having properties intermediate between the metals and the electronegative non-metals. Boron has a tendency to form anionic rather than cationic complexes (Keren and Bingham, 1985). Boron does not undergo oxidation reduction reactions or volatilisation reactions in soils (Goldberg, 1997). Boron chemistry is of covalent B compounds and not of B^{3+} ions because of its very high ionisation potentials.

Boron oxide, B_2O_3 reacts with water to form boric acid, H_3BO_3. Boric acid is moderately soluble (4.9g $100mL^{-1}$ water at 20°C). It acts as a weak Lewis acid by accepting a hydroxyl ion to form the borate anion.

Aqueous B species other than $B(OH)_3$ and $B(OH)_4^-$ can be ignored for most practical purposes in soils (Keren and Bingham, 1985). In most soils with soil solutions in the pH range 4.0 to 9.0, the uncharged $B(OH)_3$ predominates. The borate ion is expected to form a variety of complex salts with suitable metal acceptor ions. However, there is relatively little evidence for the existence of metal borate complexes in solutions. Among the organic borates, the tendency is for B to replace carbon or nitrogen in three fold coordination (Keren and Bingham, 1985). In regions of low rainfall, the B content of the soil is usually high. Boron in these soils probably exists largely as sodium-calcium borates. However, there is no information on the kinetics of dissolution of these minerals in water or on the composition of their products (Keren and Bingham, 1985).

Factors affecting the bioavailability of B in soils

Boron toxicity to plants and many soil microroganisms is a function of the bioavailability of the dissolved B species in the soil solution and the ability of the soil to buffer B concentrations in the soil solution. Various environmental factors can influence B availability and extent of B adsorption in soils, including pH, soil texture, organic matter content, soil moisture, and temperature. As B is either neutral or negatively charged under environmentally relevant conditions, cation exchange capacity seems not to play a relevant role and is therefore not considered in this dossier. Boron availability to invertebrates depends on the relative amounts taken up by the organism by dermal adsorption and/or ingestion, although the relative importance of each route in causing boron toxicity has not been determined (Vijver et al., 2001). See also PBT section for further information on the sorption behaviour of B in soils.

There are only few studies that compare B toxicity for the same endpoint in different soils (Aitken & McCallum, 1988; Gestring & Soltanpour, 1987; enzyme studies by Tabatabai and coworkers). The available results indicate a significant variation in B toxicity thresholds among soils and show a tendency of increased B toxicity in soils with low organic matter content, low clay content and pH < 7.5. The information is however too limited to allow conclusions on soil properties controlling B toxicity in soils. Studies on residual effect of boron application after a single application also indicated decreasing B toxicity to plants with increasing time since application (Gupta & Cutcliffe, 1984; Gestring & Soltanpour, 1987).

The amount of B adsorbed by soil varies greatly with the contents of various soil constituents. Boron is adsorbed onto soil particles, with the degree of adsorption depending on the type of soil minerals present, pH, salinity, organic matter content, iron and aluminium oxide oxy/ hydroxy content, and clay content (Hingston, 1964; Sims and Bingham, 1968; Bingham et al., 1970; Bingham, 1973). Boron adsorption can vary from being fully reversible to irreversible, depending on the soil type and environmental conditions (IPCS, 1998).

As the pH is increased to about 9, the $B(OH)_4^-$ concentration increases rapidly and the amount of adsorbed B increases rapidly (Keren and Bingham, 1985). Hence, the critical range of extractable B levels is generally higher in alkaline soils than in acid soils (Bell, 1999).

Boron reacts more strongly with clay than sandy soils (Keren and Bingham, 1985). Clay soils buffer B in the soil solution better than sandy soils. The rate of B adsorption on clay minerals is likely to consist of a continuum of fast adsorption reactions and slow fixation reactions. Short-term experiments have shown that B adsorption reaches an apparent equilibrium in less than one day (Hingston, 1964; Keren et al., 1981). Long-term experiments have shown that fixation of B increased even after six months of reaction time (Jasmund and Lindner, 1973). The magnitude of the B adsorption onto clay minerals is affected by the exchangeable cation (Keren and Gast, 1981; Keren and Mezuman, 1981; Keren and O'Connor, 1982; Mattigod et al., 1985). Calcium-rich clays adsorb more B than sodium and potassium clays (Keren and Gast, 1981; Keren and O'Connor, 1982; Mattigod et al., 1985).

Higher organic matter content increases the B-sorption capacity of soils (Yermiyahu et al., 1995). Adsorbed B and B adsorption maxima have been highly significantly correlated with organic carbon content (Elrashidi et al., 1982; Gupta, 1968). The uptake of B by plants can be markedly affected by the presence of other plants nutrients in soils. The most well known of these is the effect of Ca (Gupta et al., 1985).

7.2.2 Toxicity test results

7.2.2.1 Invertebrates

Data on chronic single-species toxicity tests resulting in selected NOEC/EC_{10} values for invertebrates are summarised in **Table 7.5**. All these values are considered reliable (Klimisch score 1 and 2) and relevant for the effects assessment. All NOEC or EC10 values (including selected, non-selected, unbounded and rejected values) and their corresponding robust study summaries are summarized in Annex I. All data in Table 7.5. are based on added nominal values and background concentrations are not always available. In total 29 individual high quality NOEC/EC_{10}'s (for 3 different species) are selected for the PNEC derivation, ranging from 5.2 mg B/kg dw for *Eisenia andrei* growth (Stantec Consulting & Aquaterra Environmental Consulting, 2003) to 315 mg B/kg for *Eisenia andrei* survival (Stantec Consulting & Aquaterra Environmental Consulting, 2003).

7.5 Overview of the selected ecotoxicity data for soil invertebrates. Values used for the effects assessment are marked in bold.

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/L(E) Cx (with x > 10)*	L(E)C50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Eisenia andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Mortality	**315**		630	589.2	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Juvenile production	**39.4**		78.8	77.4	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Growth (juvenile dry weight)	**78.8**		157.3	95.5	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Hatching Success	**78.8**		157.3	120.2	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Hatching Failure	**19.8**		39.4		Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (synchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Mortality	**315**		629.3	620	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (synchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Juvenile production	**78.8**		157.3	99.4	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (synchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Growth (juvenile dry weight)	**78.8**		157.3	165.8	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (synchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Hatching Success	**78.8**		157.3	86.3	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia Andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Juvenile production	**52.5**		98 / 58 (20%)	77.9	Nominal added dosis; background concentration reported
2	H_3BO	*Eisenia andrei*	Artificial	6.09	9	14.9	3.5	1	56	Growth	**5.2**		8.7 /	25.7	Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/L(E) Cx (with x > 10)*	L(E)C50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
	$_3$	(earthworm)	soil							(juvenile dry weight)			4.0 (20%)		background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Hatching Success	**52.5**		98 / 66.7 (20%)	98	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Hatching Failure	**52.5**		98		Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Cocoon production	**98**		175 / 100.1 (20%)	136.2	Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Juvenile production	**52.5**		98 / 57 (20%)	75.7	Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Growth (juvenile dry weight)	**52.5**		98 / 45.5 (20%)	59.4	Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Hatching Success	**52.5**		98 / 69.2 (20%)	90.4	Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Hatching Failure	**52.5**		98		Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Cocoon production	**98**		174.8 / 73.4 (20%)	107.6	Nominal added dosis; background concentration reported
															Stantec Consulting & Aquaterra Environmental Consulting, 2003
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Artificial soil	6.09	9	14.9	3.5	1	35	Juvenile production	**43.75**		87.5 / 72.0 (20%)	88	Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/L(E) Cx (with x > 10)*	L(E)C50	Comment
					%	%	mg B/kg_{dw}	d	d		mg B/kg_{dw}				
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Artificial soil	6.09	9	14.9	3.5	1	35	Mortality	**175**		262.5 / 181.6 (20%)	258.3	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Artificial soil	6.09	9	14.9	3.5	1	35	Reproduction	**87.5**		113.8 / 87.5 (20%)	94.8	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Clay loam soil	6.05	12.8	30.1	1.0	1	35	Juvenile production	**21.9**		43.8 / 8.1 (20%)	19.7	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Clay loam soil	6.05	12.8	30.1	1.0	1	35	Mortality	**113.8**		148.8 / 140.3 (20%)	174.6	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Clay loam soil	6.05	12.8	30.1	1.0	1	35	Reproduction	**21.9**		43.8 / 29.0 (20%)	32.4	Nominal added dosis; background concentration reported
															ESG International & Aquaterra Environmental Consulting, 2003
1	H_3BO_3	*Folsomia candida* (springtail)	Artificial soil	6.09	9.0	14.9	9.9	1	28	Mortality		**68.1**		>70	Nominal added dosis; background concentration reported
1	H_3BO_3	*Folsomia candida* (springtail)	Artificial soil	6.09	9.0	14.9	9.9	1	28	Juvenile production		**13.8**		26.1	Nominal added dosis; background concentration reported
1	H_3BO_3	*Folsomia candida* (springtail)	Clay loam soil	6.05	12.8	30.1	<0.9	1	28	Mortality		**66.2**		>70	Nominal added dosis; background concentration reported
1	H_3BO_3	*Folsomia candida* (springtail)	Clay loam soil	6.05	12.8	30.1	<0.9	1	28	Juvenile production		**17.2**		30.5	Nominal added dosis; background concentration reported
															EPFL, 2003

EP: equilibration period

*: % effect (inhibition) between brackets. The % inhibition was calculated as: (A-B)/A * 100 where A is the response of the control soil and B is the response of the treated soil.

7.2.2.2 Higher Plants

Data on chronic single-species toxicity tests resulting in selected NOEC/EC_{10} values for higher plants are summarised in **Table 7.6.**. All these values are considered reliable (Klimisch score 1 and 2) and relevant for the effects assessment. All NOEC or EC10 values (including selected, non-selected, unbounded and rejected values) and their corresponding robust study summaries are summarized in Annex II. Almost all data in Table 7.6. are based on added nominal values and background concentrations are not always available. In total 119 individual high quality NOEC/EC_{10}'s (for 28 different species) are selected for the PNEC derivation, ranging from 15.3 mg B/kg for tomato seedling emergence (Aquaterra, 1998) to 84.0 mg B/kg for wheat shoot length, canola shoot yield and western wheatgrass root yield (Aquaterra, 1998).

A large number of papers were assessed from the literature, yet only a limited toxicity dataset could be created due to the poor quality of most of the data. References of studies with data on chronic single-species toxicity tests resulting in NOEC/EC_{10} values from hydroponic/sand cultures for higher plants are presented as supporting information in Annex IV.

7.6 **Overview of the selected ecotoxicity data for higher plants. Values used for the effects assessment are marked in bold.**

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg_{dw}	d	d		mg B/kg_{dw}				
2	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Seedling emergence	**46.9****		93.8 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion riparium* (Streambank wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion riparium* (Streambank wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion smithii* (Western wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Seedling emergence	**40.1****		80.2 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion smithii* (Western wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Shoot length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion smithii* (Western	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Root length	**28.0**				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		wheatgrass)													
2	H_3BO_3	*Allium cepa* (Spanish onion)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Shoot length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Avena sativa* (oat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Avena sativa* (oat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Avena sativa* (oat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Avena sativa* (oat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Beckmannia syzigachne* (American sloughgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	24	Seedling emergence	**16.9****		33.8 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Beckmannia syzigachne* (American sloughgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	24	Seedling emergence	**36.4****		72.8 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Beckmannia syzigachne* (American sloughgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	24	Yield (whole plant)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**45.1****		90.23(20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Brassica napus* (Canola)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**84**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**84**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola))	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**23.7****		47.4 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**45.7****		91.5 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica*	Clay loam field	6.2	11.9	30.6	1.0	1	5	Yield	**56**				Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg_{dw}	d	d		mg B/kg_{dw}				
		oleracea (cabbage)	soil							(shoot)					background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica rapa* (Turnip)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Seedling emergence	**26.4****		52.8 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Seedling emergence	**32.5****		64.9 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Artificial sandy loam soil	6.5	4.0	14.8	1.0	1	7	Shoot length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Shoot length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (shoot)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (root)	**84**				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (shoot)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Calamagrostis canadensis* (Bluejoint marsh reed)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Seedling emergence	**16.6****		33.3 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Calamagrostis canadensis* (Bluejoint marsh reed)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Shoot length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Calamagrostis canadensis* (Bluejoint marsh reed)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**45.3****		90.7 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa*	Artificial sandy	6.5	4.0	14.8	3.5	1	5	Yield (root)	**28.0**				Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		(Cucumber)	loam soil												background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Daucus carota* (Carrot)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Seedling emergence	**22.0****		43.8 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Daucus carota* (Carrot)	Clay loam field soil	6.2	11.9	30.6	1.0	1	6	Seedling emergence	**27.9****		55.8 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Daucus carota* (Carrot)	Clay loam field soil	6.2	11.9	30.6	1.0	1	6	Yield (root)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Festuca rubra* (Red fescue)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Seedling emergence	**23.7****		47.4 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Festuca rubra* (Red fescue)	Clay loam field soil	6.2	11.9	30.6	1.0	1	6	Seedling emergence	**38.2****		76.5 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Festuca rubra* (Red fescue)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Yield (total plant)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Glycine max* (Soybean)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Seedling emergence	**28.2****		56.4 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Glycine max* (Soybean)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Hordeum vulgare*	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	4	Yield (shoot)	**56**				Nominal added dosis; background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		(Barley)													reported
2	H_3BO_3	*Hordeum vulgare* (Barley)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	4	Yield (root)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Hordeum vulgare* (Barley)	Clay loam field soil	6.2	11.9	30.6	1.0	1	4	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Hordeum vulgare* (Barley)	Clay loam field soil	6.2	11.9	30.6	1.0	1	4	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Koeleria macrantha* (june grass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	9	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Koeleria macrantha* (june grass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	9	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Latuca sativa* (Lettuce)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**22.5****		45 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Latuca sativa* (Lettuce)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**37.0****		74 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Latuca sativa* (Lettuce)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Latuca sativa* (Lettuce)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Latuca sativa* (Lettuce)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**55.9**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**30.4****		60.9 (20%)		Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Linum usitatissimum* (Flax)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**49.0****		98 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**34.4****		68.7 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**30.5****		61.1 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**27.7****		55.4 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Lycoperiscon*	Clay loam field	6.2	11.9	30.6	1.0	1	5	Seedling	**15.3****		30.6 (20%)		Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		esculentum (Tomato)	soil							emergence					background concentration reported
2	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Seedling emergence	**47.2****		94.5 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Seedling emergence	**34.6****		69.1 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Root length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Shoot length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Root length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense*	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Seedling emergence	**17.7****		35.2 (20%)		Nominal added dosis; background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		(Timothy)													reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Seedling emergence	**38.3****		76.7 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Shoot length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (shoot)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Raphanus sativus* (Radish)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**38.0****		76.1 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Raphanus sativus* (Radish)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**46.4****		92.9(20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Raphanus sativus* (Radish)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Schizachyrium scoparius* (Little bluestem)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	10	Seedling emergence	**46.0****		92.1 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Schizachyrium scoparius* (Little bluestem)	Clay loam field soil	6.2	11.9	30.6	1.0	1	10	Seedling emergence	**52.0****		104.1 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Trifolium pratense* (Red	Artificial sandy	6.5	4.0	14.8	3.5	1	5	Seedling	**17.1****		34.1 (20%)		Nominal added dosis; background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		clover)	loam soil							emergence					reported
2	H_3BO_3	*Trifolium pratense* (Red clover)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Trifolium pratense* (Red clover)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Trifolium pratense* (Red clover)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Trifolium pratense* (Red clover)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Triticum aestivum* (Wheat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**55.8****		111.7 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Triticum aestivum* (Wheat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**84**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Triticum aestivum* (Wheat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Triticum aestivum* (Wheat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Triticum aestivum* (Wheat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Zea mays* (Corn)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Zea mays* (Corn)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**56**				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Zea mays* (Corn)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Zea mays* (Corn)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported
															Aquaterra, 1998

EP: equilibration period

NR: not reported

*: % effect (inhibition) between brackets. The % inhibition was calculated as: (A-B)/A * 100 where A is the response of the control soil and B is the response of the treated soil.

**: calculated as ECx (x between 10 and 20%)/2

7.2.2.3 Microorganisms

Only one study (Hansveit et al 2001) rated Klimisch 1 and relevant was found 9 days before the deadline for submission of this transitional dossier. As time was not sufficient to discuss several aspects regarding EC10 calculation etc., those values could not be taken into consideration for PNEC derivation (even though the lowest NOEC could be found here). Please refer to Annex III for more information.

7.2.3 PNEC derivation

Since SSD is not applicable, PNEC is derived following the key study approach. In Table 7.7 the geometric means of the most sensitive endpoints are summarised. As the requirement of 3 species of 3 trophic levels was met, an AF of 10 was used. Therefore the $PNEC_{add,terrestrial}$ = 1.54 mg B/kg soil could be derived, based on the geometric mean of the most sensitive endpoint of the most sensitive species (juvenile production, *Folsomia candida*, EPFL 2003). Results from Hansveit et al 2001 on microorganisms should be evaluated thoroughly for future reports.

There is a substantial difference to the $PNEC_{add, terrestrial}$ derived in the Biocides report on Boric Acid and Disodium tetraborates under Council directive 98/8/EC (rapporteur MS The Netherlands). The NOECs of the Biocides report, which are lower than the key NOEC in this dossier, were excluded from this evaluation because they were derived from studies in soils outside the 10th to 90th percentiles for European soils or were derived from studies on organoborates (where Boric Acid had no adverse effect). The PNEC derived here could be lower than the soil B concentration after application of certain fertilisers used for agricultural soils. Due to the sensitivity of certain plant species on the one hand, and the essentiality of B for plants on the other, we suggest further toxicity studies for other species as well as data collection on background concentrations. It should further be noted that the risk assessment is not focused on the optimum performance of crop species in agricultural soil, but should be protective for environments with a low natural boron level.

After results from the GEMAS project, more information on B background information should be available. For future PNEC derivations, we strongly suggest ecoregions approach, as well as a distinction between a PNEC for agricultural soil based on toxicity, but also with consideration of the risk of deficiency. For natural soils, the presumption is that locally-adapted species will not be adversely affected by boron deficiency, so only boron toxicity is relevant for deriving a PNEC.

Table 7.7.: Overview of the selected geometric species mean value for the most sensitive endpoint (based on added B concentrations)

Common name	**Scientific name**	**Most sensitive endpoint**	**Geometric mean NOEC/EC_{10} value (mg B/kg dw)**
Plants			
Tomato	*Lycopersicon esculentum*	seedling emergence	20,6
Wheat	*Triticum pratense*	seedling emergence	55,8
Cucumber	*Cucumis sativa*	root length, shoot yield, root yield	28,0
Perennial ryegrass	*Lolium perenne*	root length	28,0
Red clover	*Trifolium pratense*	seedling emergence	17,0
Turnip	*Brassica rapa*	root yield	28,0
Corn	*Zea mays*	root length, root yield	48,4
Cabbage	*Brassica oleracea*	root length	28,0
Carrot	*Daucus carota*	seedling emergence	24,7
Timothy	*Phleum pratense*	seedling emergence	25,9
Red fescue	*Festuca rubra*	seedling emergence	30,1

Canola	*Brassica napus*	root yield	42,0
Barley	*Hordeum vulgare*	root yield	48,4
Flax	*Linum usitatissimum*	root yield	28,0
Onion	*Allium cepa*	Shoot length	55,9
Radish	*Raphanus sativus*	shoot yield	42,0
Little bluestem	*Schizachyrium scoparius*	seedling emergence	48,9
Lettuce	*Latuca sativa*	seedling emergence	28,8
Soybean	*Glycine max*	root length	28,0
Alfalfa	*Medicago sativa*	seedling emergence	40,4
Streambank wheatgrass	*Agropyion riparium*	root yield	28,0
Mountain bromegrass	*Bromus marginatus*	shoot yield	28,0
Western wheatgrass	*Agropyion smithii*	shoot length, root length	28,0
June grass	*Koeleria macrantha*	root yield	28,0
American sloughgrass	*Beckmannia syzigachne*	seedling emergence	24,8
Oat	*Avena sativa*	root length	48,4
Northern wheatgrass	*Agropyion dasystachyum*	root length	28,0
Bluejoint marsh reed	*Calamagrostis canadensis*	seedling emergence	16,6
Invertebrates			
Earthworm	*Eisenia andrei*	juvenile dry mass	52,5*
Springtail	*Onychirius folsomii*	juvenile production	30,9
Springtail	*Folsomia candida*	juvenile production	**15,4**

*As values for this endpoint were more than one order of magnitude apart, only a single value from the study with the highest rating (Klimisch 1) was used.

Discussion of PNEC values

The $\text{PNEC}_{\text{add, terrestrial}}$ value based on the AF method (1.54 mg B/kg dw) might result in B deficiency in plants. The risk assessment is not focused on optimal performance of crop species and should be protective for all environments, including environments with low natural boron level. A single PNEC value, only based on B toxicity for the most sensitive species in a sensitive soil, will probably be overprotective for many other situations. Therefore, more information is needed on bioavailability of both background and added B in a range of soil types since the information available (section 3.2.5.2.3) is too fragmented.

According to Guidance on IR and CSA chapter R.10, the use of the SSD approach is only allowed if data on at least 8 taxonomic groups are included. The data available for the toxicity of B on soil organisms cover 7 plant families and 2 invertebrate families. A study on soil microbial processes was submitted too late for the present evaluation and could therefore not be taken into consideration. The term “taxonomic group” set out in the Guidance Document leaves room for interpretation. Taxonomic group is indeed a broad definition, pointing to any level of classification or taxonomy (“a group or category, at any level, in a system for classifying plants or animals”) and the Guidance Document R.10 does not explicitly define the level of classification to be used. The requirements for different taxonomic groups are well defined for aquatic organisms, but not for terrestrial organisms. Moreover, the Guidance Document also states that deviations from these recommendations can be made, on a case-by-case basis, through consideration of sensitive endpoints, sensitive species, mode of toxic action and/or knowledge from structure-activity considerations.

This should be taken into account for future risk assessments under REACH.

There is a substantial difference to the $\text{PNEC}_{\text{add, terrestrial}}$ derived in the Biocides report on Boric Acid and Disodium tetraborates under Council directive 98/8/EC (rapporteur MS The Netherlands). The NOECs of the Biocides report, which are lower than the key NOEC in this dossier, were excluded from this evaluation because they were derived from studies in soils outside the 10th and 90th percentiles for European soils or were derived from studies on organoborates (where Boric Acid had no adverse effect). The PNEC derived here could be lower than the soil B concentration after application of certain fertilisers used for agricultural soils. Due to the sensitivity of certain plant species on the one hand, and the essentiality of B for plants on the other, we suggest further toxicity studies for other species as well as background concentrations.

In short, it is not possible to make conclusions on a PNEC for terrestrial organisms based on the information available at present. Further research is needed and factors to be investigated are the toxicity of boron on microbial processes and the influence of soil properties on the bioavailability and toxicity of boron to plants, invertebrates and microbial processes in soil.

7.3 Atmospheric compartment

Boron is released into the atmosphere from natural sources and by human activities. The relative contribution is unknown. According to some authors, coal-fired power plants are a major source (Cox et al., 1978; Gladney et al., 1978, both cited by Eisler, 1990). Other studies indicate that degassing of sea-salt particles and volcanic boron emissions represent almost all atmospheric boron sources and that anthropogenic sources such as coal burning and agricultural fires contribute to a minor extent (Rose et al., 2000, and citations therein). Atmospheric boron may be taken up by plants, most probably via boron enriched rain. Some evidence exists of phytotoxic effects due to direct deposition of boron via cooling tower drift from geothermal steam (Eisler, 1990). It is, however, not possible to express toxic thresholds on the basis of atmospheric concentrations.

7.4 Non compartment specific effects relevant for the food chain (secondary poisoning)

This section is not relevant as the substances are not bioaccumulative (section 8).

8 PBT AND VPVB ASSESSMENT

8.1 Assessment of PBT/vPvB properties – Comparison with criteria of Annex XIII

According to Annex XIII of REACH, criteria for the assessment of PBT and vPvB properties do not apply to inorganic substances. Therefore, the following is just an overview and a short discussion of PBT and vPvB properties of boric acid and disodium tetraborate, anhydrous.

Persistence/degradability has limited or no meaning for inorganic substances according to the Organization for Economic Cooperation and Development (OECD, 2001). Rather the substance may be transformed by normal environmental processes to either increase or decrease the availability of toxic species.

Boric acid and boron are natural inorganic substances and by definition, not degradable, meaning not subject to hydrolysis, photodegradation or biodegradation. However, boron and its inorganic compounds are subject to chemical transformation processes (adsorption, complexation, precipitation, fixation) once released to the environment.

Boron has a BCF less than 2000; nevertheless, it can accumulate in certain plant species. Boron is not biomagnified through the food chain (Howe 1998 – ex Robinson 2007), since it is readily excreted by animals.

The chronic NOEC of boron for marine or freshwater organisms is > 0.01 mg/B/L so is not considered as environmentally of special concern. Boric acid and disodium tetraborates are included in Annex I with the 30th ATP of the Dangerous Substances Regulation (67/548/EEC) as toxic for reproduction (category 2) and were assigned risk phrases R60 and R61. Boron has not historically been considered as an endocrine disruptor, although specific evaluation has not been done in this assessment. Therefore boron is considered Toxic (T).

8.2 Conclusion of PBT and vPvB assessment

The criteria for persistency can not be assessed with the traditional endpoints as they are not relevant for inorganic substances. Boron should be considered as fulfilling the criteria for Toxicity, but not for Bioaccumulation according to the definition of Annex XIII. Therefore boron does not meet the criteria as either PBT or vPvB.

9 HUMAN EXPOSURE ASSESSMENT

9.1 Occupational exposure

9.1.1 General introduction

In the following sections, unless otherwise stated, the term exposure is used to denote personal exposure as calculated considering LEV (local exhaust ventilation), if present, but without taking into account the attenuating effects of any personal protective equipment (PPE) which might have been worn as not enough information was available to take it into account.

This occupational exposure section summarizes the important issues arising from the exposure assessment and brings together predictions from the EASE model (Version 2 for Windows; Estimation and Assessment of Substance Exposure) for a variety of exposure scenarios. This tool is a general purpose predictive model for workplace exposure assessments and essentially a series of decision trees. For any substance, the system asks a number of questions about the physical properties of the substance and the circumstances of its use. For most questions, the EASE user is given a multiple-choice list from which to select the most appropriate response. Once all the questions have been answered, the exposure prediction is determined absolutely by the choices made. It can be used to estimate inhalation- and dermal exposure. Due to the manner of the described tasks dermal exposure is assessed as the potential exposure rate to the hands, face and upper surface of the forearms as maximum exposed skin surface (960 cm^2, Guidance on IR and CSA, chapter R.14, table R. 14-4). The output ranges generated by EASE for inhalation exposure relate to steady-state conditions, and estimate the average concentration of the substance in the atmosphere over the period of exposure.

In addition to using EASE to estimate exposure, the ECETOC model for inhalation and the RISKOFDERM model for dermal exposure were considered. These models are recommended for use in estimating occupational exposure in the REACH document published on the ECHA website (Guidance on information requirements and chemical safety assessment Chapter R14: Occupational Exposure Estimation). However, according to the ECETOC model, the substances will require a Tier 2 risk assessment, so has not been used in this draft. The RISKOFDERM model did not have appropriate data for all the scenarios considered here, so for the sake of consistency in this draft, the RISKOFDERM model has not been used.

Occupational exposure information has been made available by the manufacturers/importers (M/I) and users of boric acid and disodium tetraborates. Information on the manufacturers of boric acid and disodium tetraborates has been collated from visits to four of the five sites in Europe. There have been 96 submissions of data from downstream users, in the form of completed questionnaires, detailing information about the use of boric acid and disodium tetraborates, including quantities, handling and production methods (EBA 2008b). This information has been used to inform the scenarios developed in this exposure assessment. There are no exposure data available at the moment.

9.1.2 Overview of exposure

Boric acid and the anhydrous, pentahydrate and the decahydrate species of disodium tetraborate are solids at room temperature and are used as bulk material or as solutions in industry. Occupational exposure may occur during their production and in a wide variety of industries as described in chapter 2 “Manufacture and uses”. These industries account for more than 95% of the use of borates in the European Union.

Due to their use as solids (powder) inhalation of boric acid and borate dust is the predominant route of exposure during their usage and manufacture within the described industries.

Oral exposure is not considered to be a significant route of exposure under normal working practices. Amounts ingested are considered to be dependent on personal factors, upon effective supervision and provision of hygiene facilities, but are likely to be insignificant in comparison to inhalation and dermal exposure routes. According to Chapter R. 14 of the REACH guidance document, “Ingestion exposure is therefore generally not considered further in the assessment of workplace exposure.”

Descriptions of the processes and sources of occupational exposure are discussed below along with a discussion of exposure levels.

This section has been organized so that common sources of exposure across the different industries are considered together, rather than each industry being considered separately. So, for example, where discharging bulk bags is a source of exposure, this is considered across all industries. Where exposure controls or other parameters differ significantly, more than one risk assessment scenario is considered. In addition, where appropriate, exposure scenarios for mixed sources of exposure have been developed. For example, where exposure arises from a number of different activities throughout the course of a working day, exposure scenarios for “typical” working days have been developed, using the information supplied by the M/I and downstream users.

9.1.3 Summary of existing legal requirements

There is no Community occupational exposure limit for boric acid and disodium tetraborates [5], however, several European Member States have their own OELs (Table 9.1)[6]

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[5] http://ec.europa.eu/employment_social/health_safety/docs/ioelvs_en.pdf

Table 9.1: OELs of Member States of the EU

Country / Organisation	8-hr TWA OEL (mg/m^3)		Reference
	Boric acid	Disodium tetraborates	
Belgium	2	2 (all hydrates)	Belgium 2007
Denmark	-	1 (anhydrous) 2 (decahydrate) 1 (pentahydrate)	Denmark 2008
France	-	1 (anhydrous) 5 (decahydrate)	France 2008
Germany - AGS	2.6 (0.5 mg B/m^3)	2.1 (anhydrous) 4 (decahydrate) 3 (pentahydrate)	Germany 2007
Greece	-	10 (anhydrous) 10 (decahydrate)	Greece 2001
Ireland	-	1 (anhydrous) 5 (decahydrate)	Ireland 2007
Italy	2		Italy 2008
Portugal	-	1 (anhydrous) 5 (decahydrate)	Portugal 2004
Spain - INSHT	-	1 (anhydrous) 5 (decahydrate) 1 (pentahydrate)	Spain 2006
Sweden	-	2 (decahydrate)	Sweden 2007
UK - HSE	-	1 (anhydrous) 5 (decahydrate) 1 (pentahydrate)	UK 2005

References:

Belgium 2007	Moniteur Belge number 170, 7 June 2007
Denmark 2008	Danish Working Environment Authority, Arbejdstilsynet. Graensevaerdier for stoffer og materialer (Exposure Limit Values for Substances and Materials), Ann. 3.4, 3.4.2 and 3.5, 28 Mar 2008
France 2008	Threshold Limit Values (VLEP) for Occupational Exposure to Chemicals in France, INRS, 10 Jan 2008
Germany 2007	TRGS 900 Arbeitsplatzgrenzwerte, Dezember 2007
Greece 2001	Decree No. 90/1999, as amended by Decree No. 339/2001, 9 October 2001
Ireland 2007	Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations

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[6] NIOSH and ACGIH have recommended occupational exposure limits for borates. The NIOSH Recommended Exposure Level (REL) time-weighted average concentration for up to a 10-hour (10-hour TWA) workday for sodium tetraborate anhydrous and pentahydrate is 1 mg/m^3, and for decahydrate is 5 mg/m^3. OSHA, the regulatory body within the United States of America which sets occupational exposure limits does not have permissible exposure limits (PELs) for borates. ACGIH recommend a TLV–TWA of 2 mg/m^3 for all forms of disodium tetraborate and boric acid.

Italy 2005	Legislative Decree n. 626, 19 Sep 1994, as updated through ACGIH 2008 and Legislative Decree n. 81 of 9 April 2008
Portugal 2004	Np 1796-2004, Valores limite de exposicao (VLEs) professional a agents quimicos, 3rd Edition, June 2004
Spain 2006	http://www.mtas.es/insht/en/practice/vla1_en.htm
Sweden 2007	National Board of Occupational Safety and Health, Occupational Exposure Limit Values (APS 2007:2)
UK 2005	Health and Safety Executive (HSE). EH40/2005. Occupational Exposure Limits 2005. Sudbury (Suffolk), UK: HSE Books, 2005:16

2007 TLVs and BEIs: Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. ACGIH, Cincinnati, OH.

Throughout the exposure scenarios, in order to establish exposure ranges for boron, conversion factors have been applied to the estimation of inhalation and dermal exposure ranges predicted using EASE as detailed in Table 9.2 below.

Table 9.2: Conversion factors used for each of the substances for boron content.

Substance	**Chemical formula**	**Conversion factor for equivalent dose of B**
Boric acid	H_3BO_3	0.1748
Disodium tetraborate anhydrous	$Na_2B_4O_7$	0.2149
Disodium tetraborate pentahydrate	$Na_2B_4O_7 \bullet 5H_2O$	0.1484
Disodium tetraborate decahydrate	$Na_2B_4O_7 \bullet 10H_2O$	0.1134

9.1.4 Summary of effectiveness of the implemented risk management measures

This section will be addressed in more detail in the registration dossier under REACH.The effectiveness of the implemented risk management measures was not determined for this dossier, but the implemented RMMS were identified, if present and described for each scenario. Exposure levels were calculated with EASE- Local exhaust ventilation (LEV) was considered for inhalation exposure, if present, but gloves were not considered for dermal exposure, although they are standard equipment for most tasks and scenarios.

9.1.5 Exposure Scenarios for workers

9.1.5.1 Scenario 1: Discharging borates from a ship

This scenario is relevant to M/Is only. Ships arrive at the ports approximately once per month and take two to four days to unload. The bulk of the material (granular powder) is off-loaded using cranes with grabs. These materials include disodium tetraborate pentahydrate, disodium tetraborate anhydrous and boric acid. The disodium tetraborates or boric acid are discharged from the grabs into a hopper from where the material is moved by conveyor to one of a number of storage silos. The conveyors are covered and fitted with local exhaust ventilation (LEV). A small excavator is then placed in the hold to move material from the edges of the hold into the centre so that the crane grabs can lift it. This activity lasts about one and a half hour. Finally, the ship's hold is trimmed, either by two or three operatives who enter the hold to sweep it clean, or by using a small excavator fitted with a roller brush. It takes approximately three quarters of an hour to manually sweep a hold.

At all ports, bulk material also arrives in big bags stored in containers. The containers are lifted off the ship and the bulk bags moved by forklift trucks into a warehouse.

The main source of exposure during off-loading bulk material from ships is trimming by hand. In the absence of personal sampling data, EASE has been used to estimate inhalation and dermal exposure ranges during this activity. The parameters used for inhalation exposure were; a non-fibrous dust, dry manipulation, no LEV, and a non-readily aggregating dust. This gives an exposure range of 5-50mg.m^{-3}. This range does not take into account the use of respiratory protective equipment. An 8-hr TWA has not been calculated as it is unlikely that this activity would take place for more than about 45 minutes, and would not be the only source of exposure during a shift. The operatives wear overalls, safety glasses, gloves and FFP2 disposable filtering facepieces.

The parameters used for dermal exposure were dusty solid, non-dispersive use and direct handling with intermittent contact. The estimated exposure range for these parameters is 0.1-1mg/cm^2/day. Although this activity would only take place for approximately 45 minutes, the task would raise a lot of dust. This is why the parameter intermittent exposure has been used. It would be expected that the hands, face and upper surface would be exposed, which is given to be an area of 960cm^2, as per ECHA Guidance Chapter R. 14: Occupational Exposure Estimation. The total dermal exposure range would therefore be 96 to 960mg/day.

Tables 9.3 and 9.4 below show the equivalent inhalation and dermal exposure ranges for boron for boric acid, disodium tetraborate pentahydrate and anhydrous disodium tetraborate.

Table 9.3: Equivalent inhalation exposure to boron for boric acid, disodium tetraborate pentahydrate and disodium tetraborate anhydrous

Task	**EASE inhalation exposure range (total inhalable dust) [mg/m^3]**	**Equivalent exposure to boron for boric acid [mgB/m^3]**	**Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]**	**Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]**
Trimming ship by hand	5-50	0.88 – 8.75	0.74 – 7.4	1.08 – 10.75

Table 9.4 Equivalent dermal exposure to boron for the different substances applicable to this scenario

Task	**EASE dermal exposure range [mg/cm^2/day] (mg/day)**	**Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for anhydrous disodium tetraborate [mgB/cm^2/day] (mgB/day)**
Trimming ship by hand	0.1-1 (96 – 960)	0.02 – 0.18 (16.8 – 168)	0.015 – 0.15 (14.2 – 142)	0.022 – 0.22 (20.64 – 206.4)

Values taken forward to risk characterisation

The reasonable worst case inhalation values are taken to be the highest EASE value, adjusted for boron content for each of the relevant substances in the absence of any personal sampling data. The highest value has been used as the operatives are working in a relatively confined space and there are no controls (apart from respiratory protective equipment) and sweeping is known to generate relatively high levels of airborne dust. The typical exposure values taken forward for risk characterisation are the boron equivalents of the midpoint of the EASE range, as it is known that exposure will be significant during sweeping activities. See Table 9.5 below.

Table 9.5: RWC and typical exposure values for the different substances relevant to this scenario

	EASE inhalation exposure (total inhalable dust) [mg/m^3]	**Equivalent exposure to boron for boric acid [mgB/m^3]**	**Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]**	**Equivalent exposure to boron for anhydrous disodium tetraborate [mgB/m^3]**
RWC	50	8.75	7.4	10.75
Typical	27.5	4.81	4.07	5.91

The reasonable worst case dermal exposure value is taken to be the highest value for the boron equivalents to the highest EASE value and assuming an exposure area of 960cm^2. These are precautionary figures, but the sweeping occurs in a relatively confined space, so high airborne concentrations are likely and this will have an effect on the deposition of dust on skin. The typical dermal exposure values, taken forward for risk characterisation are the boron equivalents to the midpoint of the EASE range. Again, these are precautionary figures, as there were no sampling data available. See Table 9.6 below.

Table 9.6: RWC and typical dermal exposure values for the different substances relevant to this scenario

	EASE dermal exposure [mg/cm^2/day] (mg/day)	**Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for anhydrous disodium tetraborate [mgB/cm^2/day] (mgB/day)**
RWC	1 (960)	0.18 (168)	0.15 (142)	0.22 (206.4)
Typical	0.55 (528)	0.1 (92.4)	0.08 (78.1)	0.12 (113.5)

9.1.5.2 Scenario 2: Discharging borates from big bags

Boric acid and disodium tetraborates can be supplied in big bags (800-1200kg) and are also brought into the European Union in big bags, and following repackaging or purification and repackaging, are sold on to users. Users who receive boric acid and disodium tetraborates in big bags include the glass, glass fibre, cellulose insulation, chemical synthesis, metallurgy, soaps and detergents, fertilisers and the industrial fluids industries. Of the questionnaires received from downstream users, twenty-five reported receiving disodium tetraborates or boric acid in big bags. The majority use boric acid or disodium pentahydrate; two users received anhydrous sodium tetraborate in big bags and two received disodium tetraborate decahydrate in big bags. In the plants seen, the big bags were held on fork lift truck forks over a discharge hopper. The base is then slashed, either by hand using a knife or by sharp prongs arranged on the discharge hopper. The discharge hoppers are fitted with LEV, but in some cases is not completely effective at controlling the dust generated. This is particularly significant when the big bag is cut manually.

EASE has been used to estimate exposure ranges for inhalation and dermal exposure during this activity. The parameters used for inhalation were; a non-fibrous dust, dry manipulation, LEV, and a non-readily aggregating dust. This gives an exposure range of total inhalable particulate of 2-5mg.m^{-3} (table 9.7). This activity tends not to be carried out for long periods of time. At one M/I's site it was estimated that this activity would take about 20 minutes per day. At another M/I's site, road tankers were loaded by discharging big bags into a hopper which then discharged into the road tanker. Each road tanker would take between 20 and 40 minutes to load, with 7 to 8 tankers being loaded per day. So, in total, an operative would be exposed for up to five hours and twenty minutes. This operation is about to be discontinued as new plant is in the process of being commissioned. As these two M/I sites are not representative more information from the importing/distributing sites will be collected and evaluated. This description is meant to be a preliminary.

Of the information provided by the downstream users by questionnaire, the twenty-five users who take boric acid and or disodium tetraborates in bulk bags stated that the delivery process takes between 20 minutes and two hours. This includes discharging bulk bags into storage silos or into mixing vessels. For the purposes of this risk assessment it has been assumed that an operative would not spend longer than two hours discharging bulk bags into hoppers. The estimated range does not take into account the use of respiratory protective equipment. Nor does it take into account any exposures experienced during other tasks performed during the shift. The operatives were reported to wear overalls, gloves, safety glasses and respiratory protection. The standard of respiratory protection reported varied between P1, P2 and P3.

Table 9.7: Equivalent inhalation exposure to boron for boric acid and the disodium tetraborates

Task	EASE inhalation exposure range (total inhalable dust) [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/m^3]
Discharging borates from big bags	2 - 5	0.35 – 0.88	0.3 – 0.74	0.43 – 1.08	0.23 – 0.57

For dermal exposure, the EASE parameters used were non-dispersive use, direct handling with intermittent exposure. This results in an estimated exposure range of 0.1 to 1mg/cm^2/day (table 9.8). The parameter, intermittent exposure, indicates 2 to 10 exposure events per day. As the potential for exposure exists each time a big bag is opened, and when an empty bag is removed and disposed of, this EASE parameter describes the exposure scenario. It is assumed that the whole hands, face and upper surface would be exposed. This gives a surface area of 960cm^2 as described in the ECHA Chapter R. 14 guidance.

Table 9.8: Equivalent dermal exposure to boron for boric acid and the disodium tetraborates

Task	EASE dermal exposure range [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)
Discharging borates from big bags	0.1-1 (96 – 960)	0.02 – 0.18 (16.8 – 168)	0.015 – 0.15 (14.2 – 142)	0.02 – 0.22 (20.64 – 206.4)	0.01 – 0.11 (10.85 – 108.5)

Values taken forward to risk characterisation

The reasonable worst case inhalation values are the highest EASE value, adjusted for boron content of each of the relevant substances, in the absence of any personal sampling data. This is because in some cases the LEV was ineffective at controlling the dust when the base of the big bag was split open manually. The typical exposure values taken forward for risk characterisation are the boron equivalents of the midpoint of the EASE range . These are pragmatic values as there are no sampling data available. Using professional judgement, typical exposure won't be at the bottom of the range as the LEV is not always effective as observed during visits to M/I's sites. See Table 9.9 below.

Table 9.9: RWC and typical inhalation exposure values for the different substances relevant to this scenario

	EASE inhalation exposure (total inhalable dust) [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for anhydrous disodium tetraborate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/m^3]
RWC	5	0.88	0.74	1.08	0.57
Typical	3.5	0.61	0.52	0.75	0.40

The reasonable worst case dermal exposure value is taken to be the highest value for the boron equivalents to the highest EASE value and assuming an exposure area of 960cm^2. These are precautionary figures in the absence of sampling data. The typical dermal exposure values, taken forward for risk characterisation are the boron equivalents to the midpoint of the EASE range. Again, these are precautionary figures, as there were no sampling data available. See Table 9.10 below.

Table 9.10: RWC and typical dermal exposure values for the different substances relevant to this scenario

	EASE dermal exposure [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)
RWC	1 (960)	0.18 (168)	0.15 (142)	0.22 (206.4)	0.11 (105.6)
Typical	0.55 (528)	0.1 (92.4)	0.08 (78.1)	0.12 (113.5)	0.06 (59.7)

9.1.5.3 Scenario 3: Loading/unloading road tankers

Tanker loading will only occur at production locations distributing boric acid and disodium tetraborates to customers. Unloading of tankers occurs at both M/I and downstream user locations.

There is a variety of means by which tankers are loaded. At one site, the tanker was lined up with a discharge hopper. Big bags were then discharged into the hopper and the tanker filled. This means of loading is being discontinued due to investment in a new plant.

Tankers were also loaded from bulk storage at one site visited. The material is moved from the bulk storage by a front end loader to a hopper. The front end loader cab is air-conditioned, so the driver is not exposed during loading of the hopper. The material is then moved by conveyor from the loading hopper to a discharge hopper. The discharge point is attached to the loading point on the top of the tanker. The discharge point is served by LEV. The operator is potentially exposed when connecting and disconnecting the discharge chute to the tanker. Potentially up to 10 tankers are loaded per day by the M/I.

At most road tanker loading points, the tankers are charged from storage silos. The tank discharge chutes are attached to the road tanker loading points and are served by LEV so that dust is not released during loading. The tanker loading points are often in the open air, or in large warehouses. The material is transferred pneumatically.

Thirty-nine questionnaires from downstream users described delivery of boric acid and/or disodium tetraborates by tanker. Of these, none took delivery of the decahydrate and three took delivery of the anhydrous borate. The questionnaires were received from the glass, the glass fibre, chemical synthesis, ceramics, industrial fluids, soaps and detergents, metallurgy, fertiliser and other industries. The number of deliveries varied from one tanker delivery per month to three or four per day. All the downstream users stated that overalls, gloves and safety glasses were mandatory. Most also stated that respiratory protection was available (varied from P1 to P3), but it was not always described as a mandatory requirement. The whole delivery process was described by the downstream users as taking between one and two hours per tanker. However, the points of potential exposure were connecting and disconnecting the pipework, taking quality control samples, and in some cases, sweeping or vacuuming of spillages if they occurred (cleaning is discussed in Scenario 8). Whether deliveries are taken from bulk tankers, big bags or 25kg bags, most questionnaires from downstream users stated that they took a small sample for quality control purposes. These samples were kept for a certain period of time in case of a faulty batch of material. Although most of the questionnaires returned did not go into detail about the way in which samples were taken, it is usual for a small sample to be scooped from the tanker, big bag, or for a 25kg bag to be opened and some product scooped out. This activity would occur once before delivery commenced, and would not generate much, if any airborne dust. There would be an opportunity for some dermal exposure, particularly to the hands. It is not anticipated that dermal exposure would occur to the arms, or to the face due to deposition of airborne dust for the reasons stated above.

EASE has been used to determine inhalation and dermal exposure ranges during tanker loading activities. For inhalation exposure, the parameters used were non-fibrous dust, dry manipulation, LEV and not-readily aggregating powder. This gives an exposure range of 2 to 5 mg.m^{-3}. It is anticipated that exposure would be at the bottom of this range, or lower, given the description of the activity above. The only point at which any exposure might occur would be at the connection and disconnection of the charging chute, which would take approximately 1 minute each time as apart from the coupling, the process is enclosed and automatic. Assuming that an average of 10 road tankers per day would be filled, exposure could occur for 20 minutes per day. This is more than would occur at downstream user locations, where the maximum number of tankers was three per day.

Table 9.11: Equivalent inhalation exposure to boron for boric acid, disodium tetraborate pentahydrate and anhydrous disodium tetraborate

Task	**EASE inhalation exposure range (total inhalable dust) [mg/m^3]**	**Equivalent exposure to boron for boric acid [mgB/m^3]**	**Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]**	**Equivalent exposure to boron for anhydrous disodium tetraborate [mgB/m^3]**
Loading/unloading road tankers	2 - 5	0.35 – 0.88	0.3 – 0.74	0.43 – 1.08

The potential for dermal exposure at the M/I's arises when the discharge chute is connected or disconnected from the tanker. At the downstream users' the exposure would occur at the coupling and decoupling of the tanker's connecting pipework. This activity would take place up to ten times a day for M/I and from once a month to three times per day for downstream users. For dermal exposure, the parameters used were non-dispersive use, direct handling with intermittent exposure. This gives an exposure range of 0.1-1 mg/cm^2/day. However, the opportunity for exposure is limited as the discharge chute or pipework is fitted directly to the tanker, so the system is enclosed, so surface contamination would be controlled. It is estimated therefore that dermal exposure would be at the lower end of the predicted range. Given the restricted opportunity for dermal exposure, the potential surface area used is 960cm^2 as described in the ECHA Chapter R. 14 guidance.

Table 9.12: Equivalent dermal exposure to boron for boric acid, disodium tetraborate pentahydrate and disodium tetraborate anhydous

Task	**EASE dermal exposure range [mg/cm^2/day] (mg/day)**	**Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)**
Loading/unloading road tankers	0.1-1 (96 – 960)	0.02 – 0.18 (16.8 – 168)	0.015 – 0.15 (14.2 – 142)	0.02 – 0.22 (20.6 – 206.3)

Values taken forward to risk characterisation

The reasonable worst case inhalation exposure values are taken to be the boron equivalents for each relevant substance for this scenario for the midpoint of the EASE range. There are no sampling data available, but the practices seen indicate good control, as apart from coupling and decoupling, the transfer takes place in an enclosed system, and therefore exposure will generally be low. The values taken forward for typical exposure are those boron equivalents for the lowest value of the EASE range. It is a pragmatic value based on professional judgement of the M/I activities seen, and the thirty-nine questionnaires from downstream users.

Table 9.13: RWC and typical inhalation exposure values for the different substances relevant to this scenario

	EASE inhalation exposure (total inhalable dust) [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]
RWC	3.5	0.61	0.52	0.75
Typical	2	0.35	0.30	0.42

The reasonable worst case dermal exposure values are taken to be the boron equivalents for the midpoint of the predicted EASE range, with an estimated exposure area of 960cm^2. The typical dermal exposure values are boron content for the relevant borate substances equivalent to the lowest value in the predicted EASE range, as control is generally good.

Table 9.14: RWC and typical dermal exposure values for the different substances relevant to this scenario

	EASE dermal exposure [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)
RWC	0.55 (528)	0.1 (92.4)	0.08 (78.1)	0.12 (113.5)
Typical	0.1 (96)	0.02 (16.8)	0.015 (14.2)	0.02 (20.63)

9.1.5.4 Scenario 4: Packaging boric acid and disodium tetraborates into big bags (1- 1.5 tonne bags)

Again, this activity will be restricted to the production facilities of the M/I.

Generally, bulk bags are positioned beneath charging chutes. The neck of the bag is tied to the discharge chute and a pre-determined weight of borate is delivered to the bag. The discharge chute is served by LEV, so dust should not escape during filling. The operative will untie the neck of the bag, retie and then remove the bag using a fork lift truck and place it in storage. The effectiveness of the LEV varied from plant to plant. At some plants, some visible dust was seen escaping from the neck of the bag during loading, while at others, control was excellent.

EASE has been used to determine inhalation and exposure ranges during bulk bag loading activities. The parameters used to estimate the inhalation exposure range were non-fibrous dust, dry manipulation, LEV and not-readily aggregating powder. This gives an exposure range of 2 to 5mg.m^{-3}. The amount of time spent charging big bags varies, but on average, operatives would not spend more than half a day at a time on this activity, and would not usually carry out this activity every day. Although the effectiveness of the LEV was variable, it is not considered appropriate to use the EASE scenario of no LEV, as this would over-estimate the potential exposure. Therefore the highest value of the estimated range using the EASE scenario with LEV will be used to estimate exposure for the reasonable worst case exposure. Table 9.15 below shows the calculated boron equivalent exposure ranges for the different borate substances.

Table 9.15: Equivalent inhalation exposure to boron for boric acid and disodium tetraborates

Task	EASE inhalation exposure range (total inhalable dust) [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for anhydrous disodium tetraborate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/m^3]
Packaging boric acid and disodium	2 - 5	0.35 – 0.88	0.3 – 0.74	0.43 – 1.08	0.23 – 0.57

tetraborates into big bags					

The parameters used to estimate a dermal exposure range were non-dispersive use, direct handling and intermittent contact. This gives an exposure range of 0.1 to 1 mg/cm^2/day. The dermal exposure will occur when tying and untying the bags to the charging chutes. It is estimated that the exposure area would be 960cm^2. In most cases the surface area exposed could be 480cm^2, as exposure is only occurring as the bags are tied and untied, so the hands would be the only area exposed. However, in cases where the LEV is not very effective there will be some deposition on the external surface of the bag, so that there is some potential for the arms to be exposed as the bags are tied. Table 9.16 below shows the calculated boron equivalent dermal exposure ranges for the different borate substances.

Table 9.16: Equivalent dermal exposure to boron for boric acid and disodium tetraborates

Task	**EASE dermal exposure range [mg/cm^2/day] (mg/day)**	**Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for anhydrous disodium tetraborate [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)**
Packaging boric acid and disodium tetraborates into big bags	0.1-1 (96 – 960)	0.02 – 0.18 (16.8 – 168)	0.015 – 0.15 (14.2 – 142)	0.02 – 0.22 (20.64 – 206.4)	0.01 – 0.11 (10.85 – 108.5)

Values taken forward to risk characterisation

Given that at some sites the LEV was not completely effective, the inhalation value taken forward for risk characterisation for the reasonable worst case scenario is 5mg.m^{-3}. This is the highest value of the EASE range. The value taken forward for typical inhalation exposure is 3.5mg.m^{-3}. This is the middle of the EASE range and is a pragmatic value, as there are no sampling data available. It does however, take into account that there would be a range of exposures depending on the effectiveness of the LEV. If all LEV had been seen to be effective the estimated typical exposure value would have been lower than the midpoint of the EASE range.

Table 9.17: RWC and typical inhalation exposures for boric acid and disodium tetraborates

	EASE inhalation exposure (total inhalable dust) [mg/m^3]	**Equivalent exposure to boron for boric acid [mgB/m^3]**	**Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]**	**Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]**	**Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/m^3]**
RWC	5	0.88	0.74	1.08	0.57
Typical	3.5	0.61	0.52	0.75	0.4

The reasonable worst case dermal exposure value is estimated to be the highest EASE value of 1mg/cm^2/day. Using an exposure area of 960cm^2, the reasonable worst case exposure value taken forward to risk characterisation is 960mg/day.

The typical dermal exposure value is estimated to be at the low end of the EASE range, at 96mg/day (0.1/cm^2/day). The lower end of the range is taken forward, as the effect of ineffective LEV is taken into account by the use of the larger surface area exposed than would be the case when the LEV is effective.

Table 9.18: RWC and typical dermal exposures for boric acid and disodium tetraborates

	EASE dermal exposure range [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)
RWC	1 (960)	0.18 (168)	0.15 (142)	0.22 (206.4)	0.11 (108.5)
Typical	0.1 (96)	0.02 (16.8)	0.015 (14.2)	0.02 (20.64)	0.01 (10.85)

9.1.5.5 Scenario 5: Packaging borates into 25kg bags

The packaging of boric acid and disodium tetraborates into 25kg bags will only take place in the producers' plants. The plants vary from plants where the bagging is completely automatic and enclosed, to others where the bagging operations are partially automated, served by LEV, but are not enclosed. Very few of the downstream users reported packaging product into 25kg bags. Obviously, the concentration of boric acid or disodium tetraborates would be lower in these products than the pure material. Industrial fluids are packaged into drums or other containers and this is considered in Scenario 9. Cleaning is considered within Scenario 10.

Six packaging plants for 25kg bags were seen at four sites in Europe. Three plants were completely automated with no contact by operatives unless the plant was being cleaned. The other three plants were partially automated, but an operator was required at the bagging point to position the bags and remove them when filled. These plants were all served by LEV. Exposure may occur at the bagging point, and also when loading pallets manually, if there is dust on the outside of the bags, or if there are slight leaks in the bags as they are loaded onto the pallet. Boric acid, disodium tetraborate pentahydrate, disodium tetraborate decahydrate and anhydrous disodium tetraborate are all packaged in 25kg bags, with boric acid and disodium tetraborate pentahydrate making up approximately 90% of the total.

The operatives wore overalls, safety glasses and gloves. Some operatives wore FFP2 or FFP3 disposable filtering facepieces.

EASE has been used to determine inhalation and dermal exposure ranges during bagging of 25kg bags at bagging plants where there are tasks carried out by the operative. The parameters used to estimate an inhalation exposure range were non-fibrous dust, dry manipulation, LEV and not-readily aggregating powder. This gives an exposure range of 2 to 5mg.m^{-3}. At most production sites, the bagging is carried out for a few hours per day, but not necessarily every day, depending on demand for the various products. Table 9.19 below shows the calculated boron equivalent exposure ranges for the different borate substances.

Table 9.19: Equivalent inhalation exposure to boron for boric acid and disodium tetraborates

Task	EASE inhalation exposure range (total inhalable dust) [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/m^3]
Packaging boric acid and disodium tetraborates into 25kg bags	2 - 5	0.35 – 0.88	0.3 – 0.74	0.43 – 1.08	0.23 – 0.57

The parameters used to estimate an exposure range for dermal exposure were, non-dispersive use, direct handling with intermittent contact. This is because despite the presence of LEV to control dust emissions during the bagging process, there is often some dust which escapes when the bag is taken off the charging point. This will then contaminate the outside of the bag, and also the conveyor belt to the palletising station, if there is one. The estimated range for dermal exposure is 0.1-1mg/cm^2/day. It is estimated that the exposure area would be 960cm^2, which includes the face, hands and forearms. Table 9.20 below shows the calculated boron equivalent dermal exposure ranges for the different borate substances.

Table 9.20: Equivalent dermal exposure to boron for boric acid and disodium tetraborates

Task	EASE dermal exposure range [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)
Packaging boric acid and disodium tetraborates into 25kg bags	0.1-1 (96 – 960)	0.02 – 0.18 (16.8 – 168)	0.015 – 0.15 (14.2 – 142)	0.02 – 0.22 (20.64 – 206.4)	0.01 – 0.11 (10.85 – 108.5)

Values taken forward to risk characterisation

The range of bagging equipment available was variable. In order to take the variability into account, it is felt that the reasonable worst case inhalation exposure values would be equivalent to 90% of the highest EASE value which is 4.5mg.m^{-3}. The 90% value was taken, as all the plants had LEV which was at least partially, if not fully effective. Most exposure occurred as the bag was taken off the charging point. The values taken forward for typical inhalation exposure are equivalent to the value in the middle of the EASE range and are taken forward as pragmatic values as there are no sampling data currently available. See Table 9.21.

Table 9.21 RWC and typical inhalation exposures for boric acid and the disodium tetraborates

	EASE inhalation exposure (total inhalable dust) [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/m^3]
RWC	4.5	0.79	0.67	0.97	0.51
Typical	3.5	0.61	0.52	0.75	0.4

The reasonable worst case dermal exposure values have been estimated using a value of 90% of the top of the range predicted using EASE, that is, 0.9mg/cm^2/day, with an exposure area of 960cm^2. The typical dermal exposure value has been taken as the midpoint value from the range predicted using EASE, at 0.55mg/cm^2/day. With an exposure area of 960cm^2, this gives a typical dermal exposure value of 528mg/day. See Table 9.22.

Table 9.22: RWC and typical dermal exposures for boric acid and disodium tetraborates

	EASE dermal exposure [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)
RWC	0.9 (864)	0.16 (151.2)	0.13 (127.9)	0.19 (185.8)	0.1 (97.6)
Typical	0.55 (528)	0.10 (92.4)	0.08 (78.1)	0.12 (113.5)	0.06 (59.7)

9.1.5.6 Scenario 6: Discharging 25 kg bags or similar

The vast majority of users receive boric acid and disodium tetraborates, in part, at least, in 25kg bags. The bags are convenient to lift manually, and for users who only use small quantities at a time, they are a necessity. There were approximately seventy-five questionnaires returned from downstream users who take boric acid and/or disodium tetraborates in 25kg bags. These industries included glass, fibre glass, industrial fluid, metallurgy, refractory, industrial cleaning, ceramic frits and enamels, chemical synthesis, fertilisers, soap and detergents, adhesives and other industries.

This scenario covers the manual slitting of the sack and adding to a mixing vessel of some sort. It is unlikely that anyone would be carrying out this type of activity for a whole shift. The questionnaires indicated a range of task durations, from 1 minute to two hours, although for the longer times it is thought they may be referring to the entire batch-making process, not just the emptying of sacks. Sacks are more likely to be opened in batches to match the production requirements. These batch mixes may take place several times per day, depending on the needs of production. Again the frequency of the task varies widely from once per year to eight times per day. Almost all the questionnaires stated that there was LEV on the mixing vessels into which the boric acid or disodium tetraborates were being poured. The efficacy of the LEV serving the vessels will be variable, although there was no information available. Almost every questionnaire stated that workers wore overalls, gloves and safety glasses. In some cases, P2 or P3 respirators were available, and two mentioned the use of powered air helmets.

Most downstream users use whole 25kg bags to make up the mixtures in their mixing vessels. However, some use small quantities of material, or use whole and part bags, the part bags needing weighing before addition. Quantities varied from a few grams added to several kilos. The task was described generally as scooping material from a 25kg bag onto a balance from where it was poured into a container for addition to the mixer. In some cases the weighing took place next to the mixing vessel, in others in a separate area. One described the weighing area as served by LEV. It was not clear whether there was LEV present at other weighing areas. Weighing and mixing were generally reported as part of the same task, so it is not clear precisely how much time is spent weighing boric acid or disodium tetraborates. However, it is not considered to be a lengthy task as the quantities being weighed are small, and it is mostly those using borates infrequently and in small quantities that have to weigh the quantities to be added to the mixing vessel. It is estimated that the weighing of the boric acid or disodium tetraborates would not take more than 5 minutes per batch.

EASE has been used to determine inhalation and dermal exposure ranges during the discharge of the sacks into the vessel. The parameters used for inhalation exposure were non-fibrous dust, dry manipulation, LEV and not-readily aggregating powder. This gives an exposure range of 2 to 5mg.m^{-3}. Table 9.23 gives the equivalent inhalation exposure ranges to boron for boric acid and the disodium tetraborates.

Table 9.23: Equivalent inhalation exposure to boron for boric acid and disodium tetraborates

Task	EASE inhalation exposure range (total inhalable dust) [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/m^3]
Discharging 25kg bags or similar	2 - 5	0.35 – 0.88	0.3 – 0.74	0.43 – 1.08	0.23 – 0.57

Dermal exposure may occur during the slitting of the sack, weighing of material from the sack, and also during the disposal of the sack, the outside surface of which may become contaminated during discharge. The presence of effective LEV will have an effect in controlling dermal exposure as it will help to control surface contamination of the mixing vessel. To estimate a dermal exposure range, the parameters used were direct handling, non-dispersive use and intermittent contact. The range estimated using EASE was 0.1 to 1mg/cm^2/day. The area exposed will be 960cm^2 as the sacks are being manually lifted and emptied into the mixing vessels, giving the opportunity for dermal exposure to occur to hands, face and part of the arms.

Table 9.24 gives the equivalent dermal exposure ranges to boron for boric acid and the disodium tetraborates.

Table 9.24: Equivalent dermal exposure ranges to boron for boric acid and disodium tetraborates

Task	EASE dermal exposure range [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)
Discharging 25kg bags or similar	0.1-1 (96 – 960)	0.02 – 0.18 (16.8 – 168)	0.015 – 0.15 (14.2 – 142)	0.02 – 0.22 (20.64 – 206.4)	0.01 – 0.11 (10.85 – 108.5)

Values taken forward to risk characterisation

As the level of control at bag opening is variable, the values taken forward to risk characterisation for reasonable worst case are equivalent to 90 % of the highest EASE value in the range, which is 4.5mg.m^{-3}. These values were taken to take into account the likely variability in the effectiveness of the LEV on the mixing vessels, and also the varying frequencies and quantities of the Boric acid or disodium tetraborates being handled. The values taken forward for typical inhalation exposure are equivalent to the EASE value of 3.5mg^{-3}. This value is taken as the quantities and duration of this task varied widely. These are pragmatic values based on professional judgement, in the absence of any sampling data. They may be over-estimations of typical exposure, but in the absence of real data, they are cautionary values. See Table 9.25 below.

Table 9.25: RWC and typical inhalation exposure values to boron for boric acid and the disodium tetraborates

	EASE inhalation exposure [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/m^3]
RWC	4.5	0.79	0.67	0.97	0.51
Typical	3.5	0.61	0.52	0.75	0.4

The reasonable worst case dermal exposure values are estimated to be 90% of the highest EASE value. The highest value is not taken, as there is LEV present, and although not always as effective as it should be, it will have some effect in preventing dermal exposure as described above. An exposure area of 960cm^2 is assumed.

The typical dermal exposure values are estimated to be equivalent to the low end of the EASE range 0.1/cm^2/day. The operators are not directly handling the material; they are pouring it into vessels directly from the bags. The vessels have LEV, which will limit any generation of airborne dust outside the vessels, limiting deposition and surface contamination of the vessels, or direct contamination of the skin. See Table 9.26 below.

Table 9.26: RWC and typical dermal exposure values to boron for boric acid and the disodium tetraborates

	EASE dermal exposure [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)
RWC	0.9 (864)	0.16 (151.2)	0.13 (127.9)	0.19 (185.8)	0.1 (97.6)
Typical	0.55 (528)	0.1 (92.4)	0.08 (78.1)	0.12 (113.5)	0.06 (59.7)

9.1.5.7 Scenario 7: Packaging liquid products

There was little information available about packaging liquid products. The downstream user industries who manufacture liquid products for onward distribution include industrial fluids, buffer, chemical synthesis, including additives for phenol-formaldehyde resins and corrosion inhibitors, and the soap and detergent industries. Limited information on packaging these liquids were available from two metal working fluids manufacturers and the producer of corrosion inhibitors. All the processes were automated to some degree. For the MWF manufacturers, the weighing and filling of the containers was automated, but the operator had to turn the tap on and off to allow filling to take place. It was not clear whether the capping was done automatically or manually by an operator. The size of the containers varied from 5litres to 1000litres. The time taken to fill the containers varied in accordance with the size of the container, but a 1000litre container would take approximately 15 minutes to fill. The corrosion inhibitor manufacturer reported that the drumming process was completely automated.

The concentration of boric acid or disodium tetraborate was reported to be 5.4% in the metal working fluids and 2% in the corrosion inhibitor.

The operators were all reported to wear overalls, gloves and safety glasses.

The skin surface area likely to receive splashes or to contaminated through spillages is the hands, but as there is little information available, the skin surface area has been taken to be 960cm^2 which includes the hands, face and upper surface.

EASE has been used to determine potential dermal exposure, but no estimation has been made of inhalation exposure as it is not thought that there would be an aerosol generated during the filling activity, and that the only likely exposure would arise from splashes or spills of liquid during the filling process.

The EASE parameters used to estimate dermal exposure were liquid, non-dispersive use, direct handling with intermittent exposure. This gives rise to an exposure range of 0.1 to 1 mg/cm^2/day. As the concentration of boric acid or borate in the MWF was reported to be 5.4%, this exposure range is adjusted to 0.0054 to 0.054mg/cm^2/day. This has then been further adjusted to take account of boron content of the borate substance in use. The resulting exposure ranges are found in Table 9.27 below.

Table 9.27: Equivalent dermal exposure ranges for boric acid and disodium tetraborates

Task	EASE dermal exposure range [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)
Discharging 25kg bags or similar	0.0054 – 0.054 (5.18 – 51.84)	9.45×10^{-4} – 9.45×10^{-3} (0.91 – 9.07)	8×10^{-4} – 8×10^{-3} (0.77 – 7.67)	1.16×10^{-3} – 0.01 (1.1 – 11.15)	6.1×10^{-4} – 6.1×10^{-3} (0.59 – 5.86)

Values taken forward to risk characterisation

Given the lack of detailed information on packaging of liquids, the reasonable worst case dermal exposures are taken to be equivalent to the highest EASE value in the estimated range, which is 0.054 mg/cm^2/day or 51.84 mg/day. The typical dermal exposure values taken forward to risk characterisation are equivalent to the midpoint of the EASE range of 0.03mg/cm^2/day or 28.8mg/day. This is possibly an over-estimate, but in the absence of more detailed information, precautionary values have been used. These values can be found in Table 9.28 below.

Table 9.28: RWC and typical dermal exposure values to boron in boric acid and disodium tetraborates

	EASE dermal exposure [mg/cm^2/day] (mg/day)	**Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)**
RWC	0.054 (51.84)	9.45×10^{-3} (9.07)	8×10^{-3} (7.67)	0.01 (11.15)	6.1×10^{-3} (5.86)
Typical	0.03 (28.8)	5.25×10^{-3} (5.04)	4.44×10^{-3} (4.26)	6.45×10^{-3} (6.19)	3.39×10^{-3} (3.25)

9.1.5.8 Scenario 8: Cleaning

Most manufacturing plants use sweeping with brushes to clean their plants, although one plant did have a vacuum system for cleaning. On most plants visited, the plant operatives are responsible for keeping the plant clean. At one plant they had just changed their working practice so that operatives were now responsible whereas previously they had cleaners.

As the operatives clean the plant, it is unlikely that they would spend more than about 30 minutes per shift cleaning, as their priority is production. It has been assumed therefore that cleaning does not take place for more than 30 minutes per shift.

Some downstream users mentioned cleaning on the questionnaires submitted. Most stated that they used brushes or vacuum cleaners to clean up spillages that may occur during silo filling, weighing or filling mixing vessels. One mentioned using a roller brush machine in one area. Most mentioned cleaning under environmental measures if there was a spillage caused by a split bag for example. Sweeping an area at the end of a shift was a common occurrence, whereas others mentioned sweeping an area about once/week.

The downstream users generally mentioned the personal protective equipment (PPE) associated with cleaning as overalls, gloves and safety glasses, with many also specifying respiratory protective equipment (RPE). The type of RPE specified varied from P2 half-face respirators to air-powered helmets.

To take account of the different cleaning methods, EASE has been used to determine inhalation and dermal exposure during two cleaning activities; sweeping and vacuuming.

Sweeping

The EASE parameters used for inhalation exposure were non-fibrous dust, dry manipulation, not readily aggregating, without LEV. This gives an estimated inhalation exposure range for total inhalable particulate of 5 to 50mg.m^{-3}. Table 9.29 gives the equivalent boron inhalation exposure ranges for boric acid and the disodium tetraborates.

Table 9.29: Equivalent boron inhalation exposure ranges for boric acid and the disodium tetraborates

Task	EASE inhalation exposure range (total inhalable dust) [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]
Sweeping	5-50	0.88 – 8.75	0.74 – 7.4	1.08 – 10.75

The parameters used for dermal exposure were dusty solid, non-dispersive use, direct handling with intermittent contact. The estimated dermal exposure range for total inhalable particulate for these parameters is 0.1-1mg/cm^2/day. It is assumed that the hands, face and upper surface would be exposed, so the exposed area would be 960cm^2. The total dermal exposure range would therefore be 96 to 960mg/day. However, direct contact with the boric acid or disodium tetraborates is only likely to occur to the hands, when shovelling the swept material up. Deposition on the skin's surface from airborne dust will occur, but is likely to be limited as the task is relatively short duration and only small quantities will be swept up. Table 9.30 gives the equivalent boron dermal exposure ranges for boric acid and disodium tetraborates.

Table 9.30: Equivalent boron dermal exposure ranges for boric acid and the disodium tetraborates

Task	EASE dermal exposure range [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)
Sweeping	0.1-1 (96 – 960)	0.02 – 0.18 (16.8 – 168)	0.015 – 0.15 (14.2 – 142)	0.02 – 0.22 (20.64 – 206.4)	0.01 – 0.11 (10.85 – 108.5)

Vacuuming

The EASE parameters used for inhalation exposure were non-fibrous dust, dry manipulation, not readily aggregating, with LEV. This gives an estimated exposure range of 2-5mg/m^3. This is considered to be an overestimation, as it is very unlikely that any significant dust will become airborne due to the nature of the activity. An alternative range of 0 to 0.5mg/m^3 is suggested on the basis of knowledge of the process. Table 9.31 gives the equivalent boron inhalation exposure ranges for boric acid and disodium tetraborates.

Table 9.31: Equivalent boron inhalation exposure ranges for boric acid and disodium tetraborates

Task	EASE inhalation exposure range (total inhalable dust) [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/m^3]
Sweeping	0 -0.5	0 – 0.09	0 – 0.07	0 – 0.11	0 – 0.06

The parameters used to estimate dermal exposure were dusty solid, non-dispersive use, direct handling and incidental contact. This gives an estimated dermal exposure range of 0-0.1mg/cm^2/day. As the dust on the floor is being removed directly by suction, it is very unlikely that there will be any surface deposition from airborne dust, so it is predicted that dermal exposure will be very low.

Values taken forward to risk characterisation

Sweeping

There are no controls (apart from PPE) associated with sweeping dust; however it is unlikely that exposures as high as 50mg/m^3 will be obtained as in the majority of cases, the amounts being swept up will be small. In this case, the equivalent of 90% of the highest value from the EASE range has been used to provide reasonable worst case inhalation exposures for risk characterisation. The EASE value is 45mg.m^{-3}. The typical inhalation exposure values have been taken as equivalent to the EASE value of 10mg.m^{-3}. This is a pragmatic value based on the descriptions of the cleaning activities and professional judgement, in the absence of any sampling data. The quantities being swept will be small and in some cases in limited areas, for example, around the loading point to a mixing vessel or in the vicinity of the weighing area. It is unlikely therefore that airborne dust concentrations would typically exceed 10mg/m^3. See Table 9.32 below.

Table 9.32: RWC and typical inhalation exposure values for boron for boric acid and the disodium tetraborates

	EASE inhalation exposure [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/m^3]
RWC	45	7.9	6.7	9.7	5.1
Typical	10	1.75	1.48	2.15	1.13

The reasonable worst case values taken forward to risk characterisation for dermal exposure are based on 90% of the highest value in the EASE estimation, 0.9mg/cm^2/day, and an exposure area of 960cm^2. The typical exposure values are estimated on the limited direct handling of the material and the lower airborne dust concentration estimated. The typical exposure values taken forward to risk characterisation are based on 0.2mg/cm^2/day and a skin exposure of 960 cm^2. See Table 9.33 below.

Table 9.33: RWC and typical dermal exposure values for boron form boric acid and the disodium tetraborates

	EASE dermal exposure range [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)
RWC	0.9 (864)	0.16 (151.2)	0.13 (127.9)	0.19 (185.8)	0.1 (97.6)
Typical	0.2 (192)	0.04 (33.6)	0.03 (28.4)	0.04 (41.28)	0.02 (21.7)

Vacuuming

Based on the estimated exposure range, the reasonable worst case inhalation exposure values taken forward to risk characterisation are equivalent to the EASE estimate of 0.5mg.m^3.The typical inhalation values taken forward for risk characterisation are equivalent to the EASE estimate of 0.1mg.m^3 as it is unlikely that much if any dust will become airborne during vacuuming, as described in the discussion above. See Table 9.34 below.

Table 9.34: RWC and typical inhalation values for boron for boric acid and disodium tetraborates

	EASE inhalation exposure (total inhalable dust) [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/m^3]
RWC	0.5	0.09	0.07	0.11	0.06
Typical	0.1	0.02	0.015	0.02	0.01

The reasonable worst case values taken forward to risk characterisation for dermal exposure are equivalent to 0.09mg/cm^2/day, which is 90% of the highest EASE value of the estimated range. The typical dermal exposure values taken forward to risk characterisation are equivalent to 0.01mg/cm^2/day, which is almost the lowest point on the EASE range estimated. This value is used as there is little likelihood of airborne dust being generated during vacuuming, so little opportunity for deposition of the material on the skin, and there is unlikely to be much, if any, direct contact with the boric acid or disodium tetraborates as it is being vacuumed up. See Table 9.35 below.

Table 9.35: RWC and typical dermal exposure values for boron for boric acid and the disosium tetraborates

	EASE dermal exposure [mg/cm^2/day] (mg/day)	**Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate anhydrous [mgB/cm^2/day] (mgB/day)**	**Equivalent exposure to boron for disodium tetraborate decahydrate [mgB/cm^2/day] (mgB/day)**
RWC	0.09 (86.4)	0.02 (15.12)	0.01 (12.79)	0.02 (18.58)	0.01 (9.76)
Typical	0.01 (9.6)	1.75×10^{-3} (1.68)	1.48×10^{-3} (1.42)	2.15×10^{-3} (2.1)	1.13×10^{-3} (1.1)

9.1.5.9 Scenario 9: Installing glass fibre insulation materials

This scenario relates to work carried out by the second tier downstream users. Although, in general this document has not covered occupational exposure to the second tier downstream users, some data did become available for this activity and it has therefore been included.

Glass wool consists principally of sodium-, calcium- and magnesium silicates but may contain smaller amount of other elements including boron. Typical boron content in glass wool is 1.5% as B, and the maximal contents will be 3.6% as B (Jensen 2007). The highest occupational exposures are likely to occur during the installation of the glass wool insulation, particularly in attics, which are usually fairly confined spaces. Workers carrying out these tasks would be carrying out insulating work every day for the majority of their work shift. Concentrations of respirable fibres were reported to be 0.05-1 fibres/cm^3 (Jensen 2007). These data were taken from the IARC monograph Vol81; Man-made Vitreous Fibres (2002) which contains a large amount of exposure data. Workers often wear work clothes or overalls that cover the arms and legs as the fibres are irritating. Workers also often wear disposable face masks (FFP1 or FFP2), again due to the irritation from inhaling fibres.

In addition, there are some data available from a paper by Breum et al. (2003), who compared inhalation exposures to respirable fibres and inhalable dust during the installation of various insulation materials, including fibre glass (MMMF). Nine personal samples for respirable fibre were taken for those installing the fibre glass insulation in attics and in walls. The range of results (95% CI) was 0.003f/ml to 0.058f/ml.

The information available from the Jensen report and the Breum paper has been supplemented by modelling using EASE. The parameters used were inhalable, fibrous dust with a low ability to become airborne, dry manipulation with no LEV. The ability to become airborne parameter of “low” was chosen despite glass fibre being stated as an example of fibres with a medium ability to become airborne in the EASE literature. This statement appears to be based on just glass fibre, not glass fibre as insulation material which is bound with binders and oils to reduce the dustiness of the product. When the ability to become airborne parameter “low” is used, the EASE estimates a range of 0-2fibres/ml, which is a similar, although broader, range to those results reported by Jensen and Breum.

The equivalent boron exposures have been calculated by using a calculated mass of a typical respirable glass fibre of 2µm diameter (2.5×10^{-13} kg, Jensen) and figures for boron content in glass fibres reported by Jensen.

The typical content was reported to be 1.5% boron while the maximum is reported to be 3.6%. These figures have been applied to the fibre concentration range 0.003 – 1f/ml.

Table 9.36 Estimated and reported respirable fibre during installation of fibre glass insulation

Task	**EASE inhalation exposure range (respirable fibres) f/ml**	**Jensen 2007 Reported exposure range (respirable fibres) f/ml**	**Breum et al Reported exposure range 95% CI (respirable fibres) f/ml**	**Equivalent exposure to boron range [mgB/m^3]**
Installing fibre glass insulation	0-2	0.05 - 1	0.003 - 0.058	1.13×10^{-5} – 0.008

Dermal exposure has not been estimated. This is because the boron is bound within the borosilicate glass fibre structure and will not be absorbed through the skin.

Values taken forward to risk characterisation

The reasonable worst case exposure for MMMF respirable fibre concentration has been taken as1 f/ml, which is the highest value reported by Jensen. The boron equivalent exposure is 0.008mgB.m^{-3}. For this reasonable worst case value, the boron content in fibre glass of 3.6% has been used.

The typical exposure value taken forward for risk characterisation for MMMF respirable fibre concentration is 0.5f/ml, the midpoint of the range. It is a pragmatic value taken on the basis of the information available. The equivalent boron exposure value is 0.002 mgB.m^{-3}. For this typical exposure, the boron content of 1.5% has been used.

Table 9.37: RWC and typical inhalation exposure values for MMMF respirable fibres, and boron in MMMF fibre

	Respirable fibre estimated exposure f/ml	**Equivalent exposure to boron mgB.m^{-3}**
RWC	1	0.008
Typical	0.5	0.002

9.1.5.10 Scenario 10: Mixed exposures for M/I

As previously mentioned, at many plants, operatives carry out more than one activity during the course of a shift. From information gathered at producers' plants, two "typical" shifts have been put together to determine what typical shift-length exposures might be. At all plants, shifts were usually 8 hours in length. As can be seen from Tables 9.38 and 9.39, there are periods of time when the operatives spend time in the control room or are working without contact with one of the substances. At these times no exposure occurs. This task appears in the table to account for the operative's time during the shift. As EASE generates dermal exposure values for an eight hour shift, default factors are applied for the calculation of worst case and typical dermal exposure to consider shorter activity durations than 8 hours and to avoid unnecessary overestimations. These exposure modifying factors are taken from Guidance on IR and CSA, chapter R.14, table R. 14-7 (table 9.38). The 8 hour dermal exposure values were calculated by summing the tasked based dermal exposure values multiplied by the exposure modifying factor from Table 9.38. It should be noted that a higher exposure estimate results when the series of tasked based exposures are summed than predicted by an 8 hour TWA. Therefore, the 8 hour dermal exposure values reported in the following are likely to overestimate the actual dermal exposures.

Tables 9.39 to 9.45 illustrate mixed exposures calculated using EASE values and the boron equivalent exposures for boric acid and disodium tetraborate pentahydrate. These two borate substances make up about 90% of all borate substances imported/manufactured in the EU. For some of the scenarios included here, anhydrous disodium tetraborate and disodium tetraborate decahydrate are not used. This is why illustrations for the boron equivalent exposures for these two substances are not included in this scenario.

Table 9.38: Modifiers for duration of activity

Duration of activity	Exposure modifying factor
> 4 hours	1
1 – 4 hours	0.6
15 mins – 1 hour	0.2
< 15 min	0.1

Table 9.39: Mixed exposure scenario 1: mixed exposure to total inhalable particulate using EASE

Task	**Duration**	**Worst case inhalation exposure mg/m^3**	**Typical Inhalation exposure mg/m^3**	**Worst case dermal exposure mg/cm^2/day**	**Typical dermal exposure mg/cm^2/day**
Discharging borates from bulk bag	1 hour	5	3.5	1	0.55
Packaging into 25 kg bags	2 hours	4.5	3.5	0.9	0.55
Loading tankers	1 hour	3.5	2	0.55	0.1
Cleaning	1 hour	45	10	0.9	0.2
Control room/ outside	3 hours	0	0	0	0
8hr TWA exposure	**8 hours**	**7.8**	**2.8**	**1.03***	**0.50***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.40: Mixed exposure scenario 1: mixed exposure to boron in boric acid using boron equivalent conversion factors

Task	**Duration**	**Worst case inhalation exposure [mg/m^3]**	**Typical Inhalation exposure [mg/m^3]**	**Worst case dermal exposure [mg/cm^2/day]**	**Typical dermal exposure [mg/cm^2/day]**
Discharging borates from bulk bag	1 hour	0.88	0.61	0.18	0.1
Packaging into 25 kg bags	2 hours	0.79	0.61	0.16	0.1
Loading tankers	1 hour	0.61	0.35	0.1	0.02
Cleaning	1 hour	7.88	1.75	0.16	0.04
Control room/ outside	3 hours	0	0	0	0
8hr TWA exposure	**8 hours**	**1.37**	**0.49**	**0.18***	**0.09***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.41: Mixed exposure scenario 1: mixed exposure to boron in disodium tetraborate pentahydrate using boron equivalent conversion factors

Task	Duration	Worst case inhalation exposure [mg/m^3]	Typical Inhalation exposure [mg/m^3]	Worst case dermal exposure [mg/cm^2/day]	Typical dermal exposure [mg/cm^2/day]
Discharging borates from bulk bag	1 hour	0.74	0.52	0.15	0.08
Packaging into 25 kg bags	2 hours	0.67	0.52	0.13	0.08
Loading tankers	1 hour	0.52	0.3	0.08	0.015
Cleaning	1 hour	6.67	1.48	0.13	0.03
Control room/ outside	3 hours	0	0	0	0
8hr TWA exposure	**8 hours**	**1.15**	**0.41**	**0.15***	**0.07***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.42: Mixed exposure scenario 2: mixed exposure to total inhalable particulate using EASE

Task	Duration	Worst case inhalation exposure mg/m^3	Typical Inhalation exposure mg/m^3	Worst case dermal exposure mg/cm^2/day	Typical dermal exposure mg/cm^2/day
Trimming ship	45 minutes	50	27.5	1	0.55
Packaging into 25 kg bags	3 hours	4.5	3.5	0.9	0.55
Loading tankers	2 hours	3.5	2	0.55	0.1
Cleaning	1 hour	45	10	0.9	0.2
Control room/ outside	1hour 15 minutes	0	0	0	0
8hr TWA exposure	**8 hours**	**12.9**	**5.6**	**1.25***	**0.54***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.43: Mixed exposure scenario 2: mixed exposure to boron in boric acid using boron equivalent conversion factors

Task	Duration	Worst case inhalation exposure [mg/m^3]	Typical Inhalation exposure [mg/m^3]	Worst case dermal exposure [mg/cm^2/day]	Typical dermal exposure [mg/cm^2/day]
Trimming ship	45 minutes	8.75	4.8	0.18	0.1
Packaging into 25 kg bags	3 hours	0.79	0.61	0.16	0.1
Loading tankers	2 hours	0.61	0.35	0.1	0.02
Cleaning	1 hour	7.88	1.75	0.16	0.04
Control room/ outside	1hour 15 minutes	0	0	0	0
8hr TWA exposure	**8 hours**	**2.26**	**0.98**	**0.22***	**0.1***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.44: Mixed exposure scenario 2: mixed exposure to boron in disodium tetraborate pentahydrate using boron equivalent conversion factors

Task	Duration	Worst case inhalation exposure [mg/m^3]	Typical Inhalation exposure [mg/m^3]	Worst case dermal exposure [mg/cm^2/day]	Typical dermal exposure [mg/cm^2/day]
Trimming ship	45 minutes	7.4	4.07	0.15	0.08
Packaging into 25 kg bags	3 hours	0.67	0.52	0.13	0.08
Loading tankers	2 hours	0.52	0.3	0.08	0.015
Cleaning	1 hour	6.67	1.48	0.13	0.03
Control room/ outside	1hour 15 minutes	0	0	0	0
8hr TWA exposure	**8 hours**	**1.9**	**0.83**	**0.19***	**0.08***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Values taken forward to risk characterisation

Table 9.45 below shows the reasonable worst case inhalation exposure values taken forward to risk characterisation for total inhalable particulate, boric acid and disodium tetraborate pentahydrate. These values are the estimated worst case inhalation 8-hr TWAs for "mixed exposure 2". These are the higher of the two calculated worst case exposures, but it is thought that there will be some operatives exposed to this level of exposure over the course of a shift.

The typical inhalation exposure values taken forward to risk characterisation are the typical values from "mixed exposures 1". These are the lower of the two sets of values estimated for typical exposure; they are thought to be more representative, as it does not include unloading ships, which is a relatively infrequent activity.

Table 9.45: RWC and typical inhalation exposure values for mixed exposures

	EASE inhalation exposure (total inhalable dust) [mg/m^3]	Equivalent exposure to boron for boric acid [mgB/m^3]	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/m^3]
RWC	12.9	2.26	1.9
Typical	5.6	0.98	0.83

The reasonable worst case dermal exposure values taken forward to risk characterisation are boron values equivalent to the EASE worst case exposure value from "mixed exposure 2", 1.25mg/cm^2/day or assuming an exposure area of 960cm^2, 1200mg/day.

The typical dermal exposure values taken forward to risk characterisation are the boron values equivalent to the typical EASE exposure value from "mixed exposure 1", 0.50mg/cm^2/day, or assuming an exposure area of 960cm^2, 480mg/day. Table 9.46 shows the RWC and typical dermal exposure values taken forward to risk characterisation.

Table 9.46: RWC and typical dermal exposure values for mixed exposures

	EASE dermal exposure [mg/cm^2/day] (mg/day)	Equivalent exposure to boron for boric acid [mgB/cm^2/day] (mgB/day)	Equivalent exposure to boron for disodium tetraborate pentahydrate [mgB/cm^2/day] (mgB/day)
RWC	1.25 (1200)	0.22 (211.2)	0.19 (182.4)
Typical	0.5 (480)	0.09 (86.4)	0.07 (67.2)

9.1.5.11 Scenario 11: Mixed exposure for downstream users

The following mixed scenarios are for illustration only. They indicate possible mixed exposures. However, it may be that different operatives carry out different tasks, rather than carrying out all the tasks identified. Further information about work patterns will need to be collected to refine these mixed exposure scenarios. There are likely to be periods of time when the operatives spend time in the control room or are working outside, or working with other materials. At these times no exposure will occur. These tasks appear in the table to account for the operative's time during the shift.

Borosilicate glass, fibreglass industries, glass wool insulation and ceramic frits production

A mixed exposure scenario has not been developed for the larger companies in the above industries. These industries handle boric acid and disodium tetraborates in similar ways, in that the disodium tetraborates are generally delivered by road tankers, pneumatically transferred to silos, following which the processes are completely enclosed, until the glass is formed into glassware or glass fibre, at which time there is no exposure to borates. Therefore, the only exposure likely to occur is during the coupling and decoupling of the tanker pipework during deliveries, for which a scenario has been prepared.

The following tables illustrate a mixed exposure scenario for smaller glass and ceramics companies who do not take deliveries of their boric acid or disodium tetraborates in tankers, but in big bags or 25kg bags. The operatives working for these companies may be exposed during weighing of materials and cleaning of areas around weighing and discharging areas of the plant. Once the boric acid or disodium tetraborates are in the mixing vessels there is no further opportunity for exposure as they are combined within the glass articles/frits produced.

Table 9.47 Mixed exposure for small glass, glass fibre, glass wool insulation, cellulose insulation and ceramic frits production calculated using EASE

Task	Duration	Worst case inhalation exposure [mg/m^3]	Typical Inhalation exposure [mg/m^3]	Worst case dermal exposure [mg/cm^2/day]	Typical dermal exposure [mg/cm^2/day]
Delivery of big bags	1 hour	0	0	0	0
Weighing and addition of material to mixer	6 hours	5	1	0.09	0.05
Cleaning by vacuuming	30 minutes	0.5	0.1	0.09	0.01
Other tasks (no exposure)	30 minutes	0	0	0	0
8hr TWA exposure	**8 hours**	**3.78**	**0.63**	**0.12***	**0.05***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.48: Mixed exposure to boron in boric acid for small glass, glass fibre, glass wool insulation, cellulose insulation and ceramic frits production

Task	Duration	Worst case inhalation exposure [mg/m^3]	Typical Inhalation exposure [mg/m^3]	Worst case dermal exposure [mg/cm^2/day]	Typical dermal exposure [mg/cm^2/day]
Delivery of big bags	1 hour	0	0	0	0
Weighing and addition of material to mixer	6 hours	0.88	0.18	0.02	0.01
Other tasks (no exposure)	30 minutes	0	0	0	0
Cleaning by vacuuming	30 minutes	0.09	0.02	0.02	0.002

8hr TWA exposure	**8 hours**	**0.66**	**0.11**	**0.02***	**0.01***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.49: Mixed exposure to boron in disodium tetraborate pentahydrate for small glass, glass fibre, glass wool insulation, cellulose insulation and ceramic frits production

Task	**Duration**	**Worst case inhalation exposure [mg/m^3]**	**Typical Inhalation exposure [mg/m^3]**	**Worst case dermal exposure [mg/cm^2/day]**	**Typical dermal exposure [mg/cm^2/day]**
Delivery of big bags	1 hour	0	0	0	0
Weighing and addition of material to mixer	6 hours	0.74	0.15	0.01	0.007
Cleaning by vacuuming	30 minutes	0.07	0.015	0.01	0.002
Other tasks (no exposure)	30 minutes	0	0	0	0
8hr TWA exposure	**8 hours**	**0.56**	**0.09**	**0.02***	**0.007***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.50: Mixed exposure to boron in anhydrous disodium tetraborate for small glass, glass fibre, glass wool insulation, cellulose insulation and ceramic frits production

Task	**Duration**	**Worst case inhalation exposure [mg/m^3]**	**Typical Inhalation exposure [mg/m^3]**	**Worst case dermal exposure [mg/cm^2/day]**	**Typical dermal exposure [mg/cm^2/day]**
Delivery of big bags	1 hour	0	0	0	0
Weighing and addition of material to mixer	6 hours	1.08	0.22	0.02	0.01
Cleaning by vacuuming	30 minutes	0.11	0.02	0.02	0.002
Other tasks (no exposure)	30 minutes	0	0	0	0
8hr TWA exposure	**8 hours**	**0.81**	**0.14**	**0.03***	**0.01***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.51: Mixed exposure to boron in disodium tetraborate decahydrate for small glass, glass fibre, glass wool insulation, cellulose insulation and ceramic frits production

Task	**Duration**	**Worst case inhalation exposure [mg/m^3]**	**Typical Inhalation exposure [mg/m^3]**	**Worst case dermal exposure [mg/cm^2/day]**	**Typical dermal exposure [mg/cm^2/day]**
Delivery of big bags	1 hour	0	0	0	0
Weighing and addition of material to mixer	6 hours	0.57	0.11	0.01	0.006
Cleaning by vacuuming	30 minutes	0.06	0.01	0.01	0.001
Other tasks (no exposure)	30 minutes	0	0	0	0
8hr TWA exposure	**8 hours**	**0.43**	**0.07**	**0.01***	**0.006***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Industrial Fluids

This mixed exposure is based on information relating to the production of metal working fluids for which there was most information on the questionnaires returned for this sector. It assumes a concentration of boric acid or disodium tetraborates in the final product of 5.4%.

Table 9.52 Mixed exposures in the industrial fluids industry calculated using EASE

Task	Duration	Worst case inhalation exposure [mg/m^3]	Typical Inhalation exposure [mg/m^3]	Worst case dermal exposure [mg/cm^2/day]	Typical dermal exposure [mg/cm^2/day]
Delivery of 25kg bags	1 hour	0	0	0	0
Discharging 25kg bags into mixing vessel	30 minutes	4.5	3.5	0.9	0.1
Packaging fluid into containers	1 hour	-	-	0.054	0.03
Cleaning by sweeping	30 minutes	45	10	0.9	0.2
Other tasks (no exposure)	5 hours	0	0	0	0
8hr TWA exposure	**8 hours**	**3.1**	**0.84**	**0.38***	**0.07***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.53 Mixed exposures to boron in boric acid in the industrial fluids industry

Task	Duration	Worst case inhalation exposure [mg/m^3]	Typical Inhalation exposure [mg/m^3]	Worst case dermal exposure [mg/cm^2/day]	Typical dermal exposure [mg/cm^2/day]
Delivery of 25kg bags	1 hour	0	0	0	0
Discharging 25kg bags into mixing vessel	30 minutes	0.79	0.61	0.16	0.02
Packaging fluid into containers	1 hour	-	-	0.01	0.005
Cleaning by sweeping	30 minutes	7.9	1.75	0.16	0.04
Other tasks (no exposure)	0	0	0	0	0
8hr TWA exposure	**8 hours**	**0.54**	**0.15**	**0.07***	**0.01***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.54 Mixed exposures to boron in disodium tetraborate pentahydrate in the industrial fluids industry

Task	Duration	Worst case inhalation exposure [mg/m^3]	Typical Inhalation exposure [mg/m^3]	Worst case dermal exposure [mg/cm^2/day]	Typical dermal exposure [mg/cm^2/day]
Delivery of 25kg bags	1 hour	0	0	0	0
Discharging 25kg bags into mixing vessel	30 minutes	0.67	0.52	0.13	0.015
Packaging fluid into containers	1 hour	-	-	0.008	0.004
Cleaning by sweeping	30 minutes	6.66	1.48	0.13	0.03
Other tasks (no exposure)	0	0	0	0	0

8hr TWA exposure	**8 hours**	**0.46**	**0.12**	**0.06***	**0.01***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.55 Mixed exposures to boron in anhydrous disodium tetraborate in the industrial fluids industry

Task	**Duration**	**Worst case inhalation exposure [mg/m^3]**	**Typical Inhalation exposure [mg/m^3]**	**Worst case dermal exposure [mg/cm^2/day]**	**Typical dermal exposure [mg/cm^2/day]**
Delivery of 25kg bags	1 hour	0	0	0	0
Discharging 25kg bags into mixing vessel	30 minutes	0.97	0.75	0.19	0.02
Packaging fluid into containers	1 hour	-	-	0.01	0.007
Cleaning by sweeping	30 minutes	9.7	2.15	0.19	0.04
Other tasks (no exposure)	5 hours	0	0	0	0
8hr TWA exposure	**8 hours**	**0.67**	**0.18**	**0.08***	**0.015***

* Sum of tasked based dermal exposure values * exposure modifying factor.

Table 9.56 Mixed exposures to boron in disodium tetraborate decahydrate in the industrial fluids industry

Task	**Duration**	**Worst case inhalation exposure [mg/m^3]**	**Typical Inhalation exposure [mg/m^3]**	**Worst case dermal exposure [mg/cm^2/day]**	**Typical dermal exposure [mg/cm^2/day]**
Delivery of 25kg bags	1 hour	0	0	0	0
Discharging 25kg bags into mixing vessel	30 minutes	0.51	0.4	0.1	0.01
Packaging fluid into containers	1 hour	-	-	0.006	0.004
Cleaning by sweeping	30 minutes	5.09	1.13	0.1	0.02
Other tasks (no exposure)	5 hours	0	0	0	0
8hr TWA exposure	**8 hours**	**0.35**	**0.1**	**0.05***	**0.008***

* Sum of tasked based dermal exposure values * exposure modifying factor

9.1.5.12 Summary of data for all scenarios taken forward to risk characterisation

A summary of the inhalation and dermal exposures values taken forward to risk characterisation for each scenario are presented in tables 9.57 to 9.67 below.

Table 9.57: Summary of data taken forward to risk characterisation for Scenario 1

Scenario		EASE	Boric acid	Disodium tetraborate pentahydrate	Disodium tetraborate anhydrous	Disodium tetraborate decahydrate
1. Discharging borates from ships						
Inhalation exposure [mg/m^3]	**RWC**	50	8.75	7.4	10.75	-
	Typical	27.5	4.81	4.07	5.91	-
Dermal exposure [mg/cm^2/day] (mg/day)	**RWC**	1 (960)	0.18 (168)	0.15 (142)	0.22 (206.4)	-
	Typical	0.55 (528)	0.1 (92.4)	0.08 (78.1)	0.12 (113.5)	-

Table 9.58: Summary of data taken forward to risk characterisation for Scenario 2

Scenario		EASE	Boric acid	Disodium tetraborate pentahydrate	Disodium tetraborate anhydrous	Disodium tetraborate decahydrate
2. Discharging borates from big bags						
Inhalation exposure [mg/m^3]	**RWC**	5	0.88	0.74	1.08	0.57
	Typical	3.5	0.61	0.52	0.75	0.4
Dermal exposure [mg/cm^2/day] (mg/day)	**RWC**	1 (960)	0.18 (168)	0.15 (142)	0.22 (206.4)	0.11 (105.6)
	Typical	0.55 (528)	0.1 (92.4)	0.08 (78.1)	0.12 (113.5)	0.06 (59.7)

Table 9.59: Summary of data taken forward to risk characterisation for Scenario 3

Scenario		EASE	Boric acid	Disodium tetraborate pentahydrate	Disodium tetraborate anhydrous	Disodium tetraborate decahydrate
3. Loading/unloading borates into/from tankers						
Inhalation exposure [mg/m^3]	**RWC**	3.5	0.61	0.52	0.75	-
	Typical	2	0.35	0.3	0.42	-

Dermal exposure [mg/cm^2/day] (mg/day)	**RWC**	0.55 (528)	0.1 (92.4)	0.08 (78.1)	0.12 (113.5)	-
	Typical	0.1 (96)	0.02 (16.8)	0.015 (14.2)	0.02 (20.6)	-

Table 9.60: Summary of data taken forward to risk characterisation for Scenario 4

Scenario		**EASE**	**Boric acid**	**Disodium tetraborate pentahydrate**	**Disodium tetraborate anhydrous**	**Disodium tetraborate decahydrate**
4. Packaging into big bags						
Inhalation exposure [mg/m^3]	**RWC**	5	0.88	0.74	1.08	0.57
	Typical	3.5	0.61	0.52	0.75	0.4
Dermal exposure [mg/cm^2/day] (mg/day)	**RWC**	1 (960)	0.18 (168)	0.15 (142)	0.22 (206.4)	0.11 (108.5)
	Typical	0.1 (96)	0.02 (16.8)	0.015 (14.2)	0.02 20.64	0.01 (10.85)

Table 9.61: Summary of data taken forward to risk characterisation for Scenario 5

Scenario		**EASE**	**Boric acid**	**Disodium tetraborate pentahydrate**	**Disodium tetraborate anhydrous**	**Disodium tetraborate decahydrate**
5. Packaging into 25kg bags						
Inhalation exposure [mg/m^3]	**RWC**	4.5	0.79	0.67	0.97	0.51
	Typical	3.5	0.61	0.52	0.75	0.4
Dermal exposure [mg/cm^2/day] (mg/day)	**RWC**	0.9 (864)	0.16 (151.2)	0.13 (127.9)	0.19 (185.8)	0.1 (97.6)
	Typical	0.55 (528)	0.1 (92.4)	0.08 (78.1)	0.12 (113.5)	0.06 (59.7)

Table 9.62: Summary of data taken forward to risk characterisation for Scenario 6

Scenario		**EASE**	**Boric acid**	**Disodium tetraborate pentahydrate**	**Disodium tetraborate anhydrous**	**Disodium tetraborate decahydrate**
6. Discharging 25kg bags or similar						
Inhalation exposure [mg/m^3]	**RWC**	4.5	0.79	0.67	0.97	0.51
	Typical	3.5	0.61	0.52	0.75	0.4

Dermal exposure [mg/cm^2/day] (mg/day)	**RWC**	0.9 (864)	0.16 (151.2)	0.13 (127.9)	0.19 (185.8)	0.1 (97.6)
	Typical	0.55 (528)	0.1 (92.4)	0.08 (78.1)	0.12 (113.5)	0.06 (59.7)

Table 9.63: Summary of data taken forward to risk characterisation for Scenario 7

Scenario		**EASE**	**Boric acid**	**Disodium tetraborate pentahydrate**	**Disodium tetraborate anhydrous**	**Disodium tetraborate decahydrate**
7. Packaging liquids containing borates						
Inhalation exposure [mg/m^3]	**RWC**	-	-	-	-	-
	Typical	-	-	-	-	-
Dermal exposure [mg/cm^2/day] (mg/day)	**RWC**	0.054 (51.84)	9.45x10^{-3} (9.07)	8x10^{-3} (7.67)	0.01 (11.15)	6.1x10^{-3} (5.86)
	Typical	0.03 (28.8)	5.25x10^{-3} (5.04)	4.44x10^{-3} (4.26)	6.45x10^{-3} (6.19)	3.39x10^{-3} (3.25)

Table 9.64: Summary of data taken forward to risk characterisation for Scenario 8(i)

Scenario		**EASE**	**Boric acid**	**Disodium tetraborate pentahydrate**	**Disodium tetraborate anhydrous**	**Disodium tetraborate decahydrate**
8. Cleaning (i) Sweeping						
Inhalation exposure [mg/m^3]	**RWC**	45	7.9	6.7	9.7	5.1
	Typical	10	1.75	1.48	2.15	1.13
Dermal exposure [mg/cm^2/day] (mg/day)	**RWC**	0.9 (864)	0.16 (151.2)	0.13 (127.9)	0.19 (185.8)	0.1 (97.6)
	Typical	0.2 (192)	0.04 (33.6)	0.03 (28.4)	0.04 (41.28)	0.02 (21.7)

Table 9.65: Summary of data taken forward to risk characterisation for Scenario 8(ii)

Scenario		**EASE**	**Boric acid**	**Disodium tetraborate pentahydrate**	**Disodium tetraborate anhydrous**	**Disodium tetraborate decahydrate**
8. Cleaning (ii) Vacuuming						
Inhalation exposure [mg/m^3]	**RWC**	0.5	0.09	0.07	0.11	0.06
	Typical	0.1	0.02	0.015	0.02	0.01

Dermal exposure [mg/cm^2/day] (mg/day)	**RWC**	0.09 (86.4)	0.02 (15.12)	0.01 (12.79)	0.02 (18.58)	0.01 (9.76)
	Typical	0.01 (9.6)	1.75x10^{-3} (1.68)	1.48x10^{-3} (1.42)	2.15x10^{-3} (2.1)	1.13x10^{-3} (1.1)

Table 9.66: Summary of data taken forward to risk characterisation for Scenario 9

Scenario		**Estimated from reported exposure to inhalable dust**	**Boron**			
9. Installation of glass fibre insulation						
Inhalation exposure [mg/m^3]	**RWC**	1	(0.008)	-	-	-
	Typical	0.5	(0.002)	-	-	-
Dermal exposure [mg/cm^2/day] (mg/day)	**RWC**	-	-	-	-	-
	Typical	-	-	-	-	-

Table 9.67: Summary of data taken forward to risk characterisation for Scenario 10

Scenario		**EASE**	**Boric acid**	**Disodium tetraborate pentahydrate**	**Disodium tetraborate anhydrous**	**Disodium tetraborate decahydrate**
10. Mixed exposure scenario for M/Is						
Inhalation exposure [mg/m^3]	**RWC**	12.9	2.26	1.9	-	-
	Typical	5.6	0.98	0.83	-	-
Dermal exposure [mg/cm^2/day] (mg/day)	**RWC**	1.25 (1200)	0.22 (211.2)	0.19 (182.4)	-	-
	Typical	0.5 (480)	0.09 (86.4)	0.07 (67.2)	-	-

The described tasks present the current knowledge of occupational activities for which exposure from boric acid and sodium tetraborates to workers is likely to occur. The other steps of the processes done within these industries like mixing, melting of glass, glass forming etc. take place in closed systems without the presence of workers. Therefore significant exposure to humans is unlikely. If any of these process steps reveal a potential exposure to humans despite the previous assumption, these tasks and respective scenarios will be added in the registration dossier. Please note that there are no tables for boron equivalent exposures for anhydrous disodium tetraborate and disodium tetraborate decahydrate for the M/I mixed exposure scenarios for Scenario 10. This is because some of the tasks included are not carried out for these two substances, so an estimation of exposure to these two substances was not appropriate. Please also note that the mixed exposure scenarios included in Scenario 11 were for illustrative purposes only, as there is currently insufficient information to take the mixed scenarios forward for risk characterisation.

This exposure assessment is a first tier approach and the presented exposure concentration ranges base on EASE-calculated values, experts judgment and the experience of the participants of the questionnaire. Industry will collect occupational monitoring data representative of the activities and the materials being handled for the REACH registration dossier. If measured airborne concentrations should be applied, the properties of the applied powder (e.g. particle size distribution) must be considered as well. Properties like particle size could have an impact on the tendency of a powder to remain in air and as a consequence on the airborne concentration. While it could be expected that handling of the substances with the finest particle sizes would result in the highest potential exposure, this may not necessarily be reflected in the actual exposure data due to the influence of the handling method and available risk reduction measures. Exposure is affected primarily by the environment in which it is used and how the material is handled.

9.2 Exposure via consumer products

9.2.1 Introduction

This chapter covers exposure to “borates” arising from consumer products that can be the substances themselves, preparations or articles containing the substance. The following scenarios refer to members of the general public who may be of any age, either sex and in any stage of health and be exposed directly or indirectly by using these consumer products. Exposure arising from consumer products towards workers and professional users are covered by the section “occupational exposure”.

Borates are used in numerous consumer products of which the most important are glass products, ceramic products, enamel, soaps, toiletries, cosmetic products, detergents (as a bleaching agent), non-prescription pharmaceuticals adhesives, fertilizers, (see table 9.67; Beyer et al., 1983; Moore et al., 1997; IPCS 1998; Richold 1998).

Boron compounds are used in cosmetic products such as makeup, skin and hair care preparations, deodorants, moisturizing creams, breath fresheners and shaving creams, in concentrations up to 5% (Beyer *et al.*, 1983; IPCS 1998). The Scientific Committee on Cosmetic Products and Non Food Products (SCCNF) completed a risk assessment on borates and concluded that borates be prohibited from use in cosmetics products in concentrations above 5 percent based on boric acid (Directive 2000/6/EC). Thus boric acid, borates and tetraborates are permitted in cosmetic products at a maximum of 5% in powders, 0.1% in oral hygiene products and 3% in other products (excluding bath and hair waving products). Tetraborates, calculated as boric acid, are permitted at maximum levels of 18% in bath products and 8% in hair waving hair products.

The use of substances in cosmetics is covered under the Cosmetics Directive 76/768/EEC and thus is out of the scope of this risk assessment and shall not be evaluated further. A list of products covered by this directive is presented in Annex I of 76/768/EEC.

Borates are used in swimming pools as an algaecide and fungicide. Borate use in swimming pools as a biocidal product is covered under the Biocides Directive 98/8/EC, and therefore is out of the scope of this risk assessment.

Table 9.68: End use volumes of all borate substances relevant for consumer exposure (boric acid, disodium tetraborate decahydrate, disodium tetraborate pentahydrate, disodium tetraborate anhydrous) (EBA, 2008)

Use sector	Tonnage (2007) (T B_20_3)
Glass and ceramics	140,600
▪ *Borosilicate glass*	
▪ *Ceramic applications*	
▪ *IFG*	
▪ *TFG*	
Detergency	37,946
Cleaning and cosmetics	6,266
▪ *Liquid detergents*	
▪ *Laundry additives, swimming pool chemicals*	
Flame retardancy	7,137
▪ *Cellulose insulation*	
▪ *Hardboard, paper, miscellaneous (flame retardancy*	
Industrial fluids	4,492*
Antifreeze, brake fluids, motor oil	
Various chemical effects	22,134
▪ *Miscellaneous (various)*	
▪ *Abrasives*	
▪ *Wallboard*	
▪ *Starch adhesives*	

*tonnage includes metal working fluids

9.2.2 Inhalation Exposure

Glass Wool

Glass wool consists principally of sodium-, calcium- and magnesium silicates but may contain smaller amounts of other elements including boron. Typical boron content in glass wool is 5% as B_2O_3 or 1.5% as B; the maximal contents will be 12% as B_2O_3 (3.6% as B).

In residential buildings, institutions and offices the levels of respirable glass fibers are normally <0.005 fiber/cm^3. However, just after installation or repair, the concentration of respirable glass fibers may increase (Jensen 2007, IARC 2002). High concentrations of airborne fibers occur during installation of glass wool insulation, where concentrations of respirable fiber were 0.05-1 fiber/cm^3 with the highest concentration at attic insulation of existing buildings. No exposure to respirable airborne fibers is expected after installation is complete (Jensen 2007, IARC 2002). Non-occupational consumer exposure is considered to be infrequent, and of short duration (week or less) when it does occur. Consumer exposure to glass wool would only occur during removal of glass wool insulation and installation as part of a do-it-yourself home improvement projects.

Jensen (2007) estimated a maximum daily exposure of 0.03 – 0.06 mg boron based on a total work day (8 hours) amount of inhaled fibers exposure of 2.2 - 4.0 mg fibers and boron content of the fiber of 1.5%, with 100% retention and 100% solubility of the retained fibers in the lungs. These calculated intakes are worst-case scenarios and in most cases the boron intakes will be 10-100 times lower. Based on a 5 day total exposure period for consumers, the maximum exposure for a typical project would be a total inhalational uptake of approximately 0.30 mg boron/person within these 5 days. The value taken forward to risk assessment is 0.06mg/B/day.

Breum et al. (2003) compared inhalation exposures to respirable fibres and inhalable dust during the installation of various insulation materials, including fibre glass. Nine personal samples for respirable fibre were taken for those installing the fibre glass insulation in attics and in walls. The range of results by Breum was 0.003 f/ml to 0.058 f/ml, lower than the value of 1 f/ml used by Jensen (2007).

Because the assessment by Jensen (2007) is based on the IARC monograph, which includes a critical review of numerous studies on exposures to man-made vitreous fibres, the exposure values from Jensen (2007) were taken forward to risk assessment.

Detergents

Boric acid and disodium tetraborates' primary use in household cleaning products is in liquid laundry detergent products, in which they stabilize the enzymes. To a far lesser extent borates are used in automatic dishwashing liquid as a stabilizer. The levels of boric acid and disodium tetraborates in household cleaning products are low (<1% as boron). Primary exposure will therefore be through skin contact. No data are available for consumer inhalation exposure to liquid detergents; however, no inhalation exposure would be expected from liquid detergents. There are no spray products and aerosols will not be formed during pouring of the liquid. Furthermore borates have negligible volatility at room temperature (HERA 2005).

Fertilizers

Micronutrient fertilizers for lawn, garden and houseplants available for consumer use generally contain 0.02% boron as a concentrate solution or granules. The concentrate is then diluted up to 1 teaspoon per gallon of liquid, giving a final boron concentration in the working solution of 0.2 ppm. No data are available for consumer inhalation exposure to boron from fertilizers. However, since application of the fertilizer would normally occur by pouring the dilute solution around the plant, no inhalation exposure would be expected.

Values taken forward to risk characterization

Since consumer exposure to glass wool insulation would only occur during removal or installation of the insulation, and the majority of consumers hire contractors to perform the installation, there typically would be no inhalation exposure to consumers. The reasonable worst case inhalation exposure value taken forward is 0.06 mg B/person/day (5 days/year referring to the scenario glass wool).

9.2.3 Dermal Exposure

Detergents

Consumers may be exposed to boric acid through solutions used in hand washing of clothes or in some cases through direct contact of the undiluted liquid product during pre-treatment of clothes. Due to its high water solubility, no residual boric acid is expected to remain on the fabric. The intended use of automatic dishwashing liquid does not result in skin contact; however occasional misuse of this product for hand dishwashing cannot be ruled out and may result in skin exposure (HERA 2005).

Consumer exposure estimates to boron from potential laundry and cleaning scenarios were calculated by HERA (2005) and is presented in Table 9.69.

Table 9.69: Total exposure levels for consumer via detergents

Exposure Scenarios	**Boron (µg B/p/day)**	
	Worst Case Dermal Exposure	**Typical Dermal Exposure**
Hand Laundry washing	3.44	1.38
Laundry pretreatment with neat product	102	58.3
Misuse of product for hand dishwashing	2.17	0
Total external dermal consumer exposure to boron in consumer detergent products	**107.6**	**59.7**

Because of the high water solubility and low concentration levels of borates in detergents, residues of boric acid expected to remain on the fabric are negligible. Therefore, exposure from wearing of fabrics washed with detergents containing boric acid is expected to be negligible.

Values taken forward to risk characterization

The reasonable worst case and typical external dermal exposure values from detergents taken forward to risk characterization are 0.11 mg B/p/day and 0.06 mg B/p/day, respectively.

Fertilizers

Micronutrient fertilizers for lawn, garden and houseplants available for consumer use generally contain 0.02% boron as a concentrate solution or granules. The concentrate is then diluted up to 1 teaspoon per gallon of liquid, giving a final boron concentration in the working solution of 0.2 ppm. No data are available for consumer dermal exposure to boron from fertilizers. Based on a worst case estimate of 10 ml of the diluted solution spilled on the hands during each use resulting in a dermal exposure of 2 µg of boron to the hands, and skin surface area of 480 cm^2, the estimated dermal load is 4.17×10^{-6} mg/cm^2 or 3.33×10^{-5} mg/kg. A typical exposure would occur from small drops on the hands of approximately 1 ml or residue on the container with an estimated dermal exposure of 0.2 µg of boron.

Values taken forward to risk characterization

The reasonable worst case external dermal exposure value from fertilizers taken forward to risk characterization is 2 µg B/p/day of use, and a typical value would be 0.2 µg B/p/day.

9.2.4 Oral Exposure

Mineral Supplements

Persons taking mineral supplements may have an intake of 1-10 mg/p/day. The UK Expert Group on Vitamins and Minerals estimated a mean boron intake from supplements of up to 10 mg/day (UK Expert Group on Minerals and Vitamins 2002, 2003).

Glazed Ceramic Ware

The Food Standards Agency (Bradley, 2003) studied the migration of metals, including boron, from glazed ceramic ware. A total of 111 products were purchased in duplicate and the elements migrating into acetic acid were determined. Those products showing higher levels of metal ions leaching into the acetic acid solution were selected for further studies so that a total four test specimens of each article type were exposed to the acetic acid.

The products selected for purchasing were grouped into three classes:

1. Items for eating/drinking
2. Serving/storage vessels
3. Cooking ware

After washing, each of the products were exposed in duplicate to 4% acetic acid for a period of 24 hours at 22°C, according to BS 6748 (Clause 4 and Appendix). A known volume of acetic acid was added to the ceramic article and the contact area was recorded to enable the migration per unit area and per unit mass into the acetic acid to be calculated. Following the exposure the acetic acid was thoroughly mixed and a sub-sample was submitted for ICP-MS analysis.

The glazed ceramic ware was further divided into plates, cooking ware, serving vessels, mugs, bowls and storage vessels. The mean migration of boron into acetic acid from dinner and tea plates was 9.95 µg/dm^2, for a mean total migration of 33.66 µg boron, based on the surface area of the plates. No migration was observed for cooking ware. For mugs and cups, the mean migration of boron was 18.85 µg/L for a total boron migration of 5.72 µg boron. For soup and cereal bowls, mean migration of 171.35 µg B/L for a mean total of 76.38 µg B. Serving vessels was 2.25 µg/l with a mean total of 2.70 µg B. Two storage vessels were evaluated, a 1 liter storage jar and a cider jug. No migration was observed in the cider jug; however, 672.5 µg B/L was seen in the storage jar. Since it is likely that the storage jar would be used infrequently, and when used, only portions of the contents would be consumed, the contribution of total boron exposure from the storage jar would be negligible.

Using a maximal use assumption of items used for eating and drinking (plates, bowls and cups) used once each day, based on a 60 kg person would result in a maximal exposure from glazed ceramic ware of 0.116 mg B/p/day or 0.00193 mg/kg bw/day. It is unlikely that glazed ceramic ware would be used for every meal each day. Based on weekly use, a more typical exposure would be 0.017 mg B/p/day.

Values taken forward to risk characterization

The reasonable worst case exposure value of boron from glazed ceramic ware carried forward to risk characterization is 0.116 mg B/day, and a typical value carried forward is 0.017 mg B/day.

Glass

In a study of elemental migration from glass in contact with food, the migration of boron into water, acetic acid, ethanol, and olive oil was studied in borosilicate glass, soda lime silica glass and lead crystal glass (Glass Technology Services, 2002). In most cases, no boron was detected above the reporting limit of 0.03 ppm. In one study of 10 samples tested of lead crystal ware using water, one sample resulted in a value above the reporting limit (0.06 ppm). No boron was detected in water in white flint soda lime container, colored soda lime silica container, soda lime silica table/ovenware, borosilicate & glass ceramic ware or decorated articles. No migration of boron was observed in lead crystal ware when tested using acetic acid or ethanol.

Detergents

Ingestion of liquid detergents is considered negligible under conditions of normal handling and use. Borates are not expected to be retained on dishes or cutlery due to their physical properties, high water solubility and low concentration levels (HERA 2005).

Fertilizers

No data is available on exposure via ingestion of fertilizers. Oral ingestion of boron containing fertilizers is unlikely however, and would be reported as an accidental poisoning.

9.2.5 Summary: Exposure via consumer products

A release of boron in the use of glass is not significant because boron is tightly bound to glass products. Consumer exposure to glass wool would only occur during removal of glass wool insulation and installation as part of a do-it-yourself home improvement projects. The maximum exposure for a typical project would be approximately 0.30 mg boron/person. Based on the assumption of a person working on one project per year, the average daily exposure would be approximately 0.82 µg B/p/day. A maximal exposure from glazed ceramic ware of 0.116 mg B/p/day or 0.00193 mg/kg bw/day was estimated. Consumer exposure to boron containing micronutrient fertilizers and detergents is also considered insignificant at 0.002 mg B/p/day and 0.11 mg B/p/day, respectively.

The following consumer uses have not been considered: cellulose insulation, anti-freeze, brake fluids, motor oil, and non-biocidal use in swimming pools. These are minor uses and will be covered under the REACH dossier. A study on borates in consumer products was carried out on behalf of the commission. The results will be publicly available on the commission's website. However, they were not available at the time when this dossier was finalized.

In addition to the unintentional exposure to boron from consumer products, persons taking mineral supplements may have an intake of 1-10 mg/p/day.

A summary of the consumer exposure values taken forward for risk characterization are presented in Table 9.70.

Table 9.70 Summary of consumer exposure estimates. Values carried forward for risk characterisation. External exposure (mg/person/day)

Product	Route of exposure	External exposure Typical	External exposure Reasonable worst case
Glass wool	Inhalation	0	0.06 (5 days/year)
Glass	Oral	0	0
Ceramic ware	Oral	0.017	0.116
detergents	Dermal	0.06	0.11
Fertilizers	Dermal	0.0002	0.002

9.3 Indirect exposure via the environment

Some parts of this chapter and given literature are taken in their original form from the book "Boron, Environmental Health Criteria 204, IPCS, WHO 1998" (IPCS, 1998). They concern *inter alia* ambient air, soil intake and introduce descriptions of the natural boron sources for human exposure. Further recent literature is added to reveal the great possible variability of boron uptake among people due to drinking water and diet.

Boron enters the environment mainly through the weathering of rocks, boric acid volatilization from seawater and volcanic activity, but to a lesser extent it is also released from anthropogenic sources. Anthropogenic sources include agriculture, refuse, fuel and wood burning, power generation using coal and oil, glass product manufacture, use of borates/perborates in the home and industry, borate mining[7]/processing, leaching of treated wood/paper and sewage/sludge disposal.

Possible sources for indirect exposure of the general public to borates are inhalation of ambient air, consumption of food and drinking water and soil ingestion as described in the following sections.

9.3.1 Total indirect exposure of man via the environment – Regional environment

Ambient air

Atmospheric emissions of sodium tetraborates and boric acid in particulates and vapour form occur as a result of volatilization from the sea, volcanic activity, and to a lesser extent, borate refining operations, glass and ceramics manufacturing, the application of agricultural chemicals, and coal-fired power plants. Boron is not present in the atmosphere at significant levels; however, the total amount present in the atmosphere at any time is significant owing to the huge volume of the atmosphere. Based on their water solubility, borates would not be expected to persist to a significant degree in the atmosphere.

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[7] There are no borate mining activities in the EU-27.

The element boron does not appear to be present in ambient air at significant levels (Sprague, 1972). There are few studies available that estimated the concentration of boron containing compounds in ambient air, this is partly due to the difficulties of analysis at the low levels involved (ATSDR, 1992). However, Anderson et al. (1994a) have estimated the continental levels. Using their assumption that particulate boron constitutes 15% and gaseous boron constitutes 85% of the total, the range is 0,36-19,9 ng B/m^3. Culver et al. (2001) reported that the mean boron concentration in air is 20 ng/m^3 with a range of <0.5 to 80 ng/m^3. The value taken forward in this risk assessment is 20 ng B/m^3. Therefore, assuming a respiration volume of 20 m^3 per day (ECHA, 2008 Guidance on IR and CSA, chapter R. 15, table R.15-10; respiration volume for persons from 15 to 19 years, maximum value among the other respiration volumes given for other ages), a respiratory exposure of 400 ng/day (~0,4 µg B/day) is calculated and can be assumed as negligible in comparison with other natural and anthropogenic boron sources.

Soil Intake

Boron represents an essential plant micronutrient with an average total concentration of 10 mg B/kg in the earth's crust (Adriano, 2001). The natural level of B in soils largely depends upon the soil parent material. In general, soils derived from igneous rocks and those of tropical and semitropical regions of the world are considerably lower in B content compared with soils derived from sedimentary rocks and those of arid and semiarid regions. The content of total B in the latter group may range up to 200 mg B/kg, particularly in alkaline, calcareous soils, while that for the former group is usually lower than 10 mg B/kg (Swaine, 1955, cited in Adriano, 2001). An older report indicates that boron is found in soils in the USA at concentrations ranging from 10 to 300mg B/kg, with an average value of 30mg B/kg (Whetstone et al., 1942). A more recent study (Eckel & Langley, 1988) gives a similar upper boron concentration range (300mg B/kg) and average value (26 mg B/kg) for soils in the USA. Data were collected on boron concentrations in soils in the EU (reference to chapter on regional exposure – monitoring). Data were found for Finland and Sweden. Boron concentrations in topsoils ranged between 0,5 and 13 mg B/kg soil in Sweden and 1,6 and 14,2 mg B/kg soil in Finnish topsoils. An EU- PEC soil concentration of 5 mg B/kg soil was derived.

The value taken forward for exposure estimation is the EU-PEC value derived for European soils, of 5 mg B/kg.

Assuming an incidental consumption of 20mg soil/person per day (IPCS, 1998) yields an average boron intake of 0.1 µg B/day (i.e. 5 mg B/kg of soil x 0.00002 kg of soil consumed per person per day = 0,0001 mg B/p/day).

Drinking Water

Boron can be released into ground and surface water through weathering processes and, to a much smaller extent, through anthropogenic discharges such as sewage outfalls. Adsorption-desorption reactions are expected to be the only significant mechanism influencing the fate of boron in water.

Concentrations of boron in surface water are dependent on such factors as the geochemical nature of the drainage area, proximity to marine coastal regions, and inputs from industrial and municipal effluent discharges. Concentrations of boron in surface water range widely, from 0.001 to as much as 360 mg B/litre. However, mean boron concentrations for waters of Europe, Pakistan, Russia and Turkey are typically well below 0,6mg B/litre. Boron concentrations in water in Japan, South Africa, and South America are generally below 0.3mg B/litre. Typical boron concentrations in North American waters are below 0,1mg B/litre, with about 90% at or below 0,4mg B/litre.

Drinking water is derived from groundwater and/or surface water sources. In a worldwide data compilation of WHO (1998), it was found that most values were in the range of 0.1 to 0.4 mg B/L. For Germany, drinking water concentrations of <0.2mg B/L (with a median of 0.02 mg B/L) were measured (reference year: 1985/86; Krause et al., 1991) but it has to be mentioned that the boron content of the drinking water increased with an increase in the size of population. This is probably due to the fact that in large urban centres freshwater is also used for the preparation of drinking water. These results were confirmed in more recent measurements of Wiecken and Wubbold-Weber (1995) and Abke et al. (1997). Wiecken and Wubbold-Weber (1995) reported boron concentrations of less than 0,1 mg B/L in 240 drinking water samples in West-Germany between 1972-1974. Boron concentrations were measured again at 76 locations in 1993 in both West- and former East-Germany. Boron concentrations in the western part of Germany remained similar and were generally less than 0,1 mg B/L. The highest value measured was 0,21 mg B/L. Also in the former eastern part of Germany the boron concentrations were similar. The highest measured concentration was just above 0,2 mg B/L.

Abke et al (1997) measured the boron concentration in 198 groundwater samples in the drinking water catchment area of the city of Frankfurt. The mean boron concentration was 0,07 mg B/L. The 90-percentile was 0,14 mg B/L. Only 5 out of 198 sample sites exhibited concentrations above 0,3 mg B/L.

European countries such as Greece, Italy and Cyprus reveal high natural boron concentrations in their ground water (>5 mg B/l in several cases (Weinthal et al., 2005), which has also directly been used as drinking water.

Due to the European Drinking Water Directive the content of boron in drinking water is limited to 1 mg B/L in the EU (EU, 1998).

Boron content in bottled mineral water can be highly variable. Allen et al (1989) analysed 37 different brands and boron concentrations ranged from < 0,005 mg B/L (non-detectable) to 4,35 mg B/L The average content was 0,55 mg B/L. Higher levels are caused by boron containing minerals in the surroundings of the springs.

It is assumed that the content of boron in mineral water will also be limited to 1 mg/L in the EU as it was done for drinking water.

Taking the above data into account, a typical value of 0,4 mg B/L and a RWC of 1 mg B/L (the maximum limit permitted by EU Drinking Water Directive) will be taken forward for the risk characterisation. This RWC value is 2.5 times the estimated European average drinking water concentration.

Assuming a daily consumption of 2L/person/day, daily intake from drinking water is typically 0,8 mg B/person/day and in a RWC 2 mg B/person/day.

Dietary intake

Literature data

For the general population the greatest exposure to boron comes from food. The richest sources of boron are fruits, vegetables, pulses, legumes and nuts. Dairy products, fish, meat and most grains are poor sources of boron (IPCS 1998).

Hunt et al (1991), Anderson et al (1994b) and Rainey et al (1999) provide a detailed overview of boron contents in various food items from different countries.

Anderson et al (1994b) analysed B in 234 food items from the US Food and Drug Administration Total Diet Study collection (1990-1991). From these analysis they derived an average daily intake for adult man of 1,2 mg B/p/day, for adult female of 0,9-1 mg B/p/day, for teenage male of 1,1 mg B/p/day, for teenage female of 0,8 mg B/p/day and for infants and young children (<2yr) of 0,7 mg B/day.

Rainey et al 1999 estimated the daily dietary boron intake of adults in the US, Germany and UK. Estimates were based on extensive food consumption surveys performed between 1985 and 1991 in the above countries and on an extensive database of 885 food boron concentrations from USA, Finland, UK, Italy, Japan and China. Mean dietary boron intakes ranged between 1,1 and 1,7 mg B/p/day for males and between 0,9 and 1,6 mg B/p/day for females.

It should be noted that drinking water was not included in the estimate except for Germany. The most important sources of dietary intake of boron identified are beverages, with wine, coffee and tea accounting for 20-25% of the daily boron intake in Germany and the UK and 10% in the US.

Rainey et al (2002) re-assessed daily boron intakes of various age/sex groups in the US using information on diet composition of individuals collected between 1994 and 1996, through the Continuing Survey of Food Intakes by Individuals (CSFII) and literature data on boron content of individual food items. More than 15 000 individuals from different age groups and from over the US were interviewed during 2 non-consecutive days to collect information on their diet composition. Mean boron intakes for school-age children and adolescents ranged from 0,8 mg B/p/day for 4-8 year olds to 1,2 mg B/p/day for males aged 14-18. For male and female adults, the mean intakes were 1,3 and 1 mg B/p/day respectively. These values were similar to the values calculated for the period 1989-1991. Mean boron intakes were 1,2 mg B/p/day for male and 1 mg B/p/day for female.

Based on the UK National Food Survey (UK Ministry of Agriculture, Fisheries and Food, 1991), the dietary intake of boron in the UK ranges from 0,8 mg B/p/day to 1,9 mg B/p/day. Variations are related to increased intake of food items with higher boron contents such as nuts or wine (EVM, 2003). MAFF (1997) reported daily exposure estimates for males and females in the UK from food to be on average 1,5 mg B/p/day and 97,5th percentile 2,6 mg B/p/day.

The higher mean daily dietary intake of 1,5 mg B/p/day for adult male and female will be taken forward in this risk assessment.

It should be emphasized that the boron uptake via food can vary significantly due to individual nutrition behaviour (e.g. vegetarians are identified as a potential high intake group), and the origin of the food. Anderson et al (1994b) for example collected data on boron concentrations in food from different countries. High boron concentrations are for example reported in cowpeas (4,76 mg B/kg), pear (3,66 mg B/kg) and grapes (4,22 mg B/kg), while meat, fish and dairy products generally contain less then 0,5 mg B/kg. These values reveal the great range in boron concentrations found in food.

Another possible relevant boron source can be nutrition supplements, a report of the UK Expert Group on Vitamins and Minerals derived a possible daily uptake of 1-10mg/B/day via this route (UK Expert Group on Minerals and Vitamins 2002, 2003) (see chapter consumer exposure).

TGD method

Using the TGD (2003) method described in Appendix III, indirect exposure at EU-level is assessed assuming the standard consumption pattern given in Table 9.71 and using measured values of boron in food items or in absence of monitoring data, estimated values using data on biota-to-soil accumulation factors BSAF (see Fate & PBT chapter).

As boron has been measured in a wide range of food items in several countries, measured boron values will be used.

Table 9.71: Standard EU food consumption of EU consumers according the TGD (2003), Appendix III, table 4

	TGD (2003)
	kg wwt/d
Fish	0,115
Leaf crops (incl cereals, fruit)	1,2
Root crops	0,384
Meat	0,301
Dairy products	0,561

As wine and coffee can be important sources of boron intake, an additional daily portion of 0,35 L coffee and 0,2 L wine will be added to the daily consumption (Anderson et al, 1994b and WHO, 2007).

Boron content for each of the above food categories has been assessed using the databases published by Hunt et al 1991, Anderson et al 1994b and Rainey et al 1999. They report boron concentrations in a wide range of food items in the US, Finland, UK, Germany, Italy, Japan and China. These have been merged into one large dataset and the median value for each of the food categories specified in Table 1 has been calculated.

A more accurate method would be to multiply the boron content of each food item with the daily consumed amount of that food item. Data on amounts consumed for each food item is however lacking. This method can therefore not be applied.

The estimated daily intake according the above method is presented in Table 9.72.

Table 9.72: Estimated dietary intake of boron – regional environment

	TGD (2003)		
	kg wwt/d	**mg B/kg wwt**	**mg B/p/day**
Fish	0,115	0,19	0,02
Leaf crops (incl cereals, fruit)	1,2	0,70	0,83
Root crops	0,384	1,11	0,43
Meat	0,301	0,16	0,05
Dairyproducts	0,561	0,19	0,11
Coffee & wine	0,35L + 0,2L	0,083 + 0,415	0,5
Total			**1,94**

Applying the TGD method, the daily dietary intake is 1,94 mg B/p/day, which is slightly higher than the value derived from literature data.

Total indirect exposure of man via the environment - regional

Summing up all sources of indirect exposure, the total indirect exposure of man via the regional environment can be estimated:

Air: 0,4 µg B/person/day

Soil ingestion: 0,1 µg B/person/day

Dietary intake: 1,5 – 1,94 mg B/p/day

Drinking water (respectively mineral water): 0,8 resp. 2 mg/person/day

Total daily boron intake: Typical: 2,3-2,74 mg B/person/day

RWC: 3,5 – 3,94 mg B/person/day

The most important sources of exposure are food and drinking water. It should be noted that RWC values are based on a boron concentration in drinking water equal to the maximum limit permitted by EU Drinking Water Directive. This limit is 2.5 times the estimated European average drinking water concentration.

9.3.2 Total indirect exposure of man via the environment – Local environment

Ambient air

The concentrations in air derived for the local environment around boric acid and sodium tetraborates producing and using plants (chapter 10, local environmental exposure assessment) will be used. As a worst case, the maximum value for the sector with the highest emissions will be used, i.e. 1798 ng B/m³. Therefore, assuming a respiration volume of 20 m^3 per day (ECHA, 2008 Guidance on IR and CSA, chapter R. 15, table R.15-10; respiration volume for persons from 15 to 19 years, maximum value among the other respiration volumes given for other ages), a respiratory exposure of 36 µg/day is calculated.

Soil Intake

As already reported in section 9.3.1 boron concentrations found in soil can have a wide range. Values ranging between <5 up to 300 mg B/kg soil have been reported. A PEC value for European soils of 5 mg B/kg was derived (chapter 10, local environmental exposure assessment). It is quite unlikely that the boron concentrations in soil are deeply influenced by anthropogenic activities, if they are done responsibly and under normal circumstance (chapter 10, local environmental exposure assessment). Due to the high natural variability of boron concentrations in soils, it can be assumed that the anthropogenic addition of boron (local additional of <0,001-0,25 mg B/kg) is certainly within the natural range and comparable to the value of the regional environment soil intake (EU-PEC: 5 mg B/kg). Assuming a daily intake of 20 mg soil/p/day (IPCS, 1998) and taking a value 5 mg boron per kg soil, total daily intake of boron through soil is 0,1 µg B/p/day. This result is a negligible uptake in comparison with other natural and anthropogenic boron sources relevant for human exposure.

Considering a soil with a boron concentration of 300mg B/kg and the same amount of soil ingested (20mg), this results also in a negligible uptake in comparison with other natural and anthropogenic boron sources relevant for human exposure (6µg B/p/day).

Drinking water

Simsek et al (2003) measured the boron concentrations in drinking water from local wells in the mining area in Turkey. Some concentrations were very high, ranging between 1,2 and 20,8 mg B/L, but most well waters had a boron concentration below 2 mg B/L. Such high concentrations can indeed be expected in mining areas where the soil concentrations can reach concentrations up to 500 mg B/kg soil (Helvaci and Alonso, 2000).

High exposure levels of groundwater are also found in areas naturally enriched with boron in Greece, Italy and Cyprus (Weinthal et al., 2005 (>5 mg B/l in several cases)), but it should be noted that such values are not commonly found in the EU and are not expected at current emission rates around borate producing and fabricating plants (chapter 10, local environmental exposure assessment).Finally, there is an EU drinking water limit of 1 mg B/L.

As a worst case for the local environment the EU drinking water limit of 1 mg B/L will therefore be taken forward in this scenario. Assuming a daily consumption of 2L/person/day, daily intake from drinking water is 2 mg B/person/day. This value is identical to the RWC value taken for the regional environment exposure via water consumption.

Dietary intake

No literature data are available with estimates of dietary exposure to boron for people living around boric acid and sodium tetraborates producing and using plants in Europe. Also no studies have been found reporting boron concentrations in food and drinking water obtained around local sites in Europe.

An alternative approach to estimating increases in dietary intake at a local level would be to determine how large an increase would be associated with consumption of locally grown food from areas with elevated boron in the soil and groundwater.

Such a data set appears to have been prepared by Simsek et al (2003). Boron concentrations in food – mainly vegetables and fruit- and drinking water were measured in villages located in borate producing and mining areas in Turkey. As controls, they also analysed the boron content of food grown in soils relatively poor in boron, purchased from bazaars and markets in Ankara.

An enrichment factor can be derived comparing the boron content of a food item produced locally with the boron content of the same food item purchased at the market (control). Food items and their enrichment factors can then be grouped in food categories defined by the TGD (leaf crops, root crops) and a typical (50-percentile) enrichment factor can be derived for both food categories.

Applying this method, the typical enrichment factor for root crops is 1 and 1,9 for leaf crops.

As there is no evidence for biomagnification of boron through the food chain (chapter 4 and 8) the boron content derived for meat, fish and dairy products at regional level will be further used. As coffee and wine are generally obtained from the market, also for these food items, the boron content derived at regional level will be further used.

The derived concentrations from food, presented in Table 9.73, result in an estimated daily uptake of 2,7mg B/p/day via food.

Table 9.73: Estimated dietary intake of boron – local environment

	TGD (2003)		**Enrichment factor**	
	kg wwt/d	**mg B/kg wwt - regional**		**mg B/person/day using enrichment factor**
Fish	0,115	0,19	1	0,02
Leaf crops (incl cereals, fruit)	1,2	0,7	1,9	1,57
Root crops	0,384	1,11	1	0,43
Meat	0,301	0,16	1	0,05
Dairy products	0,561	0,19	1	0,11
Coffee & wine	0,35L + 0,2L	0,083 + 0,415	1	0,50
Total				**2,7**

It should be emphasized that the boron uptake via food can vary significantly due to individual nutrition behaviour among people (e.g. vegetarians are identified as a potential high intake group), and origin of food. Simsek et al (2003) measured very high boron concentrations in certain food items from borate-producing (mining) regions in Turkey where soil boron concentrations can be 10 to 20-times higher than the average background concentration (max.: pistachio 67 mg/kg; peach: 34,49 mg/kg, green beans 19,49 mg/kg, etc.). Such data reveal the great ranges of boron concentrations found in food._These high values obtained in a boron mining area cannot be considered representative for local conditions around borate producing and fabricating sites in Europe.

Total indirect exposure of man via the environment - local

Summing up all sources of indirect sources, the total indirect exposure of man via the local environment can be estimated:

Air: 36 µg B/p/day

Soil ingestion: 0,1 µg B/p/day

Dietary intake: 2,7 mg B/p/day

Drinking water: 2 mg/p/day

Total daily boron intake: 4,7 mg B/p/day

The above approach provides an alternative to estimating a worst case situation for the local environment. However, the results are likely to overestimate and not be very representative of dietary intakes at local sites in Europe for the following reasons:

- soil boron levels in these naturally enriched mining areas are 100-500 mg B/kg-dw (Helvaci and Alonso, 2000),
- the enrichment factor would be proportional to the increase in soil concentration, so a soil with only a few mg B/kg increased above background would exhibit smaller enrichments than measured in mining areas,
- the aim of the local risk assessment is to assess the risk from current emissions from producing and using sites in Europe. Historical emissions are outside the scope,
- current emissions from European producing and using sites are unlikely to lead to the high elevations seen in areas associated with mines that have been in operation for more than 50 years,
- drinking water concentrations in any EU location should not be considered to exceed the limit of 1 mg B/L and typical value is 0.4 mg B/L. To the extent that other drinks replace drinking water, coffee and wine consumption (included as a dietary intake) this would reduce the consumption of drinking water and reduce estimated total daily boron intake.

Under general circumstances boron exposure of the general public via the environment at local sites in the EU is assumed to be more similar to the predicted regional exposure level, if the general public is not already exposed to a great amount of boron from natural sources. The derived and higher level for local exposure is more representative for the uptake of people living in areas with higher natural boron concentrations in soil and water or people consuming water and food from these areas.

10 ENVIRONMENTAL EXPOSURE ASSESSMENT

Preface

The following chapter on environmental exposure was compiled by Arcadis Belgium - EURAS (contracted by EBA) and reviewed by Austria. Information gathered through questionnaires was evaluated by the consultant. Summaries were made available to the Rapporteur.

The exposure assessment is only a first Tier assessment based on information collected by Industry through questionnaires on tonnages and process descriptions of manufacturers and users. As no data were available on emission factors and as no monitoring was available, local environmental concentrations were calculated using EUSES and the default emission factors from the TGD A-tables.

For the regional scale extensive monitoring data for boron exists but the meaning of monitoring data is difficult to evaluate without a precise knowledge of the sampled sites; nevertheless it showed the lack of recent good quality data.

A further Tier exposure assessment needs to be performed before any decisive conclusions can be made whether there are risks for the environment related to the production or use of borates.

Therefore it is foressen that industry will collect monitoring data as well as information on anthropogenic input for their registration dossier under REACH.

10.1 Specific exposure issues

According to the EC Technical Guidance Documents and industry information, the local environmental exposure assessment of boric acid and sodium tetraborates (sodium tetraborate anhydrous, sodium tetraborate pentahydrate, sodium tetraborate decahydrate) should be based on industrial releases of boron during the following life cycle stages (EBAa,b; 2008):

1. Production and import of boric acid and sodium tetraborates
2. Fabrication into glass and ceramics: borosilicate glass, ceramic applications, Insulation FibreGlass, Textile FibreGlass
3. Fabrication into detergents (pentaborates)
4. Fabrication into cleaners and cosmetics: laundry additives, liquid detergents, swimming pool chemicals; cosmetics is covered under the Cosmetics Directive 76/768/EEC and thus is out of the scope of this risk assessment
5. Fabrication into product: cellulose insulation, hardboard, paper, miscellaneous (flame retardancy)
6. Fabrication into industrial fluids: metal working fluids, antifreeze, brake fluids, motor oil
7. Use in metallurgy: metal heat treatment, miscellaneous (metallurgy), brazing fluxes, electrolytic capacitators, electroplating, ferroboron, metal refining (smelting), wire drawing.
8. Agriculture (fertilisers), wood preservation (excluded from this RA since wood preservatives fall under the Biocidal Products Directive 98/8/EC)
9. Various chemical effects: miscellaneous (various), nuclear applications, cement, leather tanning, nylon manufacturing, paint, photographic chemicals, reagent chemicals, refractories, starch adhesives, wallboard, abrasives, light bulbs.

10.2 Local exposure calculation factors

Initially local environmental exposure concentrations (i.e. air, water, sediment, soil) should be calculated as generic “reasonable worst-case” exposure assessment based on modelling, to derive an EU environmental concentration. Measured data, i.e. site-specific or monitoring information (Environmental questionnaires), can then be used to revise the calculated concentrations according to the EU Technical Guidance Documents (EC 2003) and the European Union System for the Evaluation of Substances (EUSES 2.0).

In general, monitoring data are preferred over model calculations when sufficient reliable data are available. Some site-specific data may be used to replace the default data characterising the standard scenario to obtain realistic estimates of exposure.

The following input values and assumptions were used in the local exposure assessment for boron containing compounds:

- Partition coefficient solids-water in suspended matter:

  Kp_{susp} = 3.5 l/kg (section 4)

  Kpsediment = 2.78 l/kg (section 4)

- Partition coefficient soil-water

  Kp_{soil} = 1.5 l/kg (section 4)

  Fraction of emission directed to sludge by ‘on-site’ Waste Water Treatment Plant (default; if no site specific information is available):

F_{sludge} = ND (Quantitative data on removal efficiencies in wwtp is not available yet).

- Fraction of emission directed to sludge by 'off-site' municipal Sewage Treatment Plant (default; if no site specific information is available):

  Boron is not removed by conventional sewage treatment, although there is some evidence to suggest that trace quantities may be associated with sewage sludge (Eriksson, 2001). A review of removal technologies suggested that conventional approaches were not effective at removing boron to sub-parts-per-million concentrations or would be associated with high costs (Park and Edwards, 2005). While some technologies were seen as meriting further research, none was seen as ready for widespread application.

  F_{sludge} = *Fsludge=0; Fwater=1* (municipal STP; removal efficiency for B: unknown, assumed to be low, because of the low adsorption to particles).

- Default dilution factor for the freshwater compartment = 10

  Default dilution for the marine environment = 100.

  In case the site specific dilution factor for the freshwater environment exceeds 1000, a maximum dilution factor of 1000 is used (assumption of complete mixing).
  It must be noted that with the assumption of complete mixing of the effluent in the surface water, no account is taken of the fact that in reality in the mixing zone higher concentrations will occur.
  For situations with relatively low dilution factors this mixing-zone effect can be accepted. For situations with very high dilution factors, however, the mixing zones may be very long and the overall area that is impacted by the effluent before it is completely mixed can be very substantial. Therefore, in case of site-specific assessments the dilution factor that is applied for calculation of the local concentration in surface water should not be greater than 1000 (TGD, 2003).

- Number of production days = 300 d (default; B-tables; TGD) or average for sector if adequate number of data are available.

- Sludge from on site WWTP is assumed to be disposed together with waste (specified for different companies; disposal, recycling); hence it is not applied to agricultural soil. Sludge from a municipal STP is assumed to be applied to agricultural soil.

- Generic exposure scenarios are applied to the sites that did not provide any quantitative emission information and for which production/use data and/or specific process information are available. The emissions to water and air are calculated by multiplying usage/production figures with a default emission factor for water and air (A-Tables) (TGD, 2003)

- For comparative purposes, exposures to borates are often expressed in terms of boron (B) equivalents based on the fraction of boron in the source substance on a molecular weight basis. Conversion factors are given in the Table below. The B equivalents used are a generic designation rather than a designation of the element boron. Only the boric acid and borate ion are present at environmentally and physiologically relevant concentrations, so presentation of concentrations as boron equivalents is appropriate.

Conversion factors to Boron equivalents

		Conversion factor for equivalent dose of B
Boric acid	H_3BO_3	0.1748
Disodium tetraborate decahydrate	$Na_2B_4O_7.10H_2O$	0.1134
Disodium tetraborate pentahydrate	$Na_2B_4O_7.5H_2O$	0,148
Disodium tetraborate anhydrous	$Na_2B_4O_7$	0.2149
Boric oxide	B_20_3	0.3106

- The following PECregional values were selected as regional input values to add to the local environmental concentrations :
- Monitoring data are available from the report ‘Ambient concentrations of boron in the environment (water, sediment, soil), with emphasis on the European continent’ - Arcadis Belgium-EURAS (2008) (see point 10.8.6 Measured levels – Ambient concentrations of boron).

- FRESHWATER:

Country-specific measured regional PECs (µg dissolved B/l; for sites discharging to a freshwater environment located) are available for the following countries: Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Portugal and the UK. On the basis of these data a median ambient regional PEC for Europe of 110.3 µg dissolved B/l (measured data) was derived.

- SEDIMENT:

No monitoring data have been found of boron levels in sediments in the EU.

- SOIL:

Country-specific measured regional PECs (mg B/kg dw) for sites located in Sweden and Finland were available. On the basis of these monitoring data an average-90P ambient regional PEC for Europe of 5 mg B/kg dw (measured data) was derived.

10.2.1 Selection of emission factors: methodology

Since quantitative emission data have not been submitted in this stage of the assessment; emissions need to be assessed by means of default emission factors. These emission factors can be selected from EU guidance document (TGD, 2003). For this purpose, the collected sector-specific exposure information (potential for exposure) will be combined with the generic information extracted from the above mentioned guidance documents.

10.2.2 Summary of emission factors

Default data

An overview of MC, IC and UC for the boric acid and sodium tetraborates production stage with release factors for water and air is given in Table 10-1**Fehler! Verweisquelle konnte nicht gefunden werden.**. The default emission factors that are applied in the current exposure assessment have been extracted from the A-tables in the Technical Guidance Document and EUSES 2.0 (EC, 2003).

Tabelle 10.1 Overview of default emission factors for the boric acid and sodium tetraborates production sector (TGD, 2003 A-tables)

Use scenario	Industry category IC	Use category UC Function or use of the substance	Other MC	TGD Table	Release factor to air	Release factor to water
Production of boric acid/sodium tetraborate	2 Chemical industry	NR	default	A1.1	0.00001	0.003

An overview of MC, IC and UC for the different borate use scenarios (formulation and industrial use stage) with release factors for water and air is given in Table 10-2. Since boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate can have multiple functions in a certain use; The default emission factors that are applied in the current exposure assessment have been extracted from the A-tables in the Technical Guidance Document and EUSES 2.0 and represent 'worst case emission factors' for the specified use scenarios (EC, 2003).

Tabelle 10.2 Overview of default emission factors for identified use categories (TGD, 2003 A-tables)

Use scenario	Industry category IC	Use category UC Function or use of the substance	Other MC	TGD Table	Release factor to air	Release factor to water
USES						
Glass and ceramics						
Formulation: Melting	0 Others: glass & ceramics manufacturing	43 Process regulators; 49 Heat Stabiliser; 52 Viscosity adjustor	Ic; dedicated equipment, frequent cleaning	A2.1	0.001	0.003
Formulation: Melting	0 Others: glass & ceramics manufacturing	43 Process regulators; 49 Heat stabiliser; 52 Viscosity adjustor	IIc: dedicated equipment, little cleaning	A2.1	0.0005	0.003
Industrial use:* Processing: drawing, end forming	0 Others: glass & ceramics manufacturing	43 Process regulators; 49 Heat stabiliser; 52 Viscosity adjustor	II: inclusion into or onto a matrix	A3.10	0.001	0.05
Detergency						
Formulation	5 Personal/domestic	8 Bleaching agents	Default	A2.1	0.0025	0.003

Use scenario	Industry category IC	Use category UC Function or use of the substance	Other MC	TGD Table	Release factor to air	Release factor to water
Private use	5 Personal/domestic	8 Bleaching agents	Wide dispersive use	A4.1	0	0.95 (households)
Cleaners						
Formulation	5 Personal/domestic	9 Cleaning/washing agents 43 process regulator; enzyme stabiliser 40 pH regulating agents	Default	A2.1	0.00002	0.0009
Private use	5 Personal/domestic	9 Cleaning/washing agents 43 process regulator; enzyme stabiliser 40 pH regulating agents	Wide dispersive use	A4.1	0	0.99 (household products) 0.8 (cosmetics)
Industrial fluids: metal working fluids, antifreeze, brake fluids, motor oil						
Formulation: mixing of ingredients	0 Others: Industrial fluids	14 Corrosion inhibitor 40 pH regulating agents 29 Heat transferring agents (coolants), 35 Lubricants and additives	III Multi-purpose equipment	A2.1	0.0025	0.02
Industrial use: Processing:	0 Others: Industrial fluids	14 Corrosion inhibitor 40 pH regulating agents 29 Heat transferring agents (coolants), 35 Lubricants and additives	III non-dispersive use	A3.16	0.00001	0.02
Metallurgy: metal heat treatment, brazing fluxes, electroplating, miscellaneous, wire drawing						
Formulation:	8 Metal extraction, refining, processing	24 Flux agent for casting 14 Corrosion inhibitor; anti-oxidants 54 Welding and soldering agents (fluxing agents) 40 pH regulating agents 35 Lubricants and additives	III Multi-purpose equipment	A2.1	0.0025	0.02
Industrial use: Processing:	8 Metal extraction, refining, processing	24 Flux agent for casting 54 Welding and soldering agents 40 pH regulating agents	III non-dispersive use	A3.7	0	0.02
Flame retardants use: cellulose insulation, miscellaneous, paper, hardboard						
Formulation	12 Pulp, paper and board industry	22 Flame retardants and fire preventing agents	III Multi-purpose equipment	A2.1	0.0025	0.02
Industrial use: Processing:	12 Pulp, paper and board industry	22 Flame retardants and fire preventing agents	II: inclusion onto matrix	A3.12	0 (wet process) 0.0025 (dry process)	0.001
Fertiliser use						
Formulation	1 Agricultural Industry	UC 19: fertilisers	Default	A2.1	0.0025	0.02
Industrial use: Processing	1 Agricultural Industry	UC 19: fertilisers	Wide dispersive use	A3.1	0	0.05 Soil: 0.95
Various chemical effects						

Use scenario	Industry category IC	Use category UC Function or use of the substance	Other MC	TGD Table	Release factor to air	Release factor to water
Miscellaneous (various)						
Formulation	2 Chemical industry	0 Other	Default	A2.1	0.0025	0.003
Industrial use: Processing	2 Chemical industry	0 Other	Default	A3.2	0.00001	0.007

10.2.3 Description of processes & potential for exposure to the environment

Descriptions of production processes have been extracted from the submitted industry questionnaires for producers and users of boric acid and sodium tetraborates (Industry questionnaires; EBA, 2008).

But at this preliminary stage the environmental exposure is based on EUSES default values.

10.2.4 Derivation of site tonnages

Site tonnages are derived using 2 methods:
- derivation of default tonnages as described in the TGD
- using data collected through the industry questionnaires

Default

A default site tonnage will be derived in accordance to the TGD (2003) and the B-tables of the TGD. Starting from the EU-tonnage, in general, a regional tonnage is derived by applying the 10% rule. Please note that in applying this rule, it is assumed that 10% of the activities performed in the EU take place in the hypothetical region. This may be the case if there are a large number of companies – widely distributed in the EU- involved in this activity. Although this is often valid for downstream users; it is obvious that this is not the case for producers of chemicals. There are only few sites in the EU involved in the production of boric acid and sodium tetraborates. In that case, it is assumed that 100% of the EU production takes place in the hypothetical region; hence the EU tonnage equals the regional tonnage.
The local tonnage is derived from the regional tonnage applying a 'fraction of the main local source' (B-tables, TGD). The B-tables are also used to determine the number of emission days if not available.

Manufacturers/Importers

Tabelle 10.3 Summary of default tonnages for production of boric acid, sodium tetraborate anhydrous, sodium tetraborate pentahydrate and sodium tetraborate decahydrate (EBA, 2008)

Scenario	IC	UC	MC	TGD table	Fraction of main local source	Site Tonnage (T substance)	Conversion factor	Site tonnage (T B_2O_3)	N° of emission days
Production of boric acid	2 Chemical industry	0 Other	Default	Table B1.1	1 (regional tonnage<25000T)	13000	0.563	7319	300
Production of sodium tetraborate	2 Chemical	0 Other	Default	Table B1.1	1 (regional tonnage<25000T)	100	0.69	69	300

Scenario	**IC**	**UC**	**MC**	**TGD table**	**Fraction of main local source**	**Site Tonnage (T substance)**	**Conversion factor**	**Site tonnage (T B_2O_3)**	**N° of emission days**
anhydrous	industry								
Production of sodium tetraborate pentahydrate	2 Chemical industry	0 Other	Default	Table B1.1	1 (regional tonnage<25000T)	12000	0.49	5880	300
Production of sodium tetraborate decahydrate	2 Chemical industry	0 Other	Default	Table B1.1	1 (regional tonnage<25000T)	3000	0.365	1095	300
TOTAL								**14363**	**300**

Some European sites, involved in the production of borate substances (refining), reported site-specific production volumes. An overview of the average and maximum tonnages reported by the different sites is given. Next to tonnage data, information on the average number of working days was made available.

Downstream users

An overview of the default site tonnages derived for the different use sectors and life cycle stages formulation and processing is given in the table below. Tonnages are derived on the basis of use volumes for boric acid and borax substances (disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate). Please note that site tonnages are expressed as T B_2O_3.

Tabelle 10.4 Summary of default tonnages for different uses of boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate, disodium tetraborate decahydrate (as B_2O_3)

Use scenario	IC	UC	MC	TGD table	Fraction of main local source	Site Tonnage ($T B_2O_3$)	N° of emission days
Glass and ceramics							
Borosilicate							
Formulation	0 Others: glass & glass products manufacturing	43 Process regulators; 49 Heat Stabiliser; 52 Viscosity adjustor	Ic; dedicated equipment, frequent cleaning	B2.3	1 (Fsubstance in formulation: 100%)	3451	300
Formulation	0 Others: glass & glass products manufacturing	See above	Ic; dedicated equipment, frequent cleaning	B2.3	0.7 (Fsubstance in formulation: 15% B_2O_3)	2416	300
Industrial use	0 Others: glass & glass products manufacturing	See above	II: inclusion into matrix	B3.14	0.6 (Fsubstance in formulation: 100%)	2071	156
Industrial use	0 Others: glass & glass products manufacturing	See above	II: inclusion into matrix	B3.14	0.5 (Fsubstance in formulation: 15% B_2O_3)	1726	300
Glass fibres							
Formulation	0 Others: glass & glass products manufacturing	43 Process regulators; 49 Heat stabiliser; 52 Viscosity adjustor	Ic; dedicated equipment, frequent cleaning	B2.3	0.8 (Fsubstance in formulation: 100%)	4894	300
Formulation	0 Others: glass & glass products manufacturing	See above	Ic; dedicated equipment, frequent cleaning	B2.3	0.4 (Fsubstance in formulation: 5%)	2447	300
Industrial use	0 Others: glass & glass products manufacturing	See above	II: inclusion into matrix	B3.14	0.6 (Fsubstance in formulation: 100%)	3670	156
Industrial use	0 Others: glass & glass products manufacturing	See above	II: inclusion into matrix	B3.14	0.3 (Fsubstance in formulation: 5%)	1835	300
Ceramics							
Formulation	0 Others: glass & glass products manufacturing	43 Process regulators; 49 Heat stabiliser; 52 Viscosity adjustor	Ic; dedicated equipment, frequent cleaning	B2.3	1 (Fsubstance in formulation: 100%)	4492	300
Formulation	0 Others: glass & glass products manufacturing	See above	Ic; dedicated equipment, frequent cleaning	B2.3	0.7 (Fsubstance in formulation: 30%)	3144	300

Use scenario	IC	UC	MC	TGD table	Fraction of main local source	Site Tonnage (T B_2O_3)	N° of emission days
Industrial use	0 Others: glass & glass products manufacturing	See above	II: inclusion into matrix	B3.14	0.6 (Fsubstance in formulation: 100%)	2695	194
Industrial use	0 Others: glass & glass products manufacturing	See above	II: inclusion into matrix	B3.14	0.5 (Fsubstance in formulation: 30%)	2246	300
Detergency							
Formulation	5 Personal/domestic	8 Bleaching agents	III Multi-purpose equipment	B2.3	0.8	3031	300
Private use	5 Personal/domestic	8 Bleaching agents	Wide dispersive use	B4.1	0.002	7.6	365
Cleaners							
Formulation	5 Personal/domestic	9 Cleaning/washing agents 43 process regulator; enzyme stabiliser 40 pH regulating agents	III Multi-purpose equipment	B2.3	1	627	300
Private use	5 Personal/domestic	See above	Wide dispersive use	B4.1	0.002	1.3	365
Industrial fluids							
Formulation: mixing of ingredients	0 Others: Industrial fluids	14 Corrosion inhibitor 40 pH regulating agents 29 Heat transferring agents (coolants), 35 Lubricants and additives	III Multi-purpose equipment	B2.3	1 (Fsubstance in formulation: 100%)	449	300
Formulation: mixing of ingredients	0 Others: Industrial fluids	See above	III Multi-purpose equipment	B2.3	1 (Fsubstance in formulation: 50%)	449	300
Industrial use	0 Others: Industrial fluids	See above	III non-dispersive use	B3.14	0.8 (Fsubstance in formulation: 100%)	359	151
Industrial use	0 Others: Industrial fluids	See above	III non-dispersive use	B3.14	0.75 (Fsubstance in formulation: 50%)	337	135
Metallurgy							
Formulation:	8 Metal extraction, refining, processing	24 Flux agent for casting 14 Corrosion inhibitor; anti-oxidants	III Multi-purpose equipment	B2.3	1 (Fsubstance in formulation: 100%)	398	300

Use scenario	**IC**	**UC**	**MC**	**TGD table**	**Fraction of main local source**	**Site Tonnage ($T\ B_2O_3$)**	**N° of emission days**
		54 Welding and soldering agents (fluxing agents) 40 pH regulating agents 35 Lubricants and additives					
Formulation	8 Metal extraction, refining, processing	See above	III Multi-purpose equipment	B2.3	1 (Fsubstance in formulation: 20%)	398	300
Industrial use	8 Metal extraction, refining, processing	See above	III Non-dispersive use	B3.6	0.9 (Fsubstance in formulation: 100%)	358	73
Industrial use	8 Metal extraction, refining, processing	See above	III Non-dispersive use	B3.6	0.8 (Fsubstance in formulation: 20%)	318	299
Flame retardants paper							
Formulation	12 Pulp, paper and board industry	22 Flame retardants and fire preventing agents	III Multi-purpose equipment	B2.3	1 (Fsubstance in formulation: 100%)	725	300
Industrial use	12 Pulp, paper and board industry	See above	II: inclusion onto matrix	B3.10	1 (Fsubstance in formulation: 100%)	725	300
Biological effects							
Fertiliser							
Formulation	1 Agricultural Industry	UC 19: fertilisers	/	B2.2	1 (Fsubstance in formulation: 100%)	1122	300
Industrial use: Processing	1 Agricultural Industry	UC 19: fertilisers	/	B3.1	0.001 (Fsubstance in formulation: 100%)	1.1	2
Various chemical effects							
Formulation	2 Chemical industry	0 Other	Default	B2.3	1	2214	300
Industrial use: Processing	2 Chemical industry	0 Other	Default	B3.2	0.3	664	133

Specific

Manufacturers/Importers

Table 10-5 is derived on the basis of information submitted by individual sites involved in production of boric acid, sodium tetraborate pentahydrate and sodium tetraborate decahydrate. It represents average and maximum site tonnages (as substance and as B_2O_3) produced or handled by the different sites. Next to tonnage data, information on the average number of working days for the production sector was extracted from the questionnaires.

Tabelle 10.5 Tonnages derived for a generic production site on basis of questionnaire information

Scenario	Average site tonnage (T substance)	Maximum site tonnage (T substance)	Conversion factor	Average site Site tonnage (T B_2O_3)	Maximum site tonnage (T B_2O_3)	N° of emission days
Production of boric acid	9550	15000	0.563	5377	8445	365
Production of sodium tetraborate anhydrous	ND	ND	0.69	ND	ND	365
Production of sodium tetraborate pentahydrate	16820	30720	0.49	8241	15054	365
Production of sodium tetraborate decahydrate	2150	2300	0.365	785	840	365
TOTAL				**14403**	**24339**	**365**

Downstream users

Table 10-6 is derived on the basis of the information submitted by individual sites from different industry sectors and thus represents actual tonnages (as B_2O_3) of boric acid, sodium tetraborate anhydrous, sodium tetraborate pentahydrate, sodium tetraborate decahydrate used by the sites (see section 3.1.4.2). Next to tonnage data, information on the average number of working days for the different sectors was extracted from the questionnaires. Both data sets will be used in the development of generic exposure scenarios for different sectors. Please note that for some sectors i.e. cleaners & detergents no questionnaire information was submitted, hence a site-specific tonnage could not be derived. For these sectors, a default tonnage was applied.

Tabelle 10.6 Tonnages derived for a generic downstream user site on basis of questionnaire information

Sector	Boric acid, sodium tetraborate anhydrous, sodium tetraborate pentahydrate, sodium tetratborate decahydrate			Number of working days
	Number of questionnaires	**Average tonnage (T B_2O_3)**	**Maximum tonnage (T B_2O_3)**	
Glass & glass products				
Borosilicate	21	2200	7600	365
Fibre glass	10	700	2700	365
Ceramics				
glass frits and vitreous enamel frits	9	750	2500	200
Industrial fluids	12	170	370	225
Metallurgy (flux agents)	4	7	13	30
Electroplating	5	25	100	260
Chemical synthesis	7	500	1500	245
Flame retardants (cellulose	1	-	280	80

Sector	**Boric acid, sodium tetraborate anhydrous, sodium tetraborate pentahydrate, sodium tetratborate decahydrate**			**Number of working days**
	Number of questionnaires	**Average tonnage (T B_2O_3)**	**Maximum tonnage (T B_2O_3)**	
insulation)				
Fertiliser	13	150	560	135

10.3 Release from industrial/professional use

Rapporteur´s Comment to information based on Questionnaire:This information gathered from questionnaires, which was used for the site specific assessment could not be evaluated, because answers to questionnaires had not been submitted.

10.3.1 Glass and glass products

Questionnaire information

An overview of general information, availability of environmental emission data and information on risk management measures is reported below respectively.

- Information was submitted by 38 glass manufacturing IDs[8]. From these 38 IDs; 21 are involved in borosilicate glass manufacturing, 5 in continuous filament glass fibre manufacturing (CFGF), 1 is a sector input for glass wool insulation, 4 in 'glass fibre' related products and 7 are categorised as 'others'. From these 'others': some are involved in the production of 'special glass': thin glass, gobs and lenses, optical glass, dental glass, sodium potash glass,...
- The substances used by this sector are boric acid, sodium tetraborate decahydrate, disodiumtetraborate pentahydrate and disodium tetraborate anhydrous. The total amount of borate substances used by the sites from the glass and glass products sector that submitted information amounts to around 74640 T B_2O_3 (20080 T B_2O_3 for the borosilicate sector, 53900 T B_2O_3 for the glass fibre sector and 660 T B_2O_3 for the special glass sector respectively).
- On the basis of the data submitted by individual sites from this industry sector, an average and maximum use tonnage for boric acid and sodium tetraborates can be derived as **2200T B_20_3** and **7600T B_20_3** respectively for a generic site involved in borosilicate glass production. For the glass fibre production sector, it is proposed to assume **700T** B_20_3 as average and **2700T B_20_3** as maximum tonnage data. These data will be further used in the generic ES to be developed for this sector.
- The number of working days for the sector is 365 days (7 days per week, 24 hours/day). The site involved in sodium potash glass production reports 233d; a manufacturer of glass fibre mats reports 80d.
- On the basis of the process information provided by different sites involved in borosilicate, IFG and TGD manufacturing, it can be concluded that major environmental emissions are expected from the *glass melting process* where the batch is melted in the furnace at a temperature of around 1550°C in a fully automated and continuous process. Stack emissions from the furnace are controlled using filters (EP, fabric or bag filters,…). Dust is pelletized and recycled back to the raw material weighing process to produce glass. Other sources of environmental exposure are possibly raw material handling, weighing, mixing, blending, cleaning stages; although exposure is expected to be of less importance than during the melting process and more of diffuse nature, hence difficult to quantify. The sites report that dust from the exhausting system, cleaning and brushing the floor is recycled as raw material for glass production or handled as dangerous waste (in case of contamination).

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[8] The term ID will be further used, since in some cases; it is clear that there are multiple inputs (substances) for one site. However, in order to distinguish between site and ID, more detailed information on the sites is needed.

- At this stage, no quantitative emission data were submitted. However, 13 IDs reported that emission measurements are available for their site. It is highly recommended to request these data in order to get a realistic estimation of the B emissions/emission factors for the sector and related exposure concentrations. 20 sites report to have no emission data for their ID; the remaining 5 sites did not specify. The majority of the sites from the sector expressed to be willing to co-operate in a further ES development for their sector.
- The following information on Risk Management Measurements was reported:
    - for waste water, 25 IDs mentioned that an on-site WWTP was installed: the physico-chemical treatment plant consists of the following steps: sedimentation, filtration, precipitation, cooling water (borosilicate site) can also be released directly to the river (regular analysis of discharged water).
    - some sites report that waste water is being transferred to a municipal STP
    - as a result of the melting process, air emissions are highly probable: all sites report that Air Pollution Control systems are installed: fabric or bag filters, electrostatic precipitators, wet, dry, semi-dry scrubbers. One site actually reports removal efficiency for fabric or bag filters of 99.9%.
    - with respect to diffuse air emissions; sites report to have no data; in some cases it is mentioned that the storage area is covered to prevent diffuse emissions.
    - the majority of the sites report that waste is removed to an off-site location (landfill) or recycled into the process (glass cullets, filter dust).

Tabelle 10.7 Overview of general information for the glass and glass products sector (borosilicate glass, IFG, TFG)

Subsector	ID	Substance name	CAS number	Wetted/dry	Total tonnage used per year (2005-2007) (T substance)			Annual operating days	Number of working days per week	Number of working hours per day
				%	min	max	average	(days/year)	(days/week)	(hours/day)
borosilicate glass	15-02	boric acid	10043-35-3	dry	350	500	420	365	7	24
borosilicate glass	15-03	disodiumtetraborate pentahydrate	12179-04-3	dry	300	400	340	365	7	24
borosilicate glass	11-01	boric acid	10043-35-3	dry	1900	2040	1950	365	7	24
borosilicate glass	11-02	disodium tetraborate pentahydrate	12179-04-3	dry	2800	3500	3010	365	7	24
borosilicate glass	11-03	boric acid, tetraborate anhydrous, tetraborate pentahydrate	10043-35-3; 1330-43-4; 12179-04-3	ND	13700	15500	15500	365	ND	24
borosilicate glass	S1	sodium tetraborate pentahydrate	12179-04-3	<0.1%	11000	15000	12000	365	7	24
borosilicate glass	S2	boric acid technical grade	10043-35-3	<0.1%	1000	1500	1250	365	7	24
borosilicate glass	S3	anhydrous sodium tetraborate	1330-43-4	<0.1%	1000	1500	1500	365	7	24
borosilicate glass	4-02	boric acid	10043-35-3	ND	628	794	744	365	7	24
borosilicate glass	4-03	sodium tetraborate pentahydrate	12179-04-3	ND	918	1187	1085	365	7	24
borosilicate glass	4-04	sodium tetraborate pentahydrate	12179-04-3	<0.1%	11000	15000	12000	365	7	24
borosilicate glass	4-05	boric acid technical grade	10043-35-3	<0.1%	1000	1500	1250	365	7	24
borosilicate glass	4-06	anhydrous sodium tetraborate	1330-43-4	<0.1%	1000	1500	1500	365	7	24
borosilicate glass	B	sodium tetraborate pentahydrate	12179-04-3	dry	ND	ND	4644	365	7	24
borosilicate glass	18-28	boric acid	10043-35-3	dry	272	290	280	365	7	24
borosilicate glass	18-28	sodium tetraborate pentahydrate	12179-04-3	dry	704	923	811	365	7	24
borosilicate glass	22-02	boric acid	10043-35-3	less than 0.1%	750	1125	930	365	7	24
borosilicate glass	22-04	sodium tetraborate pentahydrate	12179-04-3	less than 0.1%	250	375	310	365	7	24

Subsector	ID	Substance name	CAS number	Wetted/dry	Total tonnage used per year (2005-2007) (T substance)			Annual operating days	Number of working days per week	Number of working hours per day
				%	min	max	average	(days/year)	(days/week)	(hours/day)
borosilicate glass	22-06	Boric Acid/Boric Acid(Technical Grade)	10043-35-3	dry	1000	1200	1100	365	7	24
borosilicate glass	22-07	disodium tetraborate pentahydrate	12179-04-3	ND	6000	7000	6500	365	7	12
borosilicate glass	22-09	disodium tetraborate pentahydrate	12179-04-3	ND	2350	2500	2500	365	ND	24
speciality glass	18-11	disodium tetratorate pentahydrate	12179-04-3	dry	ND	ND	320	365	7	24
speciality glass	18-05	boric acid	10043-35-3	dry	195	253	230	365	7	24
speciality glass	18-05bis	boric oxide	1303-86-2	dry	37	53	46	365	7	24
sodium potash glass production	22-22	disodium tetraborate	1303-96-4		0.612	0.732	0.663	233	5	1
speciality glass	18-08	boric oxide	1303-86-2	< 2 %	20	300	250	365	7	24
speciality glass	18-09	boric acid	10043-35-3	???	20	300	250	365	7	24
speciality glass	15-01	disodium tetraborate pentahydrate	12179-04-3	dry <0.5%	460	500	480	365	7	24
continuous filament glass fibre production (CFGF)	15-04	disodium tetraborate pentahydrate	12179-04-3	0.15% moisture typically	1385	1514	1450	365	7	24
continuous filament glass fibre production (CFGF)	C	boric acid	10043-35-3	ND	4300	5400	4767	365	7	24
continuous filament glass fibre production (CFGF)	F	colemanite mineral	ND	dry	ND	ND	7700	365	7	24
continuous filament glass fibre production (CFGF)	G	disodium tetroborate pentahydrate	12179-04-3	29.60%	212	519	486	365	0.5	24
glass wool insulation	EURIMA	disodium tetraborate pentahydrate (other forms may be used)	12179-04-3	dry		70000	130000	365	7	24
glass fibre mats	18-15	disodium tetratorate pentahydrate	12179-04-3	dry	2.4	7.2	7.2	80	1.5	24
continuous filament glass fibre production (CFGF)	A	disodium tetroborate pentahydrate	12179-04-3	1% humidity	ND	ND	1300	365	7	24

Subsector	ID	Substance name	CAS number	Wetted/dry	Total tonnage used per year (2005-2007) (T substance)			Annual operating days	Number of working days per week	Number of working hours per day
				%	**min**	**max**	**average**	**(days/year)**	**(days/week)**	**(hours/day)**
continuous filament glass fibre production (CFGF)	D	disodium tetraborate pentahydrate	12179-04-3	0.25%	581	678	582	365	5	24
thin glass fibres production	E	disodium tetraborate pentahydrate, sodium tetraborate pentahydrate	12179-04-3	dry matter 100%	607	683	650	365	7	24

Tabelle 10.8 Overview of availability of emission data and information on Risk Management Measures for the glass sector

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	**Participate in further ES work?**	**On-site WWTP present ?**	**To muncipal STP ?**	**Stack**	**Diffuse**	**Waste removal to off-site location (e.g. hazardous waste site)**	**Recycled for re-use**
borosilicate glass	15-02	ND	ND	ND	ND	electrostatic precipitators	ND	yes	yes
borosilicate glass	15-03	ND	ND	ND	ND	electrostatic precipitators	ND	yes	yes
borosilicate glass	11-01	NO	YES	ND	ND	fabric or bag filters	ND	yes	yes
borosilicate glass	11-02	NO	YES	ND	ND	fabric or bag filters	ND	yes	yes
borosilicate glass	11-03	NO	YES	no	no	electrostatic precipitators, fabric or bag filters	no	no	yes
borosilicate glass	S1	NO	YES	yes	yes	fabric or bag filters, electrostatic precipitators, dry or semi-dry scrubbers	ND	yes	yes
borosilicate glass	S2	NO	YES	yes	yes	fabric or bag filters, electrostatic precipitators, dry or semi-dry scrubbers	ND	yes	yes
borosilicate glass	S3	NO	YES	yes	yes	fabric or bag filters, electrostatic precipitators, dry or semi-dry scrubbers	ND	yes	yes
borosilicate glass	4-02	NO	YES	chemical precipitation, sedimentation, filtration	no	fabric or bag filters	storage coverage	yes	yes
borosilicate glass	4-03	NO	YES	chemical precipitation, sedimentation, filtration	no	fabric or bag filters	storage coverage	yes	yes
borosilicate glass	4-04	NO	YES	yes	yes	fabric or bag filters, electrostatic precipitators, dry or semi-dry scrubbers	ND	yes	yes
borosilicate glass	4-05	NO	YES	yes	yes	fabric or bag filters, electrostatic precipitators, dry or semi-dry scrubbers	ND	yes	yes
borosilicate glass	4-06	NO	YES	yes	yes	fabric or bag filters, electrostatic precipitators, dry or semi-dry scrubbers	ND	yes	yes
borosilicate glass	B	YES	YES	No RMM required.	no	negative pressure in oven, bag filters	no	no	dust from filter is reused in the batch; glass waste is reused in the furnace.

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	**Participate in further ES work?**	**On-site WWTP present ?**	**To muncipal STP ?**	**Stack**	**Diffuse**	**Waste removal to off-site location (e.g. hazardous waste site)**	**Recycled for re-use**
borosilicate glass	18-28	YES	YES	Yes. Chemical precipitation, sedimentation, filtration	yes	bag filters, sinter plate filter	storage coverage, funneling of rain water	yes	yes
borosilicate glass	18-28	YES	YES	Yes. Chemical precipitation, sedimentation, filtration	yes	bag filters, sinter plate filter	storage coverage, funneling of rain water	yes	yes
borosilicate glass	22-02	ND	YES	yes. Filtration.	yes	fabric or bag filters, electrostatic precipitators, dry or semi-dry scrubbers	no	yes	yes
borosilicate glass	22-04	ND	YES	yes. Filtration.	yes	fabric or bag filters, electrostatic precipitators, dry or semi-dry scrubbers	no	yes	yes
borosilicate glass	22-06	YES	YES	Cooling water is released directly to the river; Regular analysis are performed to control the quality of the released water; Waste water treatment doesn't include borates	ND	bag filters	no	yes	no
borosilicate glass	22-07	YES	YES	Cooling water is released directly to the river; Regular analysis are performed to control the quality of the released water; Waste water treatment doesn't include borates	ND	bag filters	no	yes	no
borosilicate glass	22-09	NO	YES	no	no	fabric or bag filters, electrostatic precipitators	no	no	yes
speciality glass	18-11	NO	YES	ND	ND	ND	ND	ND	ND
speciality glass	18-05	NO	YES	yes. Sedimentation (separators), other: (waste water detention system/basin, professional disposal)	no	fabric filters	storage coverage (closed building)	yes	no
speciality glass	18-	NO	YES	yes. Sedimentation (separators),	no	fabric filters	storage	yes	no

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	Participate in further ES work?	On-site WWTP present ?	To muncipal STP ?	Stack	Diffuse	Waste removal to off-site location (e.g. hazardous waste site)	Recycled for re-use
	05bis			other: (waste water detention system/basin, professional disposal)			coverage (closed building)		
sodium potash glass production	22-22	NO	NO	yes. Sedimentation, filtration, chemical precipitation	no	no	no	yes	yes
speciality glass	18-08	NO	YES	yes. Sedimentation, filtration	yes	fabric or bag filters	no	yes	no
speciality glass	18-09	NO	YES	yes. Sedimentation, filtration	yes	fabric or bag filters	no	yes	no
speciality glass	15-01	YES	YES	No	No, only cooling water	electrostatic precipitators	no	30T/year	3500 T/year glass cullets
continuous filament glass fibre production (CFGF)	15-04	YES	YES	see details					
continuous filament glass fibre production (CFGF)	15-09	YES	YES	see details					
continuous filament glass fibre production (CFGF)	C	YES	YES	yes. Chemical precipitation, filtration, biological treater	ND	wet scrubbers	storage coverage, funneling of rain water	yes	yes
continuous filament glass fibre production (CFGF)	F	YES	NO	yes. Either on-site (chemical precipitation) or off-site depending on local infrastructure	yes	electrostatic precipitators, fabric or bag filters, wet scrubbers	storage coverage, funneling of rain water	yes	no
continuous filament glass fibre production (CFGF)	G	YES	YES	ND	ND	electrostatic precipitators, fabric or bag filters	ND	yes	yes
glass wool insulation	EURIMA	YES	YES	No discharges to water of borates via municipal waste treatment or storm water systems. Closed loop process water system (wash water).	no	fabric or bag filters, electrostatic precipitators, wet scrubbers	ventilation and filtration systems	yes	yes

Subsector	**ID**			**WATER**		**AIR**		**WASTE**	
		Quantitative emission data available?	**Participate in further ES work?**	**On-site WWTP present ?**	**To muncipal STP ?**	**Stack**	**Diffuse**	**Waste removal to off-site location (e.g. hazardous waste site)**	**Recycled for re-use**
glass fibre mats	18-15	NO	YES	yes. binder solution reused in process. Cleaning water treatedin on site biological treatment plant.	no	other: regenerative thermal oxidizer	ND	no	yes. Pieces or segments of non-woven waste will be shreddered and used for recultivation. Edge trims will be grinded and recycled in brick industry.
continuous filament glass fibre production (CFGF)	A	NO	YES	yes, chemical precipitation, sedimentation	yes	fabric or bag filters: 99.9% efficiency	storage coverage	yes; landfill	yes
continuous filament glass fibre production (CFGF)	D	YES	ND	yes. Chemical precipitation.	no	electrostatic precipitators	storage coverage	yes	no
thin glass fibres production	E	ND	ND	yes. Chemical precipitation, sedimentation, filtration (appropriate for all plants); biological waste water treatment (appropriate for plant 3 SGV)	yes. Appropriate for plant 1 SGV.	dry or semi-dry scrubbers	no	yes	yes

10.3.2 Ceramics

Questionnaire information

An overview of general information, availability of environmental emission data and information on risk management measures is reported below respectively. Next to this information, detailed flow charts and descriptions on the different manufacturing steps and potential for exposure have been provided by different sites.

- Information was submitted by 9 frits and enamel manufacturing IDs[9]. The sites are involved in the manufacture of glass frits and vitreous enamel frits for coating metals.
- The sites mention that borates are added to improve the ability to control thermal expansion and refining properties.
- The substances used by this sector are boric acid, sodium tetraborate decahydrate, disodiumtetraborate pentahydrate and disodium tetraborate anhydrous. The total amount of borate substances used by the sites from the ceramics sector that submitted information amounts to around 3800T B_2O_3.
- On the basis of the data submitted by individual sites from this industry sector, an average and maximum use tonnage for boric acid and sodium tetraborates can be derived as **750T B_2O_3** and **2500T B_2O_3** respectively for a generic site involved in manufacturing of glass frits and vitreous enamel frits. These data will be further used in the generic ES to be developed for this sector.
- The number of working days for the sector is variable and depends on the volume processed; from 20d-350d (1-5 days per week, 8-24 hours/day). *The annual average number of working days for the sector is 200d.*
- On the basis of the process information provided by different sites involved in glass frits and vitreous enamel frits manufacturing, it can be concluded that major environmental emissions are expected from the *batch melting process (air emissions)* where the batch is melted in the kiln or furnace at a temperature of 1200-1500°C in a fully automated and continuous process. Stack emissions from the kiln are controlled using bag filters. Bag filters are cleaned once/week and the dust is recycled to produce frit. Other sources of environmental exposure to air are possibly raw material handling, weighing, mixing, blending, drying and cleaning stages; although exposure is expected to be of less importance than during the melting process and more of diffuse nature, hence difficult to quantify. The sites report that dust from the exhausting system, cleaning and brushing the floor is recycled as raw material for glass production or handled as dangerous waste (in case of contamination). *Waste water emissions can be expected from the quenching step.* Once molten the glass exits the kiln at the opposite end to where the batch is fed in. The molten glass is quenched in water. Due to the extreme thermal shock, the molten glass is turned into water insoluble particles called frits. However, to ensure a constant temperature of the water used for quenching, *water is recycled*. Also, new water is added to compensate for the amount lost due to evaporation. During recycling of the water, particles are removed by sedimentation of particles. The resulting sludge is recycled for frit production. Additionally, some waste water arises from cleaning activities, the waste water is treated in the on-site wwtp (sedimentation). Water is recycled, sludge is reused in the process.
- For this sector, no quantitative emission data were submitted. 6 sites report to have no emission data for their ID; the remaining 3 sites did not specify. The majority of the sites from the sector expressed to be willing to co-operate in a further ES development for their sector.

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[9] The term ID will be further used, since in some cases; it is clear that there are multiple inputs for one site. However, in order to distinguish between site and ID, more detailed information on the sites is needed.

- The following information on Risk Management Measurements was reported:
    - for waste water, 8 IDs mentioned that an on-site treatment of waste water is occurring: in most cases, the treatment is limited to sedimentation. In one case, the waste water is collected and reused.
    - One site reports that waste water is being transferred to a municipal STP
    - as a result of the melting process, air emissions are highly probable: all sites report that fabric or bag filters are installed.
    - with respect to diffuse air emissions; sites report to have no data; in some cases it is mentioned that the storage area is covered or that rainwater funnelling is taking place in order to prevent diffuse emissions.
    - the majority of the sites report that waste is removed to an off-site location (landfill). The general process scheme indicates that filter dust is recycled into the process.

Tabelle 10.9 Overview of general information for the ceramics sector (frits and enamels)

Subsector	ID	Substance name	CAS number	Wetted/dry	Total tonnage used per year (2005-2007) (T substance)			Annual operating days	Number of working days per week	Number of working hours per day
				%	min	max	average	(days/year)	(days/week)	(hours/day)
Frits, enamels; clay industry for brick production	15-08	disodiumtetraborate pentahydrate (43%) blended with boric acid (57%)	12179-04-3 and 1303-86-2	wetted	R+D anticipated tonnage never reached<1000 tonnes per annum.			20	ND	8
Vitreous enamel frits production	18-12	disodium tetraborate decahydrate	1303-96-4	ND	1.6	3.6	2.5	20	5	24
Vitreous enamel frits production	18-13	Boric acid	10043-35-3	ND	12	34	24	30	5	24
Vitreous enamel frits production	18-14	disodium tetraborate pentahydrate	12179-04-3	ND	640	879	799	230	5	24
Manufacturer of glass frits for use in many industries	18-17	disodium tetraborate anhydrous	1330-43-4	dry	ND	ND	133	253	0.85	24
Manufacturer of glass frits	18-18	Boric acid	10043-35-3	dry	ND	ND	65	253	0.42	24
Manufacturer of glass frits	18-20	disodium tetraborate pentahydrate	12179-04-3	dry	ND	ND	548	253	3.4	24
Manufacture of glass frits	18-23	disodium tetraborate pentahydrate	12179-04-3	dry	4865	5390	5170	316	7	24
Manufacture of frits	18-24	boric acid; tetraborate pentahydrate	233-139-2 215-540-4.	ND	400	1000	400	350	ND	24

Tabelle 10.10 Overview of availability of emission data and information on Risk Management Measures for the ceramics sector

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	Participate in further ES work?	On-site WWTP present ?	To muncipal STP ?	Stack	Diffuse	Waste removal to off-site location (e.g. hazardous waste site)	Recycled for re-use
Frits, enamels; clay industry for brick production	15-08	ND	ND	waste water specific to this substance is collected and reused	ND	no	storage coverage	yes	no
Vitreous enamel frits production	18-12	NO	YES	yes. Sedimentation	no	fabric or bag filters - HF capture by calcium hydroxide powder	ND	yes; spent lime disposed off to landfill	no
Vitreous enamel frits production	18-13	NO	YES	yes. Sedimentation	no	fabric or bag filters - HF capture by calcium hydroxide powder	ND	yes; spent lime disposed off to landfill	no
Vitreous enamel frits production	18-14	NO	YES	yes. Sedimentation	no	fabric or bag filters - HF capture by calcium hydroxide powder	ND	yes; spent lime disposed off to landfill	no
Manufacturer of glass frits	18-17	NO	YES	yes. Sedimentation.	no	fabric or bag filters	storage coverage, funneling of rain water	yes	no
Manufacturer of glass frits	18-18	NO	YES	yes. Sedimentation.	no	fabric or bag filters	storage coverage, funneling of rain water	yes	no
Manufacturer of glass frits	18-20	NO	YES	yes. Sedimentation.	no	fabric or bag filters	storage coverage, funneling of rain water	yes	no
Manufacture of glass frits	18-23	ND	YES	yes. Central sedimentation	yes	fabric or bag filters	funneling of rainwater into canal	yes	yes
Manufacture of frits	18-24	ND	ND	ND	ND	ND	ND	ND	ND

10.3.3 Cleaners

Specific information was not yet submitted by this sector. Data will be collected by the sector in the framework of REACH and submitted to EBA by the end of the year. The only available information con be found in the HERA RAR on boric acid (HERA, 2006).

10.3.4 Industrial fluids

Questionnaire information

An overview of general information, availability of environmental emission data and information on risk management measures is reported below respectively.

- Information was submitted by 12 industrial fluids manufacturing IDs[10]. The sites are involved in the manufacture of metalworking fluids, quenching liquids, lubricating greases, fluids for cooling and lubricating.
- The borate additives are added to impart corrosion inhibition properties to the fluids.
- The substances used by this sector are boric acid, sodium tetraborate decahydrate, disodiumtetraborate pentahydrate and disodium tetraborate anhydrous. The total amount of borate substances used by the sites from the industrial fluids sector that submitted information amounts to around 1020T B_2O_3.
- On the basis of the data submitted by individual sites from this industry sector, an average and maximum use tonnage for boric acid and sodium tetraborates can be derived as 170T B_2O_3 and 370T B_2O_3 respectively for a generic site involved in industrial fluids manufacturing. These data will be further used in the generic ES to be developed for this sector.
- The number of working days for the sector is variable and depends on the volume processed; 20-255d in general, 5 days per week; only few hours per day. The annual average number of working days for the sites is 225d.
- On the basis of the process information provided by different sites involved in industrial fluids manufacturing, it can be concluded that major environmental emissions are expected from the *weighing and mixing steps* since weighing and mixing vessels are connected to pipes which carry fumes/dusts to a filter before release to the atmosphere (roof filters). Other sites mention that dusts or vapours are removed from the blending vessels by an extraction system which leads to a wet scrubber. Waste water arises from floor cleaning, cleaning of vessels. The waste water can be treated in an on site wwtp (sedimentation, filtration) or off-site (STP, disposed).
- For this sector, no quantitative emission data were submitted. 3 IDs report to have emission data available; 6 sites do not have data; the remaining 3 sites did not specify. The majority of the sites from the sector expressed to be willing to co-operate in a further ES development for their sector.
- The following information on Risk Management Measurements was reported:
    - for waste water, only 2IDs (probably same site) mentioned that an on-site treatment of waste water is installed: sedimentation and filtration is occurring. The waste water is treated in the on-site ultra-filtration unit. The oils are separated from the water and recycled while the water is filtered and channelled to the city waste water. In most cases, there is no treatment plant installed.

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[10] The term ID will be further used, since in some cases; it is clear that there are multiple inputs for one site. However, in order to distinguish between site and ID, more detailed information on the sites is needed.

- Three IDs report that waste water is being transferred to a municipal STP
- With respect to stack air emissions; 3 IDs report that the following air reduction equipment is installed: fabric or bag filters, wet scrubbers. The other sites did not specify.
- with respect to diffuse air emissions; one site reports the installation of roof filters. In some cases it is mentioned that the storage area is covered in order to prevent diffuse emissions.
- the majority of the sites report that waste is removed to an off-site location (landfill). The site with an on-site wwtp reports that the oil from the wwtp is recycled into the process.

Tabelle 10.11 Overview of general information for the industrial fluids sector

Subsector	**ID**	**Substance name**	**CAS number**	**Wetted/dry**	**Total tonnage used per year (2005-2007) (T substance)**			**Annual operating days**	**Number of working days per week**	**Number of working hours per day**
				%	**min**	**max**	**average**	**(days/year)**	**(days/week)**	**(hours/day)**
metalworking fluids	15-06	boric acid	10043-35-3	dry	491	535	515	255	5	1.5-2
metalworking fluids	15-07	disodium tetraborate decahydrate	1303-96-4	dry	2	2.9	2.4	31	1	1.5
metalworking fluids	18-01	boric acid	10043-35-3	dry			7			
metalworking coolants, quenching liquids	18-30	boric acid	10043-35-3	ND	96	126	116	200	5	2
carburizing protection pastes production	18-31	boric oxide	1303-86-2	ND	0	4	2.3	20	5	2
hardening salts production	18-32	disodium tetraborate anhydrous	1330-43-4	ND	0.6	0.6	0.6	20	5	2
Lubricating grease manufacturing.	22-14	boric acid	10043-35-3	dry	55	60	60	200	5	8
Production of metalworking fluids (concentrates)	22-15	boric acid	10043-35-3	dry	550	750	650	220	6	24
Production of lubricating greases for rolling bearings	22-16	disodium tetraborate decahydrate	1303-96-4	dry	ND	ND	5	225	5	16
Production of metalworking fluids (concentrates)	22-17	boric acid	10043-35-3	dry (granules)	400	500	450	250	5	8
fluids for cooling and lubricating	22-19	disodium tetraborate pentahydrate	12179-04-3	dry (granules)	ND	ND	2	12	1 day per month	8

Tabelle 10.12 Overview of availability of emission data and information on Risk Management Measures for the industrial fluids sector

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	**Participate in further ES work?**	**On-site WWTP present ?**	**To muncipal STP ?**	**Stack**	**Diffuse**	**Waste removal to off-site location (e.g. hazardous waste site)**	**Recycled for re-use**
metalworking fluids	15-06	ND	YES	Yes. Sedimentation, filtration. The waste water is treated in the on-site ultra-filtration unit. The oils are separated from the water and recycled while the water is filtered and channelled to the city waste water.	Yes.	Other: roof filters	Other: roof filters	ND	oil from wwtp recycled
metalworking fluids	15-07	ND	YES	Yes. Sedimentation, filtration. The waste water is treated in the on-site ultra-filtration unit. The oils are separated from the water and recycled while the water is filtered and channelled to the city waste water.	Yes.	Other: roof filters	Other: roof filters	ND	oil from wwtp recycled
metalworking fluids	18-01			no	yes	wet scrubbers		yes	
metalworking coolants, quenching liquids	18-30	NO	YES	No special	No special	No special	No special	No special	No special
carburizing protection pastes production	18-31	NO	YES	No special	No special	No special	No special	No special	No special
hardening salts production	18-32	NO	YES	No special	No special	No special	No special	No special	No special
Lubricating grease manufacturing.	22-14	YES	YES	ND	ND	ND	ND	ND	ND
Production of metalworking fluids (concentrates)	22-15	YES	YES	Off site waste water treatment for special contaminated waste water	no	fabric or bag filters	storage coverage, funneling of rain water	yes	no
Production of lubricating greases for rolling bearings	22-16	YES	YES	Off site waste water treatment for special contaminated waste water	no	fabric or bag filters	storage coverage, funneling of rain water	yes	no

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	**Participate in further ES work?**	**On-site WWTP present ?**	**To muncipal STP ?**	**Stack**	**Diffuse**	**Waste removal to off-site location (e.g. hazardous waste site)**	**Recycled for re-use**
Production of metalworking fluids (concentrates)	22-17	NO	ND	ND	ND	ND	ND	ND	ND
fluids for cooling and lubricating	22-19	NO	ND	ND	ND	ND	ND	ND	ND

10.3.5 Metallurgy

An overview of general information, availability of environmental emission data and information on risk management measures is reported below respectively.

- Information was submitted by 4 metallurgy IDs[11] and 5 electroplating IDs. The sites are involved in the manufacture of flux agents for metal production, fluxes for welding, soldering and brazing and electroplating.
- Borates are added to improve the smelting process and fluxes are used as deoxidizers in soldering processes. In electroplating, boric acid is added as buffer to keep a constant value of pH.
- The substances used by this sector are boric acid, sodium tetraborate decahydrate and disodiumtetraborate pentahydrate. The total amount of borate substances used by the sites from the metallurgy sector that submitted information amounts to around 20T B_2O_3 (majority is used in production of wire products, pentahydrate used as soap carrier in drawing process).
- On the basis of the data submitted by individual sites from this industry sector, an average and maximum use tonnage for boric acid and sodium tetraborates can be derived as 7T B_2O_3 and 13T B_2O_3 respectively for a generic site involved in metallurgy. These data will be further used in the generic ES to be developed for this sector.
- The number of working days for the sector is variable and depends on the volume *processed; 20-*30d for flux agent in production metals; 20-48d for flux production soldering, welding brazing, 20-350 for electroplating (average 260). The annual average number of working days is 30d for flux production, 260d for electroplating.
- On the basis of the process information provided by different sites involved in manufacturing of fluxes, it can be concluded that environmental emissions are expected from the *weighing, mixing, packaging, cleaning and maintenance steps.* However, it should be noted that the type of emissions here is diffuse since no stacks, dust from the LEV and cleaning is recycled in the process. From the electroplating process, emissions to waste water are expected (cleaning process). The waste water is usually treated in a wwtp.
- For this sector, no quantitative emission data were submitted. 1 ID report to have emission data available; 6 sites do not have data; the remaining 2 sites did not specify. Half of the sites from the sector expressed to be willing to co-operate in a further ES development for their sector.
- The following information on Risk Management Measurements was reported:
    - for waste water, 6IDs (probably same site) mentioned that an on-site treatment of waste water is installed (plating and flux manufacturing for solders): chemical precipitation sedimentation and filtration is occurring.
    - With respect to stack air emissions; 5 IDs report that the following air reduction equipment is installed: fabric or bag filters. The other sites did not specify.
    - with respect to diffuse air emissions; in some cases it is mentioned that the storage area is covered in order to prevent diffuse emissions.
    - the majority of the sites report that waste is removed to an off-site location (landfill), in some cases, waste (e.g. dust) is recycled in the process.

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[11] The term ID will be further used, since in some cases; it is clear that there are multiple inputs for one site. However, in order to distinguish between site and ID, more detailed information on the sites is needed.

Tabelle 10.13 Overview of general information for the metallurgy sector

Subsector	ID	Substance name	CAS number	Wetted/dry	Total tonnage used per year (2005-2007) (T substance)			Annual operating days	Number of working days per week	Number of working hours per day
				%	min	max	average	(days/year)	(days/week)	(hours/day)
Flux agent (steel & non-ferrous metal production)										
production of lead and silver; substance is used as flux.	18-21	disodium tetraborate decahydrate	1303-96-4	dry	ND	ND	1-2	20	ND	24
production of fluxes for foundry industry	18-26	disodium tetraborate pentahydrate	12179-04-3	ND	20	35	27	30	1-2	8
Welding, brazing and soldering fluxes										
fluxes production used in brazing processes.	22-10	boric acid	10043-35-3	ND	8	12	10	48	1	4
flux coating paste production for welding brass	22-11	disodium tetraborate pentahydrate	12179-04-3	ND	ND	ND	0.15	20	1	8
Plating										
production of wire products from wire rod.	18-33	boric acid	10043-35-3	nd	0.5	1	0.75	300	6	24
production of brass bathroom accessoires, galvanising layer of chrome and nickel	22-21	disodium tetraborate	10043-35-3		0.16	0.23	0.19	233	5	8
Production of wire products from wire rod.	18-29	disodium tetraborate pentahydrate	12179-04-3	ND	173.4	235.5	204.6	350	7	24
Coatings: used as pH regulator in nickel baths for getting nickel layers on electronic components	15-05	boric acid	10043-35-3	99.50%	ND	ND	0.23	150	0	24
Electroplating is carried out (zinc, nickel, chrom) of parts supplied by customers. Boric acid is used as	15-12	boric acid	10043-35-3	99.90%	0.6	1.1	0.78	20-30	0-1	24

Subsector	ID	Substance name	CAS number	Wetted/dry	Total tonnage used per year (2005-2007) (T substance)			Annual operating days	Number of working days per week	Number of working hours per day
				%	min	max	average	(days/year)	(days/week)	(hours/day)
buffer to keep constant value of pH.										

Tabelle 10.14 Overview of availability of emission data and information on environmental Risk Management Measures for the metallurgy sector

Subsector	**ID**			**WATER**		**AIR**		**WASTE**	
		Quantitative emission data available?	**Participate in further ES work?**	**On-site WWTP present ?**	**To muncipal STP ?**	**Stack**	**Diffuse**	**Waste removal to off-site location (e.g. hazardous waste site)**	**Recycled for re-use**
Flux agent (steel & non-ferrous metal production)									
production of lead and silver; substance is used as flux.	18-21	ND	ND	no	no	fabric or bag filters	no	no	recycling in blast furnace for production of lead
production of fluxes for foundry industry	18-26	NO	YES	ND	ND	ND	ND	ND	ND
Welding, brazing and soldering fluxes									
fluxes production used in brazing processes.	22-10	NO	YES	yes. Sedimentation	no	fabric or bag filters	storage coverage	yes	yes
flux coating paste production for welding brass	22-11	NO	YES	yes. Sedimentation	no	fabric or bag filters	storage coverage	yes	yes
Plating									
production of wire products from wire rod.	18-33	NO	YES	Yes. Chemical precipitation.	No	fabric or bag filters	storage coverage	no	no
Production of brass bathroom accessoires, galvanising layer of chrome and nickel	22-21	NO	NO	yes. Sedimentation, filtration, chemical precipitation	no	no	no	yes	yes
Production of wire products from wire rod.	18-29	YES	ND	Yes. Chemical precipitation.	No	fabric or bag filters	ND	yes	no
Coatings: used as pH regulator in nickel baths for getting nickel layers on electronic components	15-05	ND	ND	ND	ND	ND	ND	ND	ND

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	**Participate in further ES work?**	**On-site WWTP present ?**	**To muncipal STP ?**	**Stack**	**Diffuse**	**Waste removal to off-site location (e.g. hazardous waste site)**	**Recycled for re-use**
Electroplating is carried out (zinc, nickel, chrom) of parts supplied by customers.	15-12	NO	NO	yes. Chemical precipitation.	no	exhaust without scrubber	storage coverage	yes	no

10.3.6 Remaining data from different use sectors/applications:

(flame retardancy, biological effects (fertilisers, biocides), various chemical effects: chemical synthesis, buffers, adhesive, printing ink, glue production, gypsum fibre board production, nuclear power plants, plaster board production, refractory use & Others: powder (frit), industrial ceramics, detergency)

I **Tabelle 10.15 Overview of general information for diverse sectors**

Subsector	ID	Substance name	CAS number	Wetted/dry	Total tonnage used per year (2005-2007) (T substance)			Annual operating days	Number of working days per week	Number of working hours per day
				%	**min**	**max**	**average**	**(days/year)**	**(days/week)**	**(hours/day)**
Flame retardancy										
cellulose insulation (flame retardants).	18-25	boric acid and sodium tetraborate decahydrate	10043-35-3 / 1303-96-4	100 % dry	400	600	500	80	5	24
Biological effects										
Fertiliser										
	11-04	disodium tetraborate decahydrate	1303-96-4		ND	ND	0.2	260	5	8
	18-02	disodium tetratorate pentahydrate	1330-43-4		50	400	400	263	7	24
	18-03	Mixture of boric acid and sodium tetraborate pentahydrate	ND		ND	ND	88	30-150	1-5	8
	18-06	Mixture of boric acid and sodium tetraborate	10043-35-3 + 12179-04-3 +		ND	ND	ND	ND	ND	ND

Subsector	ID	Substance name	CAS number	Wetted/dry	Total tonnage used per year (2005-2007) (T substance)			Annual operating days	Number of working days per week	Number of working hours per day
				%	min	max	average	(days/year)	(days/week)	(hours/day)
		pentahydrate	12631-71-9							
	18-07	Mixture of boric acid and sodium tetraborate pentahydrate	12280-03-4		ND	ND	ND	ND	ND	ND
	14-74	Boric acid	10043-35-3	99.9% pure min.	ND	ND	1000	120-180	2-3	8
	14-07	Boric acid	10043-35-3	dry	ND	ND	325	15	ND	ND
	14-27	sodium tetraborate pentahydrate	12179-04-3	dry	ND	ND	50	10	5	24
	14-28	Boric acid	10043-35-3	dry	ND	ND	2.5	2	1	8
	14-34	borax	1303-96-4	ND	ND	ND	2	ND	ND	ND
	14-70	sodium tetraborate pentahydrate	12179-04-3	dry	ND	ND	447	150	7	3
Various chemical effects										
Chemical synthesis										
production of corrosion inhibitors	18-34	boric acid	10043-35-3	dry	3	5	4	12	sporadically	nd
Raw material for production of technical phenol-formaldehyde resins.	22-12	boric acid	10043-35-3	ND	ND	ND	0.12	4	0.08	24
Raw material for production of technical phenol-formaldehyde resins.	22-13	disodium tetraborate decahydrate	1303-96-4	ND	ND	ND	0.12	4	0.08	24
Chemical synthesis	14-35	disodium tetraborate decahydrate, borax	1303-96-4	dry	ND	ND	350	350/365	7	24
Chemical synthesis	14-04	boric acid	10043-35-3	>99%	ND	ND	>1000	360	7	24
Chemical synthesis	14-82	boric acid	10043-35-3	ND	2455	2935	2666	355	7	24
Chemical synthesis	14-01	boric acid	10043-35-3	ND	ND	ND	>1000	365	7	24
Buffer										
adjusting buffer capacity in formaldehyde resins by	15-11	disodium tetraborate decahydrate	1303-96-4		ND	ND	120	365	7	1

Subsector	ID	Substance name	CAS number	Wetted/dry	Total tonnage used per year (2005-2007) (T substance)			Annual operating days	Number of working days per week	Number of working hours per day
				%	min	max	average	(days/year)	(days/week)	(hours/day)
adding to the resin reactor; glue production										
Adhesive										
Production of tires rubber adhesion promotors.	4-01	ground colemanite	12291-65-5; 16389-88-1; 1319-33-1	ND	ND	2	5	ND	1	.
Printing ink										
fountain solution for the offset printing industry	18-10	disodium tetraborate decahydrate	1303-96-4	>99.2% as is	ND	ND	33	261	5	7.5
Glue production (adhesive)										
glue production	15-10	disodium tetraborate decahydrate, sodium tetraborate decahydrate	1303-96-4	dry (100%)	0.7	1.5	1	3?	3	24
Nuclear power plants										
nuclear power plants.	18-04	boric acid	10043-35-3	fine powder	ND	ND	300	365	5 to 8 days/year/reactor	8
Plaster board production										
plaster board production for building industry	22-01	boric acid	10043-35-3	dry	nd	nd	480	350	7	24
plaster board production for building industry	22-03	boric acid	10043-35-3	>99%	nd	nd	500	340	6	24
plasterboard production	11-05	boric acid	10043-35-3		ND	ND	120	240	5	24
Refractory use										
refractory use	15-13	boric acid	10043-35-3	dry	ND	ND	300	50	2	2
refractory use?	15-14	disodium tetraborate anhydrous	1330-43-4	dry	ND	ND	230	ND	ND	ND

Subsector	ID	Substance name	CAS number	Wetted/dry	Total tonnage used per year (2005-2007) (T substance)			Annual operating days	Number of working days per week	Number of working hours per day
				%	min	max	average	(days/year)	(days/week)	(hours/day)
Other										
Powder, frit										
glass frit powder making	18-16	disodium tetraborate anhydrous	1330-43-4	dry	ND	ND	95	253	0.85	8.5
glass frit powder making	18-19	disodium tetraborate decahydrate	1303-96-4	dry	ND	ND	5	253	0.25	8.5
Industrial ceramics										
industrial ceramics (coating steel industry)	22-20	disodium tetraborate anhydrous	1330-43-4		35	43	39	72	2	8
Detergents										
	14-76	Boric acid	10043-35-3	99.9%	0.100	0.15	0.11	NA	NA	NA
	14-50	disodium tetraborate decahydrate	1303-96-4		0.05	0.2		2-5	ND	8

Tabelle 10.16 Overview of availability of emission data and information on environmental Risk Management Measures for the ‘others’ sector

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	**Participate in further ES work?**	**On-site WWTP present ?**	**To 315unnellin STP ?**	**Stack**	**Diffuse**	**Waste removal to off-site location (e.g. hazardous waste site)**	**Recycled for re-use**
Flame retardancy									
cellullose insulation (flame retardants).	18-25	NO	YES	ND	ND	ND	ND	ND	ND
Biological effects									
Fertiliser									
	11-04	NO	YES	ND	ND	ND	ND	ND	ND
	18-02	YES	NO	no	no	wet scrubbers	storage coverage,	yes	no

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	**Participate in further ES work?**	**On-site WWTP present ?**	**To 315unnellin STP ?**	**Stack**	**Diffuse**	**Waste removal to off-site location (e.g. hazardous waste site)**	**Recycled for re-use**
							316unnelling of rain water		
	18-03	ND	ND	no	yes? The plant is under retention.	Fabric or bag filters		yes	no
	18-06	ND	ND	ND	ND	ND	ND	ND	ND
	18-07	ND	ND	ND	ND	ND	ND	ND	ND
	14-74	NO	YES	Re-use of washings	no	fabric or bag filters	Storage coverage	yes	yes
	14-07	NO	YES	Biological waste water treatment plant	no	fabric or bag filters	ND	no	yes
	14-27	NO	YES	no	yes	no	no	yes	no
	14-28	NO	YES	no	yes	no	no	yes	no
	14-34	ND	ND	ND	ND	ND	ND	ND	ND
	14-70	NO	YES	Biological waste water treatment plant	no	no	no	yes	yes
Various chemical effects									
Chemical synthesis									
production of corrosion inhibitors	18-34	NO	NO	Yes. Sedimentation, biological treatment.	No	No	storage coverage	yes	no
Raw material for production of technical phenol-formaldehyde resins.	22-12	NO	NO	no	yes	no	no	yes	no
Raw material for production of technical phenol-formaldehyde resins.	22-13	NO	NO	no	yes	no	no	yes	no
Chemical synthesis	14-35	YES	YES	Total recycling of waste water	no	Wet scrubbers	ND	ND	ND

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	**Participate in further ES work?**	**On-site WWTP present ?**	**To 315unnellin STP ?**	**Stack**	**Diffuse**	**Waste removal to off-site location (e.g. hazardous waste site)**	**Recycled for re-use**
Chemical synthesis	14-04	YES	YES	no	yes	ND	ND	ND	ND
Chemical synthesis	14-82	NO	YES	ND	ND	Wet scrubbers	ND	ND	ND
Chemical synthesis	14-01	YES	YES	ND	ND	Bag filters	ND	ND	yes
Buffer									
adjusting buffer capacity in formaldehyde resins by adding to the resin reactor; glue production	15-11	NO	NO	ND	ND	ND	ND	ND	ND
Adhesive									
Production of tires rubber adhesion promotors.	4-01	NO	YES	ND	ND	ND	ND	ND	ND
Printing ink									
fountain solution for the offset printing industry	18-10	ND	ND	ND	ND	ND	ND	ND	ND
Glue production (adhesive)									
glue production	15-10	NO	YES	irrelevant	irrelevant	fabric or bag filters	No	yes	yes
Nuclear power plants									
nuclear power plants	18-04	NO	YES	other: internal operation exists to recycle boric acid solution in order to limit boric acid consumption and discharge in water and waste production. We have to respect the concentration limit of boric acid in chemical releases to river or sea. This limit	No discharge	no discharge	no discharge	yes, there is a specific company which burns radioactive waste. The batching room is in the radiation controlled area of	NO

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	Participate in further ES work?	On-site WWTP present ?	To 315unnellin STP ?	Stack	Diffuse	Waste removal to off-site location (e.g. hazardous waste site)	Recycled for re-use
				is given by government.				the plant.	
Plaster board production									
plaster board production for building industry	22-01	NO	YES	no	no	fabric or bag filters	no	yes	yes
plaster board production for building industry	22-03	NO	YES	ND	ND	ND	ND	ND	ND
plasterboard production	11-05	YES	YES	zero waste	zero waste	fabric or bag filters	no	yes	no
Refractory use									
refractory use	15-13	NO	YES	ND	ND	ND	ND	ND	ND
refractory use?	15-14	NO	ND	ND	ND	ND	ND	ND	ND
Other									
Powder, frit									
glass frit powder making	18-16	NO	YES	yes. Sedimentation.	No	fabric or bag filters	storage coverage, 318unnelling of rain water	yes	no
glass frit powder making	18-19	NO	YES	yes. Sedimentation.	No	fabric or bag filters	storage coverage, 318unnelling of rain water	yes	no
Industrial ceramics									
industrial ceramics (coating steel industry)	22-20	YES	YES	dry product processed – no emissions to water	no	bag filters	no	yes	no

Subsector	ID			WATER		AIR		WASTE	
		Quantitative emission data available?	**Participate in further ES work?**	**On-site WWTP present ?**	**To 315unnellin STP ?**	**Stack**	**Diffuse**	**Waste removal to off-site location (e.g. hazardous waste site)**	**Recycled for re-use**
Detergents									
	14-76	NO	NO	ND	ND	ND	ND	ND	ND
	14-50	NO	NO	ND	ND	ND	ND	ND	ND

10.4 Generic exposure scenarios

This section gives an overview of the input data and results of the exposure assessment performed for the chemicals production/importing sector and results of the generic exposure assessment performed for different industry use sectors.

One scenario is used for the producers/importers. A generic tonnage is estimated from EU data and B-tables from the TGD (fraction of main local source). The number of working days is estimated from the TGD (B-tables, default) or can be based on specific data. Emissions to air and water are estimated applying default emission factors for the sector (A-tables, TGD).

The daily emissions to air and surface water for the default scenario have been estimated as follows:

- Generic tonnage for a production site (or default TGD, B-tables)
- Application of default emission factors (air, water) for the sector (A-tables, TGD)
- Application of default number of emission days (from B-tables, TGD)
- Calculation of daily emissions to air, water
- Calculation of environmental concentrations for a TGD defined environment (discharge rate STP: 2000 m^3/d, dilution factor surface water: 10)

For the downstream use sectors, generic scenarios have been derived as no emission or exposure data is available. These are developed using TGD default assumptions for a generic environment and as a consequence present realistic worst case exposure concentrations for the different downstream use sectors. The results from this exercise should be used with caution and considered as provisional estimates of environmental exposure.

The Exposure Scenarios developed in this section reflect emissions and exposure from the use of boric acid, disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate pentahydrate in different use sectors.

For the major sectors, two types of generic scenarios are addressed. In the first scenario, a generic tonnage is estimated from EU data and B-tables from the TGD (10% rule, fraction of main local source). In the second specific scenario, real tonnage data are applied if available (average, maximum site). Tonnage information is extracted for the major use sectors from the questionnaire data (see section 10.2.4). The number of working days is estimated from the TGD (B-tables, default) and additonally is based on specific data in the specific assessment. Emissions to air and water are estimated applying default emission factors for the sector (A-tables, TGD).
Although for some sectors, general information on potential for exposure and applied Risk Management Measures is available, it is not possible to take this into account in this stage of the assessment (due to the non-availability of quantitative information).

The daily emissions to air and surface water for each scenario have been estimated as follows:

- Generic tonnage for a site in a specific sector (avg and max from questionnaires, or default TGD, B-tables)
- Application of default emission factors (air, water) for the sector (A-tables, TGD)
- Application of default number of emission days (from questionnaires or B-tables, TGD)
- Calculation of daily emissions to air, water
- Calculation of environmental concentrations for a TGD defined environment (discharge rate STP: 2000 m^3/d, dilution factor surface water: 10)

For comparative purposes, exposures to borates are often expressed in terms of boron (B) equivalents based on the fraction of boron in the source substance on a molecular weight basis.

10.5 Aquatic compartment (incl. sediment)

10.5.1 Calculation of predicted environmental concentrations (PEClocal)

Calculation of PEClocal for boric acid and sodium tetraborates producers/importers

An overview is given of input values and results from the exposure assessments for the boric acid and sodium tetraborates production sector (refining) for the aquatic compartment (water, sediment).

From the Table, the following conclusions can be drawn:

Tonnage

- Site production volumes in the EU for boric acid, sodium tetraborate anhydrous, sodium tetraborate pentahydrate and sodium tetraborate decahydrate are reported as 13000T, 100T, 12000T and 3000T respectively (EBA, 2008). Please note that there is no real primary production in the EU; manufacturing in the EU merely involves refining processes (from technical grade chemical to high purity chemicals). Site-specific production volumes for boric acid, sodium tetraborate pentahydrate and sodium tetraborate decahydrate amount to 9550-15000T, 16820-30720T, and 2150-2300 T.

Release factors

- The water emission factor for the production stage (refining) of the chemicals sector is 0.003 (A-tables, TGD).

Local concentrations

- As a result of the low adsorption of borates to suspended solids (low Kp), boron is mainly present in the water phase.
- *Default scenario:* Clocal for the production sector is between 2231 µg B/l (for a site involved in production of boric acid and sodium tetraborates; reasonable worst case). PEClocal for the production stage is 2328 µg B/l (regional background of 110.3 µg B/l taken into account). The Csediment level is derived on the basis of partitioning i.e. 15.7 mg B/kg dw. The added PEClocal for the production stage is 17.3 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 223 µg B/l; PECadd local marine is 241 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 1.72 mg/kg dw (PECadd regional sediment marine of 0.16 mg/kg dw taken into account).
- *Specific scenario:* Clocal for the average-maximum site is 1838-3107 µg B/l. PEClocal for the production stage is 1948-3217 µg B/l (regional background of 110.3 µg B/l taken into account). The Csediment level is derived on the basis of partitioning i.e. 12.9-21.8 mg B/kg dw. The added PEClocal for the production stage is 14.5 – 23.4 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a specific site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 184-311 µg B/l; PECadd local marine is 202-329 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 1.45-2.32 mg/kg dw (PECadd regional sediment marine of 0.16 mg/kg dw taken into account). At this stage, quantitative emission data was not

submitted. Therefore, default emission factors for production of chemicals were used for the emission estimation. It is recommended to request site-specific emission data in order to get a realistic estimation of the B emissions/emission factors and exposure concentrations.

Tabelle 10.17 Overview of results of generic and specific scenarios for the chemicals production sector (boric acid, sodium tetraborate anhydrous, sodium tetraborate pentahydrate and sodium tetraborate decahydrate) for the aquatic compartment (fresh water and sediment). It is assumed that no emission reduction measures are applied.

	Scenario	**Regional tonnage (T B_2O_3)**	**Fraction of main local source (B-tables TGD)**	**Site tonnage (T B_2O_3)**	**Default emission factor water (-)**	**Number of production days**	**Emission to water (kg B/d)**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal water (µg B/l)**	**PEC_{total} local water (µg B/l) (PECtotal reg: 110,3 µg/l)**	**Csediment (mg B/kg dw)**	**PEC_{total} sediment (mg B/kg dw) (PECtotalreg: 1.58 mg B/kg dw**
Default scenario (TGD)													
Default	Production of boric acid and borax compounds	14363 No 10% rule!, only few sites	1	14363	0.003	300	44.6	22.3	10	2231	2341	15.7	17.3
Specific scenario (specific tonnages)													
Specific average	Production of boric acid and borax compounds			14403	0.003	365	36.8	18.4	10	1838	1948	12.9	14.5
Specific maximum	Production of boric acid and borax compounds			24339	0.003	365	62.1	31.1	10	3107	3217	21.8	23.4

NR: not relevant

Csediment is calculated from Cwater applying the partitioning value for Kp_{susp}=3.5 l/kg.

Tabelle 10.18 Overview of results of generic and specific scenarios for the chemicals production sector (boric acid, sodium tetraborate anhydrous, sodium tetraborate pentahydrate and sodium tetraborate decahydrate) for the aquatic compartment (marine water and sediment). It is assumed that no emission reduction measures are applied. Please note that the PECadd local for marine water and sediment is calculated as the sum of the Clocal and the modelled PECadd regional concentration for marine water and sediment of 18.2 µg/l and 0.16 mg/kg dw respectively (EUSES 2.0; regional exposure report)

	Scenario	**Regional tonnage ($T B_2O_3$)**	**Fraction of main local source (B-tables TGD)**	**Site tonnage ($T B_2O_3$)**	**Default emission factor water (-)**	**Number of production days**	**Emission to water (kg B/d)**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal marine (µg B/l)**	**PEC_{add} local marine (µg B/l) (PECaddreg: 18.2 µg/l)**	**Csediment marine (mg B/kg dw)**	**PEC_{add} sediment (mg B/kg dw) (PECaddreg : 0.16 mg/kg dw)**
Default scenario (TGD)													
Default	Production of boric acid and borax compounds	14363 No 10% rule!, only few sites	1	14363	0.003	300	44.6	22.3	100	223	241	1.56	1.72
Specific scenario (specific tonnages)													
Specific average	Production of boric acid and borax compounds			14403	0.003	365	36.8	18.4	100	184	202	1.29	1.45
Specific maximum	Production of boric acid and borax compounds			24339	0.003	365	62.1	31.1	100	311	329	2.18	2.32

Calculation of PEClocal for industrial/professional use

An overview is given of input values and results from the generic exposure assessments for different borate industry user sectors for the aquatic compartment (water, sediment).

Two types of generic scenarios were developed. In the first scenario, a generic tonnage is estimated from EU-data and B-tables from the TGD. In the refined scenario, real tonnage data and number of working days are applied.

From the Table, the following conclusions can be drawn:

Tonnage

- Borosilicate glass: the site tonnages derived for the formulation step using the TGD methodology resemble quite well the average tonnage reported for specific sites (2416-3451T B_20_3 versus 2200T B_20_3). The maximum tonnage reported by a site is 7600T.
- IFG/TFG: the site tonnages derived on the basis of the TGD method are situated in the same range as the maximum tonnage reported by specific sites (2447-4994T B_20_3 versus 2700T B_20_3). The default tonnages are situated a factor of 4-7 above the average use volume for specific sites of 700T B_20_3.
- Ceramics: for this sector, the same observation is made as for the IFG/TFG sector. The site tonnages derived applying the B-tables -3144-4492T B_20_{3-} are situated in the same range as the maximum of real tonnage levels from specific sites (2500T B_20_3). The default tonnages are situated a factor of 4-6 above the average use volume for specific sites of 750T B_20_3.
- For the industrial fluids sector; the default tonnage of 449T B_20_3 is in agreement with the maximum of the reported site tonnage for specific sites (i.e. 370T B_20_3).
- For metallurgy sites, the default tonnage -398T B_20_3- is 40-fold the specific site tonnage (7-13T B_20_3).
- For the chemical synthesis sector (i.e. various chemical effects); the site tonnage derived for the formulation step using the TGD methodology of 2214T B_20_3 is in the same range as the maximum site-specific tonnage for the sector of 1500T B_20_3; and is 4-fold the average site-specific tonnage of 500T $B_20_{3.}$
- For the flame retardants sector; the site tonnage derived for the formulation step using the TGD methodology -725T B_20_{3-} is 3-fold the maximum site-specific tonnage -280T $B_20_{3.}$
- The fertiliser sector reports specific tonnages of 150-650T $B_20_{3;}$ while a default tonnage for formulation of 2214T B_20_3 was calculated. This means that the default tonnage is 3-15 fold the specific tonnages.
-

Release factors

- Release factors for formulation stages from different use sectors vary from 0.003 to 0.02 (A-tables, TGD). Although very different use functions were identified for the different use sectors, this was not reflected in the choice of the release factors, which remained fairly constant. The minimum and maximum water emission factors applied for this stage vary only with one order of magnitude. For cleaners and cosmetics, a release factor of 0.0009 was derived. Sector-specific information, e.g. that water used for quenching in the ceramics sector is recycled, cannot be taken into account in the default estimation of releases. In order to assess this; site measurements are needed.

- Release factors for processing and private use stages from different use sectors vary from 0.02 to 0.99 (A-tables, TGD). The same observation is made as with the formulation step; the min-max variation is only one order of magnitude. For chemical applications and agricultural use; emission factors of 0.007 and 0.05 are reported.

Local concentrations

- As a result of the low adsorption of borates to suspended solids (low Kp), B is mainly present the water phase.
- Clocal freshwater for glass and ceramics *formulation stages* vary between 89 µg B/l and 970 µg B/l (dependent on the use tonnage). PEClocal for the formulation stage is 199-1080 µg B/l (regional background of 110.3 µg B/l taken into account). The Csediment levels are derived on the basis of partitioning i.e. 0.6-6.8 mg B/kg dw. The added PEClocal is 2.2-8.4 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 8.9-97 µg B/l; PECadd local marine is 27.1-115.2 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.22-0.84 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).
- Clocal freshwater for industrial fluids formulation is 235-511 µg B/l. PEClocal is 345-621 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 1.7-3.6 mg B/kg dw. The added PEClocal is 3.3-5.2 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 23.5-51.1 µg B/l; PECadd local marine is 41.7-69.3 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.32-0.52 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).
- Clocal freshwater for metallurgy formulation is 73-412 µg B/l. PEClocal is 183-522 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 0.5-2.9 mg B/kg dw. The added PEClocal is 2.1-4.5 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 7.3-41.2 µg B/l; PECadd local marine is 25.4-59.4 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.21-0.45 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).
- Clocal freshwater for flame retardancy formulation is 751-1087 µg B/l. PEClocal is 861-1198 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 5.3-7.6 mg B/kg dw. The added PEClocal is 6.9-9.2 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 75-108.7 µg B/l; PECadd local marine is 93-127 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.69-0.92 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).
- Clocal freshwater for detergents formulation is 471 µg B/l. PEClocal is 581 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 3.3 mg B/kg dw. The added PEClocal is 4.9 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following

concentrations are derived; Clocal seawater is 47.1 µg B/l; PECadd local marine is 65.3 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.49 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

- Clocal freshwater for cleaners and cosmetics formulation is 29.2 µg B/l. PEClocal is 139 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 0.2 mg B/kg dw. The added PEClocal is 1.8 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 2.9 µg B/l; PECadd local marine is 21.1 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.18 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

- Clocal freshwater for agricultural use (fertiliser) formulation is 52-193 µg B/l. PEClocal is 162-303 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 0.4-1.4 mg B/kg dw. The added PEClocal is 2.0-3.0 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 5.2-19.3 µg B/l; PECadd local marine is 23.4-37.5 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.20-0.30 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

- Clocal freshwater for various chemical effects formulation is 95-344 µg B/l. PEClocal is 205-454 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 0.7-2.4 mg B/kg dw. The added PEClocal is 2.3-4.0 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 9.5-34.4 µg B/l; PECadd local marine is 27.7-52.6 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.23-0.40 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

- Clocal freshwater for glass and ceramics *processing stages* vary between 4467 µg B/l and 16167 µg B/l (dependent on the use tonnage). PEClocal is 4577-16277 µg B/l (regional background of 110.3 µg B/l taken into account). The Csediment levels are derived on the basis of partitioning i.e. 31-113 mg B/kg dw. The added PEClocal is 32.6-114.6 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 447-1617 µg B/l; PECadd local marine is 465-1635 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 3.3-11.5 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

- Clocal freshwater for industrial fluids *processing* is 511-775 µg B/l. PEClocal is 621-885 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 3.6-5.4 mg B/kg dw. The added PEClocal is 5.2-7.0 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 51-78 µg B/l; PECadd local marine is 69-96 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.52-0.70 mg/kg dw (PECadd regional marinesediment marine of 0.16 mg/kg dw taken into account).

- Clocal freshwater for metallurgy *processing* is 135-330 µg B/l. PEClocal is 245-440 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 0.9-2.3 mg B/kg dw. The added PEClocal is 2.5-3.9 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 13.5-33.0 µg B/l; PECadd local marine is 32-51 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.25-1.23 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

- Clocal freshwater for flame retardancy *processing* is 37.5-54 µg B/l. PEClocal is 148-164 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 0.3-0.4 mg B/kg dw. The added PEClocal is 1.9-2.0 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 3.8 µg B/l; PECadd local marine is 22.0 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.19 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

- Clocal freshwater for detergents *private use* is 306 µg B/l. PEClocal is 416 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 2.2 mg B/kg dw. The added PEClocal is 3.8 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 30.6 µg B/l; PECadd local marine is 48.8 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.37 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

- Clocal freshwater for cleaners and cosmetics *private use* is 52.8 µg B/l. PEClocal is 163 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 0.4 mg B/kg dw. The added PEClocal is 2.0 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 5.3 µg B/l; PECadd local marine is 23.5 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.20 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

- Clocal freshwater for agricultural use (fertiliser) *processing* is 436 µg B/l. PEClocal is 546 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 3.1 mg B/kg dw. The added PEClocal is 4.7 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 43.6 µg B/l; PECadd local marine is 61.8 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.47 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

- Clocal freshwater for various chemical effects *processing* is 543-666 µg B/l. PEClocal is 653-776 µg B/l. The Csediment levels are derived on the basis of partitioning i.e. 3.8-4.7 mg B/kg dw. The added PEClocal is 5.4-6.3 mg B/kg dw (added PEC regional of 1.58 mg B/kg dw taken into account). For a generic site discharging its effluent to a marine environment; the following concentrations are derived; Clocal seawater is 54.3-66.6 µg B/l; PECadd local marine is 72.5-84.8 µg B/l (PECadd regional marine of 18.2 µg/l taken into account) and PECadd sediment marine is 0.54-0.63 mg/kg dw (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

In conclusion; the C_local water levels (contribution from the site) for *formulation stages* for different use sectors vary from 29-760 µg B/l (generic assessment) and from 52-970 µg B/l (specific assessment); hence very comparable for both approaches. The PEClocal water concentrations are 139-870 µg B/l (generic assessment) and 162-1080 µg B/l (specific assessment) (regional background of 110.3 µg B/l taken into account). The C_local levels (contribution from the site) for formulation stages for different use sectors for sediment vary from 0.2-5.3 mg B/kg dw (generic assessment) and from 0.4-6.8 mg/kg dw (specific assessment). The added PEClocal for *formulation stages* for different use sectors for sediment vary from 1.8-6.9 mg B/kg dw (generic assessment) and from 2.0-8.4 mg/kg dw (specific assessment) (added PEC regional of 1.58 mg B/kg dw taken into account).

The C_local water levels (contribution from the site) for *processing stages* for different use sectors vary from 38-5813 µg B/l (generic assessment) and 54-16167 µg B/l (specific assessment). The C_local water (contribution from the site) for private use stages for detergents and cleaners and the industrial use stage for agriculture vary from 53-436 µg/l (generic assessment). The PEClocal water concentrations for *processing stages* for different use sectors are 148-5923 µg B/l (generic assessment) and 165-16278 µg B/l (specific assessment). The PEClocal water concentrations for *private use stages for detergents and cleaners and the industrial use stage for agriculture* vary from 163-546 µg B/l (generic assessment). The C_local levels (contribution from the site) for *processing stages* for different use sectors for sediment vary from 0.3-41 mg B/kg dw (generic assessment) and from 0.4-113 mg/kg dw (specific assessment). The C_local sediment (contribution from the site) for *private use stages for detergents and cleaners and the industrial use stage for agriculture* vary from 0.4-3.1 mg B/kg dw (generic assessment). The added PEClocal for *processing stages* for different use sectors for sediment vary from 1.9-42.6 mg B/kg dw (generic assessment) and from 2.0-114.6 mg/kg dw (specific assessment) (added PEC regional of 1.58 mg B/kg dw taken into account). The added PEClocal for *private use stages for detergents and cleaners and the industrial use stage for agriculture* for sediment vary from 2.0-4.7 mg B/kg dw (generic assessment) (added PEC regional of 1.58 mg B/kg dw taken into account).

The C_local marine levels (contribution from the site) for *formulation stages* for different use sectors vary from 2.9-76 µg B/l (generic assessment) and from 52-97 µg B/l (specific assessment); hence very comparable for both approaches. The PECadd local seawater concentrations are 21.1-94.2 µg B/l (generic assessment) and 23.4-115 µg B/l (specific assessment) (PECadd regional marine of 18.2 µg B/l taken into account). The C_local levels (contribution from the site) for formulation stages for different use sectors for marine sediment vary from 0.02-0.53 mg B/kg dw (generic assessment) and from 0.04-0.68 mg/kg dw (specific assessment). The PECadd marine sediment levels for formulation stages for different use sectors vary from 0.18-0.69 mg B/kg dw (generic assessment) and from 0.20-0.84 mg/kg dw (specific assessment) (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

The C_local seawater levels (contribution from the site) for *processing stages* for different use sectors vary from 3.8-581 µg B/l (generic assessment) and 3.8-1617 µg B/l (specific assessment). The C_local seawater (contribution from the site) for *private use stages for detergents and cleaners and the industrial use stage for agriculture* vary from 3.8-30.6 µg/l (generic assessment). The PECadd local seawater concentrations for *processing stages* for different use sectors are 22-600 µg B/l (generic assessment) and 22-1635 µg B/l (specific assessment). The PECadd local seawater concentrations for *private use stages for detergents and cleaners and the industrial use stage for agriculture* vary from 23.5-49 µg B/l (generic assessment). The C_local levels (contribution from the site) for *processing stages* for different use sectors for marine sediment vary from 0.03-4.1 mg B/kg dw (generic assessment) and from 0.4-11.3 mg/kg dw (specific assessment). The C_local marine sediment (contribution from the site) for *private use stages for detergents and cleaners and the industrial use stage for agriculture* vary from 0.04-0.2 mg B/kg dw (generic assessment). The PECadd marine sediment levels for processing stages for different use sectors vary from 0.2-4.2 mg B/kg dw (generic assessment) and from 0.20-11.5 mg/kg dw (specific assessment) (PECadd regional marine sediment of 0.16 mg/kg dw taken into account).

Tabelle 10.19 Overview of results of generic scenarios for the aquatic compartment (freshwater and sediment). It is assumed that no emission reduction measures are applied.

Sector	**Scenario**	**Regional tonnage (10%) (T B_2O_3)**	**Fraction of main local source (B-tables TGD)**	**Site tonnage (T B_2O_3)**	**Default emission factor water (-)**	**Number of production days**	**Emission to water (kg B/d)**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal water (µg B/l)**	**PEC_{total} local water (µg B/l) ($PECtotal_{reg}$: 110.3 µg/l)**	**Csediment (mg B/kg dw)**	**PEC_{total} sediment (mg B/kg dw) (PECtotal reg: 1.58 mg B/kg dw**
Glass and ceramics													
Borosilicate													
Formulation	Default (100% form)	3451	1.0	3451	0.003	300	10.72	5.36	10	536.0	646.3	3.76	5,34
Formulation	Default (15% form)	3451	0.7	2416	0.003	300	7.50	3.75	10	375.2	485.5	2.63	4,21
Formulation	Max. tonnage	Quest. info		7600	0.003	365	19.40	9.70	10	970.0	1080.3	6.81	8,39
Formulation	Avg. tonnage	Quest. info		2200	0.003	365	5.62	2.81	10	280.8	391.1	1.97	3,55
				2200-7600T	**0.003**	**300-365**	**5.6-19.4 kg/d**	**2.8-9.7 mg/l**		**281-970 µg/l**	**391-1080 µg/l**	**2.0-6.8 mg/kg dw**	**3.6-8.4 mg/kg dw**
Industrial use	*Default (15% form)*	*3451*	*0.5*	*1726*	*0.05*	*300*	*89.33*	*44.67*	*10*	*4466.5*	*4576.8*	*31.34*	*32,92*
	Max. tonnage	*Quest. info*		*7600*	*0.05*	*365*	*323.36*	*161.68*	*10*	*16167.4*	*16277.7*	*113.43*	*115,01*
IFG/TFG													
Formulation	Default (100% form)	6117	0.8	4894	0.003	300	15.20	7.60	10	760.0	870.3	5.33	6,91
Formulation	Default (5% form)	6117	0.4	2447	0.003	300	7.60	3.80	10	380.0	490.3	2.67	4,25
Formulation	Max. tonnage	Quest. info		2700	0.003	365	6.89	3.45	10	344.6	454.9	2.42	4.0
Formulation	Avg. tonnage	Quest. info		700	0.003	365	1.79	0.89	10	89.3	189.6	0.63	2,21
				700-4894T	**0.003**		**1.8-15.2 kg/d**	**0.9-7.6 mg/l**		**89-760 µg/l**	**189-870 µg/l**	**0.6-5.3 mg/kg dw**	**2.2-6.9 mg/kg dw**
Industrial	*Default*	*6117*	*0.3*	*1835*	*0.05*	*300*	*95.00*	*47.50*	*10*	*4749.7*	*4850.0*	*33.32*	*34,9*

Sector	**Scenario**	**Regional tonnage (10%) (T B_2O_3)**	**Fraction of main local source (B-tables TGD)**	**Site tonnage (T B_2O_3)**	**Default emission factor water (-)**	**Number of production days**	**Emission to water (kg B/d)**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal water (µg B/l)**	**PEC$_{total}$ local water (µg B/l) (PECtotal$_{reg}$: 110.3 µg/l)**	**Csediment (mg B/kg dw)**	**PEC$_{total}$ sediment (mg B/kg dw) (PECtotal reg: 1.58 mg B/kg dw**
use	*(5% form)*												
Industrial use	*Max. tonnage*	*Quest. info*		*2700*	*0.05*	*365*	*114.88*	*57.44*	*10*	*5743.7*	*5854.0*	*40.30*	*41,88*
Ceramics													
Formulation	Default (100% form)	4492	1.0	4492	0.003	300	13.95	6.98	10	697.6	807.9	4.89	6,47
Formulation	Default (30%form)	4492	0.7	3144	0.003	300	9.77	4.88	10	488.3	598.6	3.43	5,01
Formulation	Max. tonnage	Quest. info		2500	0.003	200	11.65	5.82	10	582.3	692.6	4.09	5,67
Formulation	Avg. tonnage	Quest. info		750	0.003	200	3.49	1.75	10	174.7	285.0	1.23	2,81
				750-4492T	**0.003**		**3.5-14.0 kg/d**	**1.8-7.0 mg/l**		**175-698 µg/l**	**285-808 µg/l**	**1.2-4.9 mg/kg dw**	**2.8-6.5 mg/kg dw**
Industrial use	*Default (30%form)*	*4492*	*0.5*	*2246*	*0.05*	*300*	*116.27*	*58.13*	*10*	*5813.1*	*5923.4*	*40.78*	*42,36*
Industrial use	Max. tonnage	Quest. info		2500	*0.05*	*200*	*194.13*	*97.06*	*10*	*9705.7*	*9816.0*	*68.09*	*69,67*
Industrial fluids													
Formulation	Default (100% form)	449	1.0	449	0.02	300	9.30	4.65	10	464.8	574.1	3.26	4,84
Formulation	Default (50% form)	449	1.0	449	0.02	300	9.30	4.65	10	464.8	575.1	3.26	4,84
Formulation	Max. tonnage	Quest. info		370	0.02	225	10.22	5.11	10	510.7	621.1	3.58	5,16
Formulation	Avg. tonnage	Quest. info		170	0.02	225	4.69	2.35	10	234.7	345.0	1.65	3,23
				170-449T	**0.02**		**4.7-10.2**	**2.4-5.1**		**235-511**	**345-621**	**1.7-3.6**	**3.2-5.2**

Sector	**Scenario**	**Regional tonnage (10%)** **(T B_2O_3)**	**Fraction of main local source (B-tables TGD)**	**Site tonnage** **(T B_2O_3)**	**Default emission factor water (-)**	**Number of production days**	**Emission to water** **(kg B/d)**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal water** **(µg B/l)**	**PEC_{total} local water (µg B/l) ($PECtotal_{reg}$: 110.3 µg/l)**	**Csediment** **(mg B/kg dw)**	**PEC_{total} sediment (mg B/kg dw) (PECtotal reg: 1.58 mg B/kg dw**
							kg/d	**mg/l**		**µg/l**	**µg/l**	**mg/kg dw**	**mg/kg dw**
Industrial use	*Default (50%form)*	*449*	*0.80*	*359*	*0.02*	*135*	*15.49*	*7.75*	*10*	*774.7*	*885.0*	*5.43*	*7,01*
	Max. tonnage	*Quest. info*		*370*	*0.02*	*225*	*10.22*	*5.11*	*10*	*510.7*	*621.0*	*3.58*	*5,16*
Metallurgy													
Formulation	Default (100% form)	398	1.0	398	0.02	300	8.23	4.12	10	411.5	521.8	2.89	4,47
Formulation	Default (20% form)	398	1.0	398	0.02	300	8.23	4.12	10	411.5	521.8	2.89	4,47
Formulation	Max. tonnage	Quest. info		13	0.02	30	2.69	1.35	10	134.6	244.9	0.94	2,52
Formulation	Avg. tonnage	Quest. info		7	0.02	30	1.45	0.72	10	72.5	182.8	0.51	2,09
				7-398T			**1.5-8.2 kg/d**	**0.6-2.6 mg/l**		**73-412 µg/l**	**183-522 µg/l**	**0.5-2.9 mg/kg dw**	**2.1-4.5 mg/kg dw**
Industrial use	*Default (20% form)*	*398*	*0.80*	*318*	*0.02*	*299*	*6.61*	*3.30*	*10*	*330.3*	*440.7*	*2.32*	*3,9*
Industrial use	*Max. tonnage*	Quest. info		*13*	*0.02*	*30*	*2.69*	*1.35*	*10*	*134.6*	*244.9*	*0.94*	*2,52*
Flame retardants													
Formulation	Default (100% form)	725	1.0	725	0.02	300	15.01	7.51	10	750.5	860.8	5.27	6,85
Formulation	Default (8% form)	725	1.0	725	0.02	300	15.01	7.51	10	750.5	860.8	5.27	6,85
Formulation	Max. tonnage	Quest. info		280	0.02	80	21.74	10.87	10	1087.0	1197.3	7.63	9,21
				280-725T			**15-21.7**	**7.5-10.9**		**751-1087**	**861-1197**	**5.3-7.6**	**6.9-9.2**

Sector	**Scenario**	**Regional tonnage (10%) (T B_2O_3)**	**Fraction of main local source (B-tables TGD)**	**Site tonnage (T B_2O_3)**	**Default emission factor water (-)**	**Number of production days**	**Emission to water (kg B/d)**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal water (µg B/l)**	**PEC$_{total}$ local water (µg B/l) (PECtotal$_{reg}$: 110.3 µg/l)**	**Csediment (mg B/kg dw)**	**PEC$_{total}$ sediment (mg B/kg dw) (PECtotal reg: 1.58 mg B/kg dw**
							kg/d	**mg/l**		**µg/l**	**µg/l**	**mg/kg dw**	**mg/kg dw**
Industrial use	*Default (8% form)*	*725*	*1*	*725*	*0.001*	*300*	0.75	0.38	*10*	37.5	147.8	0.26	1,84
Detergents													
Formulation	Default (100% form)	3788	0.8	3031	0.003	300	9.41	4.71	10	470.6	580.9	3.30	4,88
Private use	*Default (100% form)*	3788	0.0020	7.58	*0.95*	*365*	6.12	3.06	*10*	306.2	416.5	2.15	3,73
Cleaners and cosmetics													
Formulation	Default (100% form)	627	1.0	627	$9x10^{-4}$	300	0.58	0.29	10	29.2	139.5	0.20	1,78
Private use	*Default (100% form)*	627	0.0020	1.25	*0.99*	*365*	1.06	0.53	*10*	52.8	163.1	0.37	1,95
Agriculture (fertiliser use)													
Formulation	Default	1122	1.0	1122	0.003	300	3.49	1.74	10	174.3	284.6	1.22	2,8
Formulation	Max. tonnage	Quest. info		560	0.003	135	3.87	1.93	10	193.3	303.6	1.36	2,94
Formulation	Avg. tonnage	Quest. info		150	0.003	135	1.04	0.52	10	51.8	162.1	0.36	1,94
				150-1122		**135-300**	**1.0-3.9**	**0.5-1.9**		**52-193**	**162-304**	**0.4-1.4**	**0,4-3.1**
Industrial use	*Default*	1122	0.001	1.1	*0.05*	*2*	8.72	4.36	*10*	435.8	546.1	3.06	4,64
Various chemical effects													
Formulation	Default	2214	1.0	2214	0.003	300	6.88	3.44	10	343.9	454.2	2.41	3,99

Sector	**Scenario**	**Regional tonnage (10%) <u>(T B$_2$O$_3$)</u>**	**Fraction of main local source (B-tables TGD)**	**Site tonnage <u>(T B$_2$O$_3$)</u>**	**Default emission factor water (-)**	**Number of production days**	**Emission to water <u>(kg B/d)</u>**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal water <u>(µg B/l)</u>**	**PEC$_{total}$ local water (µg B/l) (PECtotal$_{reg}$: 110.3 µg/l)**	**Csediment <u>(mg B/kg dw)</u>**	**PEC$_{total}$ sediment (mg B/kg dw) (PECtotal reg: 1.58 mg B/kg dw**
Formulation	Max. tonnage	Quest. info		1500	0.003	245	5.70	2.85	10	285.2	395.5	2.00	3,58
Formulation	Avg. tonnage	Quest. info		500	0.003	245	1.90	0.95	10	95.1	205.4	0.67	2,25
				500-2214		**245-300**	**1.9-6.9**	**1.0-3.4**		**95-344**	**205-454**	**0.7-2.4**	**2.3-4.1**
Industrial use	*Default*	*2214*	*0.30*	*664*	*0.007*	*133*	*10.86*	*5.43*	*10*	*543.0*	*653.0*	*3.81*	*5,39*
Industrial use	*Max. tonnage*			*1500*	*0.007*	*245*	*13.31*	*6.66*	*10*	*665.5*	*775.8*	*4.67*	*6,25*

Tabelle 10.20 Overview of results of generic scenarios for the aquatic compartment (marine water and sediment). It is assumed that no emission reduction measures are applied. Please note that the PECadd local for marine water and sediment is calculated as the sum of the Clocal and the modelled PECadd regional concentration for marine water and sediment of 18.2 µg/l and 0.16 mg/kg dw respectively (EUSES 2.0; regional exposure report)

Sector	**Scenario**	**Regional tonnage (10%) <u>(T B$_2$O$_3$)</u>**	**Fraction of main local source (B-tables TGD)**	**Site tonnage <u>(T B$_2$O$_3$)</u>**	**Default emission factor water (-)**	**Number of production days**	**Emission to water <u>(kg B/d)</u>**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal marine water <u>(µg B/l)</u>**	**PEC$_{add}$ local marine water (µg B/l) (PECadd$_{reg}$: 18.2 µg/l)**	**Csediment marine <u>(mg B/kg dw)</u>**	**PEC$_{add}$ sediment (mg B/kg dw) (PECaddreg: 0.16 mg/kg dw)**
Glass and ceramics													
Borosilicate													
Formulation	Default (100% form)	3451	1.0	3451	0.003	300	10.72	5.36	100	53.6	71.8	0.38	0.54
Formulation	Default (15% form)	3451	0.7	2416	0.003	300	7.50	3.75	100	37.5	55.7	0.26	0.42
Formulation	Max.	Quest. info		7600	0.003	365	19.40	9.70	100	97.0	115.2	0.68	0.84

Sector	**Scenario**	**Regional tonnage (10%) (T B_2O_3)**	**Fraction of main local source (B-tables TGD)**	**Site tonnage (T B_2O_3)**	**Default emission factor water (-)**	**Number of production days**	**Emission to water (kg B/d)**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal marine water (µg B/l)**	**PEC_{add} local marine water (µg B/l) ($PECadd_{reg}$: 18.2 µg/l)**	**Csediment marine (mg B/kg dw)**	**PEC_{add} sediment (mg B/kg dw) (PECaddreg: 0.16 mg/kg dw)**
	tonnage												
Formulation	Avg. tonnage	Quest. info		2200	0.003	365	5.62	2.81	100	28.1	46.3	0.20	0.36
				2200-7600T	**0.003**	**300-365**	**5.6-19.4 kg/d**	**2.8-9.7 mg/l**		**28.1-97.0 µg/l**	**46.3-115.2 µg/l**	**0.20-0.68 mg/kg dw**	**0.36-0.84 mg/kg dw**
Industrial use	*Default (15% form)*	*3451*	*0.5*	*1726*	*0.05*	*300*	*89.33*	*44.67*	*100*	*446.7*	*464.8*	*3.13*	*3.29*
	Max. tonnage	*Quest. info*		*7600*	*0.05*	*365*	*323.36*	*161.68*	*100*	*1616.7*	*1634.9*	*11.34*	*11.50*
IFG/TFG													
Formulation	Default (100% form)	6117	0.8	4894	0.003	300	15.20	7.60	100	76.0	94.2	0.53	0.69
Formulation	Default (5% form)	6117	0.4	2447	0.003	300	7.60	3.80	100	38.0	56.2	0.27	0.43
Formulation	Max. tonnage	Quest. info		2700	0.003	365	6.89	3.45	100	34.5	52.7	0.24	0.40
Formulation	Avg. tonnage	Quest. info		700	0.003	365	1.79	0.89	100	8.9	27.1	0.06	0.22
				700-4894T	**0.003**		**1.8-15.2 kg/d**	**0.9-7.6 mg/l**		**8.9-76 µg/l**	**27.1-94.2 µg/l**	**0.06-0.53 mg/kg dw**	**0.22-0.69 mg/kg dw**
Industrial use	*Default (5% form)*	*6117*	*0.3*	*1835*	*0.05*	*300*	*95.00*	*47.50*	*100*	*475.0*	*493.2*	*3.33*	*3.49*
Industrial use	*Max. tonnage*	*Quest. info*		*2700*	*0.05*	*365*	*114.88*	*57.44*	*100*	*574.4*	*592.6*	*4.03*	*4.19*
Ceramics													
Formulation	Default (100% form)	4492	1.0	4492	0.003	300	13.95	6.98	100	69.8	88.0	0.49	0.65
Formulation	Default (30%form)	4492	0.7	3144	0.003	300	9.77	4.88	100	48.8	67.0	0.34	0.50
Formulation	Max.	Quest. info		2500	0.003	200	11.65	5.82	100	58.2	76.4	0.41	0.57

Sector	**Scenario**	**Regional tonnage (10%) (T B_2O_3)**	**Fraction of main local source (B-tables TGD)**	**Site tonnage (T B_2O_3)**	**Default emission factor water (-)**	**Number of production days**	**Emission to water (kg B/d)**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal marine water (µg B/l)**	**PEC_{add} local marine water (µg B/l) ($PECadd_{reg}$: 18.2 µg/l)**	**Csediment marine (mg B/kg dw)**	**PEC_{add} sediment (mg B/kg dw) (PECaddreg: 0.16 mg/kg dw)**
	tonnage												
Formulation	Avg. tonnage	Quest. info		750	0.003	200	3.49	1.75	100	17.5	35.7	0.12	0.28
				750-4492T	**0.003**		**3.5-14.0 kg/d**	**1.8-7.0 mg/l**		**17.5-69.8 µg/l**	**35.7-88.0 µg/l**	**0.12-0.49 mg/kg dw**	**0.28-0.65 mg/kg dw**
Industrial use	*Default (30%form)*	*4492*	*0.5*	*2246*	*0.05*	*300*	*116.27*	*58.13*	*100*	*581.3*	*599.5*	*4.08*	*4.24*
Industrial use	Max. tonnage	Quest. info		2500	*0.05*	*200*	*194.13*	*97.06*	*100*	*970.6*	*988.8*	*6.81*	*6.97*
Industrial fluids													
Formulation	Default (100% form)	449	1.0	449	0.02	300	9.30	4.65	100	46.5	64.7	0.33	0.49
Formulation	Default (50% form)	449	1.0	449	0.02	300	9.30	4.65	100	46.5	64.7	0.33	0.49
Formulation	Max. tonnage	Quest. info		370	0.02	225	10.22	5.11	100	51.1	69.3	0.36	0.52
Formulation	Avg. tonnage	Quest. info		170	0.02	225	4.69	2.35	100	23.5	41.7	0.16	0.32
				170-449T	**0.02**		**4.7-10.2 kg/d**	**2.4-5.1 mg/l**		**23.5-51.1 µg/l**	**41.7-69.3 µg/l**	**0.16-0.36 mg/kg dw**	**0.32-0.52 mg/kg dw**
Industrial use	*Default (50%form)*	*449*	*0.80*	*359*	*0.02*	*135*	*15.49*	*7.75*	*100*	*77.5*	*95.7*	*0.54*	*0.70*
	Max. tonnage	*Quest. info*		*370*	*0.02*	*225*	*10.22*	*5.11*	*100*	*51.1*	*69.3*	*0.36*	*0.52*
Metallurgy													
Formulation	Default (100% form)	398	1.0	398	0.02	300	8.23	4.12	100	41.2	59.4	0.29	0.45
Formulation	Default	398	1.0	398	0.02	300	8.23	4.12	100	41.2	59.4	0.29	0.45

Sector	**Scenario**	**Regional tonnage (10%) (T B_2O_3)**	**Fraction of main local source (B-tables TGD)**	**Site tonnage (T B_2O_3)**	**Default emission factor water (-)**	**Number of production days**	**Emission to water (kg B/d)**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal marine water (µg B/l)**	**PEC$_{add}$ local marine water (µg B/l) (PECadd$_{reg}$: 18.2 µg/l)**	**Csediment marine (mg B/kg dw)**	**PEC$_{add}$ sediment (mg B/kg dw) (PECaddreg: 0.16 mg/kg dw)**
	(20% form)												
Formulation	Max. tonnage	Quest. info		13	0.02	30	2.69	1.35	100	13.5	31.7	0.09	0.25
Formulation	Avg. tonnage	Quest. info		7	0.02	30	1.45	0.72	100	7.3	25.4	0.05	0.21
				7-398T			**1.5-8.2 kg/d**	**0.6-2.6 mg/l**		**7.3-41.2 µg/l**	**25.4-59.4 µg/l**	**0.05-0.29 mg/kg dw**	**0.21-0.45 mg/kg dw**
Industrial use	*Default (20% form)*	*398*	*0.80*	*318*	*0.02*	*299*	*6.61*	*3.30*	*100*	*33.0*	*51.2*	*0.23*	*1.23*
Industrial use	*Max. tonnage*	Quest. info		*13*	*0.02*	*30*	*2.69*	*1.35*	*100*	*13.5*	*31.7*	*0.09*	*0.25*
Flame retardants													
Formulation	Default (100% form)	725	1.0	725	0.02	300	15.01	7.51	100	75.0	93.2	0.53	0.69
Formulation	Default (8% form)	725	1.0	725	0.02	300	15.01	7.51	100	75.0	93.2	0.53	0.69
Formulation	Max. tonnage	Quest. info		280	0.02	80	21.74	10.87	100	108.7			
				280-725T			**15-21.7 kg/d**	**7.5-10.9 mg/l**		**75.0-108.7 µg/l**	**93-127µg/l**	**0.53-0.76 mg/kg dw**	**0.69-0.92 mg/kg dw**
Industrial use	*Default (8% form)*	*725*	*1*	*725*	*0.001*	*300*	0.75	0.38	*100*	3.8	22.0	0.03	0.19
Detergents													
Formulation	Default (100% form)	3788	0.8	3031	0.003	300	9.41	4.71	100	47.1	65.3	0.33	0.49
Private use	*Default (100% form)*	3788	0.0020	7.58	*0.95*	*365*	6.12	3.06	*100*	30.6	48.8	0.21	0.37
Cleaners													

Sector	**Scenario**	**Regional tonnage (10%) (T B_2O_3)**	**Fraction of main local source (B-tables TGD)**	**Site tonnage (T B_2O_3)**	**Default emission factor water (-)**	**Number of production days**	**Emission to water (kg B/d)**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal marine water (µg B/l)**	**PEC_{add} local marine water (µg B/l) ($PECadd_{reg}$: 18.2 µg/l)**	**Csediment marine (mg B/kg dw)**	**PEC_{add} sediment (mg B/kg dw) (PECaddreg: 0.16 mg/kg dw)**
and cosmetics													
Formulation	Default (100% form)	627	1.0	627	9x10^{-4}	300	0.58	0.29	100	2.9	21.1	0.02	0.18
Private use	*Default (100% form)*	627	0.0020	1.25	*0.99*	*365*	1.06	0.53	*100*	5.3	23.5	0.04	0.20
Agriculture (fertiliser use)													
Formulation	Default	1122	1.0	1122	0.003	300	3.49	1.74	100	17.4	35.6	0.12	0.28
Formulation	Max. tonnage	Quest. info		560	0.003	135	3.87	1.93	100	19.3	37.5	0.14	0.30
Formulation	Avg. tonnage	Quest. info		150	0.003	135	1.04	0.52	100	5.2	23.4	0.04	0.20
				150-1122T		**135-300**	**1.0-3.9 kg/d**	**0.5-1.9 mg/l**		**5.2-19.3 µg/l**	**23.4-37.5 µg/l**	**0.04-0.14 mg/kg dw**	**0.20-0.30 mg/kg dw**
Industrial use	*Default*	1122	0.001	1.1	*0.05*	*2*	8.72	4.36	*100*	43.6	61.8	0.31	*0.47*
Various chemical effects													
Formulation	Default	2214	1.0	2214	0.003	300	6.88	3.44	100	34.4	52.6	0.24	0.40
Formulation	Max. tonnage	Quest. info		1500	0.003	245	5.70	2.85	100	28.5	46.7	0.20	0.36
Formulation	Avg. tonnage	Quest. info		500	0.003	245	1.90	0.95	100	9.5	27.7	0.07	0.23
				500-2214T		**245-300**	**1.9-6.9 kg/d**	**1.0-3.4 mg/l**		**9.5-34.4 µg/l**	**27.7-52.6 µg/l**	**0.07-0.24 mg/kg dw**	***0.23-0.40* mg/kg dw**
Industrial use	*Default*	*2214*	*0.30*	*664*	*0.007*	*133*	*10.86*	*5.43*	*100*	*54.3*	*72.5*	*0.38*	*0.54*
Industrial	*Max.*			*1500*	*0.007*	*245*	*13.31*	*6.66*	*100*	*66.6*	*84.8*	*0.47*	*0.63*

Sector	**Scenario**	**Regional tonnage (10%) $\underline{(T\ B_2O_3)}$**	**Fraction of main local source (B-tables TGD)**	**Site tonnage $\underline{(T\ B_2O_3)}$**	**Default emission factor water (-)**	**Number of production days**	**Emission to water <u>(kg B/d)</u>**	**Ceffluent (mg B/l)** (discharge rate STP: 2000 m^3/d)	**Dilution factor (Default TGD)**	**Clocal marine water <u>(µg B/l)</u>**	**PEC_{add} local marine water (µg B/l) ($PECadd_{reg}$: 18.2 µg/l)**	**Csediment marine <u>(mg B/kg dw)</u>**	**PEC_{add} sediment (mg B/kg dw) (PECaddreg: 0.16 mg/kg dw)**
use	*tonnage*												

10.6 Atmospheric and Terrestrial compartment

10.6.1 Calculation of PEClocal

Calculation of PEClocal for chemical producers/importers

An overview is given of input values and results from the generic exposure assessments of the boric acid and sodium tetraborates production stage (refining) for the atmospheric and terrestrial compartment.

Release factors

- The air release factors for boric acid and sodium tetraborates production is 0.00001 (A-tables, TGD). Site-specific emission information is not submitted by the manufacturing companies; hence no comparison of emission factors can be made at this stage.
- However, the companies involved in *refining activities* report that the following air pollution control systems are installed: fabric or bag filters and/or scrubbers. No quantitative emission information is presently available, although the companies mention that emission data are available. Therefore, a request will be directed to the sites in order to obtain the relevant information.
- Please note that for the companies involved in *loading and packaging activities* only, the the air emissions (dust) arising from these activities will be of a diffuse nature. Since it is very difficult to quantify diffuse emissions, it is questionable if it will be possible to assess the environmental impact of this type of emissions. Please note that in general, air emission factors reported in the A-tables (TGD) relate to stack emissions as a result from processes performed and not to diffuse emissions. Therefore, there is no default method to estimate diffuse emissions from processes. The collection of local imission data around the sites is recommended to quantify this source.

Local concentrations

- Clocal for air for refining activities is 34-57 ng B/m^3 (for a site involved in production of boric acid and sodium tetraborates; reasonable worst case). As the added PECregional is only 9.41 10^{-5} ng B/m^3, added PEClocal in air levels can be considered the same as Clocal air (34-57 ng B/m^3). The Csoil levels are derived on the basis of partitioning i.e. 0.004-0.007 mg B/kg dw. PEClocal soil level is 5.0 mg/kg dw (PECregional = 5 mg/kg dw). Please note that in these estimations, diffuse emissions are not taken into account. The Cporewater and PECporewater under agricultural soil is 0003-0.005 mg B/l & 3.5 mg B/l respectively.

Tabelle 10.21 Overview of results of generic and specific scenarios for the chemicals production sector (boric acid, sodium tetraborate anhydrous, sodium tetraborate pentahydrate and sodium tetraborate decahydrate) for the air and soil compartment. It is assumed that no emission reduction measures are applied.

	Scenario	**Regional tonnage (T B_2O_3)**	**Fraction of main source**	**Site tonnage (T B_2O_3)**	**Default emission factor air**	**Number of production days**	**Emission to air (kg B/d)**	**Clocal air (ng B/m^3)**	**PEC$_{add}$ local air (ng B/m^3) (PEC$_{add}$ reg air: 9.41 10^{-5})**	**Aerial deposition rate (mg B/m^2.d)**	**Csoil (mg B/kg dw)**	**Cporewater soil (mg/l)**	**PEC$_{total}$ soil (mg B/kg dw) (PECaddreg : 5 mg/kg dw)**	**PEC porewater soil (mg/l)**
Default scenario (TGD)														
Default	Production of boric acid and borax compounds	14363T No 10% rule!, only few sites	1	14363	0.00001*	300	0.15	34.0	34.0	1.22E-03	0.004	0.003	5.0	3.47
Specific scenario (specific tonnages)														
	Specific average			14403	0.00001*	365	0.12	34.1	34.1	1.23E-03	0.004	0.003	5.0	3.47
	Specific maximum			24339	0.00001*	365	0.21	57.6	57.6	2.07E-03	0.007	0.005	5.0	3.47

* Please note that this emission factor deals with stack emissions only.

Calculation of PEClocal for industrial/professional use

An overview is given of input values and results from the generic exposure assessments for different borate industry sectors for the atmospheric and terrestrial compartment.

Release factors

- Release factors for formulation stages from different use sectors vary from 0.001 to 0.0025 (A-tables, TGD). Although very different use functions were identified for the different use sectors, this was not reflected in the choice of the release factors, which remained fairly constant. The minimum and maximum air emission factors applied for this stage vary only with one order of magnitude. For cleaners and cosmetics, a release factor of 0.00002 was derived. Sector-specific information, e.g. that glass and ceramics manufacture involve high temperatures where some volatilization of boron is likely cannot be taken into account in the default estimation of releases. In order to assess this, site measurements are needed.
- Release factors for processing and private stages from different use sectors vary from 0 to 0.0025 (A-tables, TGD).

Local concentrations

- Clocal for air for glass and ceramics *formulation stages* vary between 40 ng B/m^3 and 1798 ng B/m^3 (dependent on the use tonnage). As the added PECregional is only 9.41 10^{-5} ng B/m^3, added PEClocal in air levels can be considered the same as Clocal air (40-1798 ng B/m^3). The Csoil levels are derived on the basis of partitioning i.e. 0.01-0.21 mg B/kg dw. PEClocal soil level is 5.0-5.2 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.02-0.15 mg B/l & 3.5-3.6 mg B/l respectively.
- Clocal for industrial fluids formulation is 101-266 ng B/m^3. As the added PECregional is only 9.41 10^{-5} ng B/m^3, added PEClocal in air levels can be considered the same as Clocal air (101-266 ng B/m^3). The Csoil levels are derived on the basis of partitioning i.e. 0.01-0.03 mg B/kg dw. PEClocal soil level is 5.0 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.008-0.02 mg B/l & 3.5 mg B/l respectively.
- Clocal for metallurgy formulation is 4-235 ng B/m^3. As the added PECregional is only 9.41 10^{-5} ng B/m^3, added PEClocal in air levels can be considered the same as Clocal air (4-235 ng B/m^3). The Csoil levels are derived on the basis of partitioning i.e. 0.0005-0.03 mg B/kg dw. PEClocal soil level is 5.0 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.0003-0.02 mg B/l & 3.5 mg B/l respectively.
- Clocal for flame retardancy formulation is 166-429 ng B/m^3. As the added PECregional is only 9.41 10^{-5} ng B/m^3, added PEClocal in air levels can be considered the same as Clocal air (166-429 ng B/m^3). The Csoil levels are derived on the basis of partitioning i.e. 0.02-0.05 mg B/kg dw. PEClocal soil level is 5.0-5.1 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.01-0.04 mg B/l & 3.5 mg B/l respectively.
- Clocal for detergents formulation is 1792 ng B/m^3. As the added PECregional is only 9.41 10^{-5} ng B/m^3, added PEClocal in air levels can be considered the same as Clocal air (1792 ng B/m^3). The Csoil levels are derived on the basis of partitioning i.e. 0.21 mg B/kg dw. PEClocal soil level is 5.2 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.15 mg B/l & 3.6 mg B/l respectively.
- Clocal for cleaners and cosmetics formulation is 3 ng B/m^3. As the added PECregional is only 9.41 10^{-5} ng B/m^3, added PEClocal in air levels can be considered the same as Clocal air (3 ng

B/m³). The Csoil levels are derived on the basis of partitioning i.e. 0.0004 mg B/kg dw. PEClocal soil level is 5.0 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.0002 mg B/l & 3.5 mg B/l respectively.

- Clocal for agricultural use (fertiliser) formulation is 89-664 ng B/m^3. As the added PECregional is only 9.41 10^{-5} ng B/m³, added PEClocal in air levels can be considered the same as Clocal air (89-644 ng B/m³). The Csoil levels are derived on the basis of partitioning i.e. 0.01-0.08 mg B/kg dw (only through aerial deposition, no direct application to agricultural soil). PEClocal soil level is 5.0-5.1 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.007-0.06 mg B/l & 3.5 mg B/l respectively.
- Clocal for various chemical effects formulation is 296-1310 ng B/m^3. As the added PECregional is only 9.41 10^{-5} ng B/m³, added PEClocal in air levels can be considered the same as Clocal air (296-1310 ng B/m³). The Csoil levels are derived on the basis of partitioning i.e. 0.04-0.2 mg B/kg dw. PEClocal soil level is 5.0-5.2 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.002-0.11 mg B/l & 3.5 mg B/l respectively.
- Clocal for agricultural and metallurgy *processing stages* and detergents and cleaners *private use stages* are not derived because no emissions to air are expected from this stage (cfr. A-tables TGD; air emission factor = 0 for these uses)
- Clocal for glass and ceramics *processing* is 408-1798 ng B/m^3. As the added PECregional is only 9.41 10^{-5} ng B/m³, added PEClocal in air levels can be considered the same as Clocal air (408-1798 ng B/m³). The Csoil levels are derived on the basis of partitioning i.e. 0.05-0.21 mg B/kg dw. PEClocal soil level is 5.1-5.2 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.03-0.15 mg B/l & 3.5 mg B/l respectively.
- Clocal for industrial fluids *processing* is 0.8-0.9 ng B/m^3. As the added PECregional is only 9.41 10^{-5} ng B/m³, added PEClocal in air levels can be considered the same as Clocal air (0.8-0.9 ng B/m³). The Csoil levels are derived on the basis of partitioning i.e. 0.0001 mg B/kg dw. PEClocal soil level is 5.0 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.00007 mg B/l & 3.5 mg B/l respectively.
- Clocal for flame retardants *processing* is 166-429 ng B/m^3. As the added PECregional is only 9.41 10^{-5} ng B/m³, added PEClocal in air levels can be considered the same as Clocal air (166-429 ng B/m³). The Csoil levels are derived on the basis of partitioning i.e. 0.02-0.05 mg B/kg dw. PEClocal soil level is 5.0-5.1 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.01-0.04 mg B/l & 3.5 mg B/l respectively.
- Clocal for various chemical effects *processing* is 2-3.5 ng B/m$^{3.}$ As the added PECregional is only 9.41 10^{-5} ng B/m³, added PEClocal in air levels can be considered the same as Clocal air (2-3.5 ng B/m³). The Csoil levels are derived on the basis of partitioning i.e. 0.0002-0.0004 mg B/kg dw. PEClocal soil level is 5.0 mg B/kg dw (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.0001-0.0003 mg B/l & 3.5 mg B/l respectively.

In conclusion; the C_local and added PNEC local air levels for *formulation stages* for different use sectors vary from 3-1792 ng B/m^3 (generic assessment) and 4-1798 ng B/m^3 (specific assessment). The C_local levels (contribution from the site) for formulation stages for different use sectors for soil vary from 0.0004-0.25 mg B/kg dw (generic assessment) and 0.0005-0.21 mg B/kg dw (specific assessment). PEClocal soil level is 5.0-5.3 mg B/kg dw (generic assessment) and 5.0-5.2 mg B/kg dw (specific assessment) (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.0002-0.15 mg B/l (generic assessment) and 0.0003-0.15 mg B/l (specific assessment) & 3.5-3.6 mg B/l (generic assessment & specific assessment) respectively.

The C_local air levels and added PNEC local air levels for *processing stages for different use sectors* vary from 0.8-531 ng B/m^3 (generic assessment) and from 0.9-1798 ng B/m^3 (specific assessment). The C_local air levels and added PNEC local air levels for *private use stages for detergents and cleaners and the industrial use stage for agriculture* were not reported, since no emissions to air expected from these uses. The C_local levels (contribution from the site) for *processing stages for different use sectors* for soil vary from 0.0001-0.06 mg B/kg dw (generic assessment) and 0.0001-0.2 mg/kg dw (specific assessment). PEClocal soil level is 5.0-5.1 mg B/kg dw (generic assessment) and 5.0-5.2 mg/kg dw (specific assessment) (PECregional = 5 mg/kg dw). The Cporewater and PECporewater under agricultural soil is 0.00007-0.4 mg B/l (generic assessment) and 0.00007-0.15 mg B/l (specific assessment) & 3.5 mg B/l (generic assessment & specific assessment) respectively.

Tabelle 10.22 Overview of results of generic scenarios for the air and soil compartment. It is assumed that no emission reduction measures are applied.

Sector	**Scenario**	**Regional tonnage (10%) (T B_2O_3)**	**Fraction of main source**	**Site tonnage (T B_2O_3)**	**Default emission factor air**	**Number of production days**	**Emission to air (kg B/d)**	**Clocal air (ng B/m^3)**	**PEC_{add} local air (ng B/m^3) (PEC_{add} reg air: 9.41 10^{-5} ng B/m³)**	**Aerial deposition rate (mg B/m^2.d)**	**Csoil (mg B/kg dw)**	**Cporewater soil (mg/l)**	**PEC_{total} soil (mg B/kg dw) (PECadd reg: 5 mg/kg dw)**	**PEC porewater soil (mg/l)**
Glass and ceramics														
Borosilicate														
Formulation	Default (100% form)	3451	1	3451	0.001	300	3.57	816	816	2.94E-02	0.10	0.068	5.10	3.54
Formulation	Default (15% form)	3451	0.7	2416	0.001	300	2.50	572	572	2.06E-02	0.07	0.047	5.07	3.52
Formulation	Max. tonnage	Quest. info		7600	0.001	365	6.47	1798	1798	6.47E-02	0.21	0.149	5.21	3.62
Formulation	Avg. tonnage	Quest. info		2200	0.001	365	1.87	520	520	1.87E-02	0.06	0.043	5.06	3.51
				2200-7600T	***0.001***	***300-365***	***1.9-6.5 kg/d***	***520-1798 ng/m^3***	***520-1798 ng/m^3***		***0.06-0.21 mg/kg dw***		***5.10-5.21 mg/kg dw***	
Industrial use	*Default*	*3451*	*0.5*	*1726*	*0.001*	*300*	*1.79*	*408*	*408*	*1.47E-02*	*0.05*	*0.034*	*5.05*	*3.50*
	Max. tonnage				*0.001*	*365*	*6.47*	*1798*	*1798*	*6.47E-02*	*0.21*	*0.149*	*5.21*	*3.62*
IFG/TFG														
Formulation	Default (100% form)	6117	0.8	4894	0.001	300	5.07	1158	1158	4.16E-02	0.14	0.096	5.14	3.57
Formulation	Default (5% form)	6117	0.4	2447	0.001	300	2.53	579	579	2.08E-02	0.07	0.048	5.07	3.52
Formulation	Max. tonnage	Quest. info		2700	0.001	365	2.30	639	639	2.30E-02	0.08	0.053	5.08	3.52
Formulation	Avg. tonnage	Quest. info		700	0.001	365	0.60	166	166	5.96E-03	0.02	0.014	5.02	3.48
				700-4894T	***0.001***		***0.6-5.1 kg/d***	***166-1158 ng/m^3***	***166-1158 ng/m^3***		***0.02-0.14 mg/kg dw***		***5.0-5.1 mg/kg dw***	

Sector	**Scenario**	**Regional tonnage (10%) <u>(T B$_2$O$_3$)</u>**	**Fraction of main source**	**Site tonnage <u>(T B$_2$O$_3$)</u>**	**Default emission factor air**	**Number of production days**	**Emission to air <u>(kg B/d)</u>**	**Clocal air (ng B/m^3)**	**PEC$_{add}$ local air (ng B/m^3) (PEC$_{add}$ reg air: 9.41 10^{-5} ng B/m³)**	**Aerial deposition rate (mg B/m^2.d)**	**Csoil (mg B/kg dw)**	**Cporewater soil (mg/l)**	**PEC$_{total}$ soil (mg B/kg dw) (PECadd reg: 5 mg/kg dw)**	**PEC porewater soil (mg/l)**
Industrial use	*Default*	*6117*	*0.3*	*1835*	*0.001*	*300*	*1.90*	*434*	*434*	*1.56E-02*	*0.05*	*0.036*	*5.05*	*3.51*
	Max. tonnage			*2700*	*0.001*	*365*	*2.30*	*639*	*639*	*2.30E-02*	*0.08*	*0.053*	*5.08*	*3.52*
Ceramics														
Formulation	Default (100% form)	4492	1.0	4492	0.001	300	4.65	1063	1063	3.82E-02	0.13	0.088	5.13	3.56
Formulation	Default (30%form)	4492	0.7	3144	0.001	300	3.26	744	744	2.68E-02	0.09	0.062	5.09	3.53
Formulation	Max. tonnage			2500	0.001	200	3.88	591	591	2.13E-02	0.07	0.049	5.07	3.52
Formulation	Avg. tonnage			750	0.001	200	1.16	177	177	6.38E-03	0.02	0.015	5.02	3.48
				750-4492T	***0.001***		***0.3-1.7 kg/d***	***40-396 ng/m3***	***40-396 ng/m3***		***0.01-0.06 mg/kg dw***		***5.0-5.1 mg/kg dw***	
Industrial use	*Default*	*4492*	*0.5*	*2246*	*0.001*	*300*	*2.33*	*531*	*531*	*1.91E-02*	*0.06*	*0.044*	*5.06*	*3.51*
	Max. tonnage			*2500*	*0.001*	*200*	*3.88*	*591*	*591*	*2.13E-02*	*0.07*	*0.049*	*5.07*	*3.52*
Industrial fluids														
Formulation	Default (100% form)	449	1	449	0.0025	300	1.16	266	266	9.55E-03	0.03	0.022	5.03	3.49
Formulation	Default (50% form)	449	1	449	0.0025	300	1.16	266	266	9.55E-03	0.03	0.022	5.03	3.49
Formulation	Max. tonnage	Quest. info		370	0.0025	225	1.28	219	219	7.87E-03	0.03	0.018	5.03	3.49
Formulation	Avg. tonnage	Quest. info		170	0.0025	225	0.59	101	101	3.62E-03	0.01	0.008	5.01	3.48
				170-449T	**0.0025**		***0.6-1.3 kg/d***	***101-266 ng/m3***	***101-266 ng/m3***		***0.01-0.03 mg/kg dw***		***5.0 mg/kg dw***	

Sector	**Scenario**	**Regional tonnage (10%) (T B_2O_3)**	**Fraction of main source**	**Site tonnage (T B_2O_3)**	**Default emission factor air**	**Number of production days**	**Emission to air (kg B/d)**	**Clocal air (ng B/m^3)**	**PEC_{add} local air (ng B/m^3) (PEC_{add} reg air: 9.41 10^{-5} ng B/m³)**	**Aerial deposition rate (mg B/m^2.d)**	**Csoil (mg B/kg dw)**	**Cporewater soil (mg/l)**	**PEC_{total} soil (mg B/kg dw) (PECadd reg: 5 mg/kg dw)**	**PEC porewater soil (mg/l)**
Industrial use	*Default*	*449*	*0.8*	*359*	*0.00001*	135	*0.008*	*0.80*	*0.80*	*2.87E-05*	*0.00011*	0.00007	5.00	3.47
Industrial use	*Max. tonnage*	*Quest. info*		*370*	*0.00001*	225	*0.005*	*0.88*	*0.88*	*3.15E-05*	*0.00010*	0.00007	5.00	3.47
Metallurgy														
Formulation	Default (100% form)	398	1	398	0.0025	300	1.03	235	235	8.46E-03	0.03	0.019	5.03	3.49
Formulation	Default (20% form)	398	1	398	0.0025	300	1.03	235	235	8.46E-03	0.03	0.019	5.03	3.49
Formulation	Max. tonnage	Quest. info		13	0.0025	30	0.34	8	8	2.77E-04	0.0009	0.001	5.00	3.47
Formulation	Avg. tonnage	Quest. info		7	0.0025	30	0.18	4	4	1.49E-04	0.0005	0.0003	5.00	3.47
				7-398T	**0.0025**		***0.2-1.0 kg/d***	***4-235 ng/m^3***	***4-235 ng/m^3***		***0.0005-0.03 mg/kg dw***		***5.0 mg/kg dw***	
Industrial use	*Default (20% form)*	*398*	*0.8*	*318*	*0*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Flame retardants														
Formulation	Default (100% form)	725	1	725	0.0025	300	1.88	429	429	1.54E-02	0.05	0.036	5.05	3.50
Formulation	Default (8% form)	725	1	725	0.0025	300	1.88	429	429	1.54E-02	0.05	0.036	5.05	3.50
Formulation	Max. tonnage both substances	Quest. info		280	0.0025	80	2.72	166	166	5.96E-03	0.02	0.014	5.02	3.48
				500-826T			***1.2-2.7 kg/d***	***166-275 ng/m3***	***166-275 ng/m3***		***0.02-0.04 mg/kg dw***			

Sector	**Scenario**	**Regional tonnage (10%) (T B_2O_3)**	**Fraction of main source**	**Site tonnage (T B_2O_3)**	**Default emission factor air**	**Number of production days**	**Emission to air (kg B/d)**	**Clocal air (ng B/m^3)**	**PEC_{add} local air (ng B/m^3) (PEC_{add} reg air: $9.41\ 10^{-5}$ ng B/m³)**	**Aerial deposition rate (mg B/m^2.d)**	**Csoil (mg B/kg dw)**	**Cporewater soil (mg/l)**	**PEC_{total} soil (mg B/kg dw) (PECadd reg: 5 mg/kg dw)**	**PEC porewater soil (mg/l)**
Industrial use	*Default (8% form)*	*725*	*1*	*725*	*0.0025 (dry process)* *0 (wet process)*	*300*	*1.88*	*429*	*429*	*1.54E-02*	*0.05*	*0.036*	*5.05*	*3.50*
				280	*0.0025 (dry process)* *0 (wet process)*	*80*	*2.72*	*166*	*166*	*5.96E-03*	*0.02*	*0.014*	*5.02*	*3.5*
Detergents														
Formulation	Default (100% form)	3788	*0.8*	3031	0.0025	300	7.84	1792	1792	6.45E-02	0.21	0.148	5.21	3.62
Private use	*Default (100% form)*	*3788*	*0.002*	*7.58*	*0*	*365*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Cleaners and cosmetics														
Formulation	Default (100% form)	627	*1*	627	*0.00002*	*300*	0.01	3	3	1.07E-04	0.0004	0.0002	5.00	3.47
Private use	*Default (100% form)*	*627*	*0.002*	*1.25*	*0*	*365*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Biological effects														
Fertiliser use														
Formulation	Default	1122	1.0	1122	0.0025	300	2.91	664	664	2.39E-02	0.08	0.055	5.08	3.52
Formulation	Max. tonnage	Quest. info		560	0.0025	135	1.45	331	331	1.19E-02	0.04	0.027	5.04	3.50
Formulation	Avg. tonnage	Quest. info		150	0.0025	135	0.39	89	89	3.19E-03	0.01	0.007	5.01	3.48

Sector	**Scenario**	**Regional tonnage (10%) (T B_2O_3)**	**Fraction of main source**	**Site tonnage (T B_2O_3)**	**Default emission factor air**	**Number of production days**	**Emission to air (kg B/d)**	**Clocal air (ng B/m^3)**	**PEC_{add} local air (ng B/m^3) (PEC_{add} reg air: $9.41\ 10^{-5}$ ng B/m^3)**	**Aerial deposition rate (mg B/m^2.d)**	**Csoil (mg B/kg dw)**	**Cporewater soil (mg/l)**	**PEC_{total} soil (mg B/kg dw) (PECadd reg: 5 mg/kg dw)**	**PEC porewater soil (mg/l)**
Industrial use	*Default*	*1122*	*0.001*	*1.1*	*0*	2	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Various chemical effects														
Formulation	Default	2214	*1.0*	2214	0.0025	300	5.73	1310	1310	4.71E-02	0.16	0.108	5.16	3.58
Formulation	Max. tonnage	Quest. info		1500	0.0025	245	3.88	887	887	3.19E-02	0.11	0.073	5.11	3.54
Formulation	Avg. tonnage	Quest. info		500	0.0025	245	1.29	296	296	1.06E-02	0.04	0.024	5.04	3.49
Industrial use	*Default*	*2214*	0.3	*664*	*0.00001*	*133*	*0.02*	*2*	*2*	*5.65E-05*	*0.0002*	0.0001	5.00	3.47
Industrial use	*Max. tonnage*	*Quest. info*		*1500*	*0.00001*	*245*	*0.02*	*3.5*	*3.5*	*1.28E-04*	*0.0004*	0.0003	*5.00*	3.47

NR: not relevant to calculate PEC due to zero emissions for the particular sector/life cycle stage combination

10.7 Conclusion on PEClocal for production and processing

Manufacturing/importing steps

*Generic assessment, freshwater**

Industry sector	**Life cycle stage**	**Cwater (µg B/l)**	**PECwater (µg B/l)**	**Csediment (mg B/kg dw)**	**PECadd sediment (mg B/kg dw)**	**Cair (ng B/m^3)**	**PECadd air (ng B/m^3)**	**Csoil (mg B/kg dw)**	**Cporew Soil (mg B/l)**	**PECtotal soil (mg B/kg dw)**	**PECporew Soil (mg B/l)**
Producers	Production/import	2231	2341	15.7	17.3	34	34	0.004	0.003	5.0	3.47

* It is assumed that no emission reduction measures are applied.

*Generic assessment, marine environment**

Industry sector	**Life cycle stage**	**Cmarine water (µg B/l)**	**PECadd marine water (µg B/l)**	**C marine sediment (mg B/kg dw)**	**PECadd marine sediment (mg B/kg dw)**
Producers	Production/import	223.0	241.2	1.56	1.72

* It is assumed that no emission reduction measures are applied.

*Specific assessment, freshwater**

Industry sect	**Life cycle stage**	**Cwater (µg B/l)**	**PECwater (µg B/l)**	**Csediment (mg B/kg dw)**	**PECadd sediment (mg B/kg dw)**	**Cair (ng B/m^3)**	**PECadd air (ng B/m^3)**	**Csoil (mg B/kg dw)**	**Cporew Soil (mg B/l)**	**PECtotal soil (mg B/kg dw)**	**PECporew Soil (mg B/l)**
Producers	Production/import	1838-3107	1949-3217	12.9-21.8	14.5-23.4	34.1-57.6	34.1-57.6	0.004-0.007	0.003-0.005	5.0	3.47

* It is assumed that no emission reduction measures are applied.

*Specific assessment, marine environment**

Industry sector	**Life cycle stage**	**C marine water (µg B/l)**	**PECadd marine water (µg B/l)**	**C marine sediment (mg B/kg dw)**	**PECadd marine sediment (mg B/kg dw)**
Producers	Production/import	184-311	202-329	1.3-2.2	1.5-2.3

* It is assumed that no emission reduction measures are applied.

Formulation stages

*Generic assessment, freshwater**

Industry sector	**Life cycle stage**	**Cwater (µg B/l)**	**PECwater (µg B/l)**	**Csediment (mg B/kg dw)**	**PECadd Sediment (mg B/kg dw)**	**Cair (ng B/m^3)**	**PECadd air (ng B/m^3)**	**Csoil (mg B/kg dw)**	**Cporew Soil (mg B/l)**	**PECtotal soil (mg B/kg dw)**	**PECporew Soil (mg B/l)**
Borosilicate	Formulation	375-536	486-646	2.6-3.8	4.2-5.4	572-816	572-816	0.08-0.11	0.05-0.07	5.1	3.5
IFG/TFG	Formulation	380-760	490-870	2.7-5.3	4.3-6.9	579-1158	579-1158	0.08-0.16	0.05-0.10	5.1-5.2	3.5-3.6
Ceramics	Formulation	488-698	598-807	3.4-4.9	5.0-6.5	744-1063	744-1063	0.10-0.15	0.06-0.09	5.1-5.2	3.5-3.6
Industrial fluids	Formulation	465	574	3.3	4.9	266	266	0.04	0.02	5.0	3.5
Metallurgy	Formulation	412	522	2.9	4.5	235	235	0.03	0.02	5.0	3.5
Flame retardants	Formulation	751	861	5.3	6.9	429	429	0.06	0.04	5.1	3.5
Detergents	Formulation	471	581	3.3	4.9	1792	1792	0.25	0.148	5.2	3.6
Cleaners	Formulation	29	140	0.2	1.8	3	3	0.0004	0.0002	5.0	3.5
Agriculture (fertilisers)	Formulation	174	285	1.2	2.8	664	664	0.09	0.06	5.1	3.5
Various chemical effects	Formulation	344	454	2.4	4	1310	1310	0.16	0.11	5.2	3.6
		29-760µg/l	**140-870µg/l**	**0.2-5.3 mg/kg dw**	**1.8-6.9**	**3-1792 ng/m^3**	**3-1792 ng/m^3**	**0.0004-0.25 mg/kg dw**	**0.0002-0.15 mg/l**	**5.0-5.3 mg/kg dw**	**3.5-3.6 mg/l**

* It is assumed that no emission reduction measures are applied.

*Generic assessment, marine water**

Industry sector	**Life cycle stage**	**C marine water (µg B/l)**	**PECadd marine water (µg B/l)**	**C marine sediment (mg B/kg dw)**	**PEC add marine sediment (mg B/kg dw)**
Borosilicate	Formulation	37.5-53.6	55.7-71.8	0.26-0.38	0.42-0.54
IFG/TFG	Formulation	38-76	56.2-94.2	0.27-0.53	0.43-0.69
Ceramics	Formulation	48.8-69.8	67-88.0	0.34-0.49	0.50-0.65
Industrial fluids	Formulation	46.5	64.7	0.33	0.49
Metallurgy	Formulation	41.2	59.4	0.29	0.45
Flame retardants	Formulation	75	93.2	0.53	0.69
Detergents	Formulation	47.1	65.3	0.33	0.49
Cleaners	Formulation	2.9	21.1	0.02	0.18
Agriculture (fertilisers)	Formulation	17.4	35.6	0.12	0.28
Various chemical effects	Formulation	34.4	52.6	0.24	0.40
		2.9-76 µg/l	**21-94 µg/l**	**0.02-0.5 mg/kg dw**	**0.2-0.7 mg/kg dw**

* It is assumed that no emission reduction measures are applied.

*Specific assessment, freshwater**

Industry sector	**Life cycle stage**	**Cwater (µg B/l)**	**PECwater (µg B/l)**	**Csediment (mg B/kg dw)**	**PECadd sediment (mg B/kg dw)**	**Cair (ng B/m^3)**	**PECadd air (ng B/m^3)**	**Csoil (mg B/kg dw)**	**Cporew Soil (mg B/l)**	**PECtotal soil (mg B/kg dw)**	**PECporew Soil (mg B/l)**
Borosilicate	Formulation	281-970	391-1080	2.0-6.8	3.6-8.4	520-1798	520-1798	0.06-0.21	0.04-0.15	5.1-5.2	3.5-3.6
IFG/TFG	Formulation	89-345	190-455	0.6-2.4	2.2-4.0	166-639	166-639	0.02-0.08	0.01-0.05	5.0-5.1	3.5
Ceramics	Formulation	175-582	285-693	1.2-4.1	2.8-4.0	177-591	177-591	0.02-0.07	0.02-0.05	5.0-5.1	3.5
Industrial fluids	Formulation	235-511	345-621	1.7-3.6	3.3-5.2	101-219	101-219	0.01-0.03	0.01-0.02	5.0	3.5
Metallurgy	Formulation	73-135	183-245	0.5-0.9	2.1-2.5	4-8	4-8	0.0005-0.0009	0.0003-0.001	5.0	3.5
Flame retardants	Formulation	1087	1197	7.6	9.2	166	166	0.02	0.014	5.0	3.5
Detergents	Formulation	/	/	/	/	/	/	/	/	/	/

Cleaners	Formulation	/	/	/	/	/	/	/	/	/	/
Agriculture (fertilisers)	Formulation	52-193	162-304	0.4-1.4	2.0-3.0	89-331	89-331	0.01-0.04	0.007-0.027	5.01-5.04	3.5
Various chemical effects	Formulation	95-285	205-396	0.7-2.0	*2.3-3.4*	*296-887*	*296-887*	0.04-0.11	0.02-0.07	5.0-5.1	3.5
		52-970 µg/l	**162-1197 µg/l**	**0.4-7.6 mg/kg dw**	**2.0-9.2 mg/kgdw**	**4-1798 ng/m^3**	**4-1798 ng/m^3**	**0.0005-0.21 mg/kg dw**	**0.0003-0.15 mg B/l**	**5.0-5.2 mg/kg dw**	**3.5-3.6 mg B/l**

* It is assumed that no emission reduction measures are applied.

*Specific assessment, marine water**

Industry sector	**Life cycle stage**	**C marine water (µg B/l)**	**PECadd marine water (µg B/l)**	**C marine sediment (mg B/kg dw)**	**PECadd marine sediment (mg B/kg dw)**
Borosilicate	Formulation	28.1-97.0	46.3-115.2	0.20-0.68	0.36-0.84
IFG/TFG	Formulation	8.9-34.5	27.1-52.7	0.06-0.24	0.22-0.40
Ceramics	Formulation	17.5-58.2	35.7-76.4	0.12-0.41	0.28-0.57
Industrial fluids	Formulation	23.5-51.1	41.7-69.3	0.16-0.36	0.32-0.52
Metallurgy	Formulation	7.3-13.5	25.4-31.7	0.05-0.09	0.21-0.25
Flame retardants	Formulation	108.7	127	0.76	0.92
Detergents	Formulation	/	/	/	/
Cleaners	Formulation	/	/	/	/
Agriculture (fertilisers)	Formulation	5.2-19.3	23.4-37.5	0.04-0.14	0.20-0.30
Various chemical effects	Formulation	9.5-28.5	27.7-46.7	0.07-0.20	0.23-0.36
		5.2-97 µg/l	**23-115µg/l**	**0.04-0.68 mg/kg dw**	**0.20-0.84 mg/kg dw**

* It is assumed that no emission reduction measures are applied.

Industrial and private use stages

*Generic assessment, freshwater**

Industry sector	**Life cycle stage**	**Cwater (µg B/l)**	**PECwater (µg B/l)**	**Csediment (mg B/kg dw)**	**PECadd sediment (mg B/kg dw)**	**Cair (ng B/m^3)**	**PECadd air (ng B/m^3)**	**Csoil (mg B/kg dw)**	**Cporew Soil (mg B/l)**	**PECtotal soil (mg B/kg dw)**	**PECporew Soil (mg B/l)**
Borosilicate	Industrial use	4467	4577	31	32.6	408	408	0.05	0.034	5.05	3.5
IFG/TFG	Industrial use	4750	4850	33	34.6	434	434	0.05	0.036	5.05	3.5
Ceramics	Industrial use	5813	5923	41	42.6	531	531	0.06	0.044	5.06	3.5
Industrial fluids	Industrial use	775	872	5.4	7.0	0.80	0.80	0.0001	0.00007	5.0	3.5
Metallurgy	Industrial use	330	441	2.3	3.9	NR	NR	NR	NR	NR	NR
Flame retardants	Industrial use	37.5	148	0.3	1.9	429	429	0.05	0.036	5.05	3.5
Detergents	Private use	306	417	2.2	3.8	NR	NR	NR	NR	NR	NR
Cleaners	Private use	52.8	163	0.4	2.0	NR	NR	NR	NR	NR	NR
Agriculture (fertilisers)	Industrial use	436	546	3.1	4.7	NR	NR	NR	NR	NR	NR
Various chemical effects	Industrial use	543	653	3.8	5.4	2		0.0002	0.0001	5.0	3.5
Detergents & Cleaners (private use)		**53-306 µg/l**	**163-417 µg/l**	**0.4-2.2 mg/kg dw**	**2.0-3.8 mg/kg dw**	**NR**	**NR**	**NR**	**NR**	**NR**	**NR**
Agriculture		**436 µg/l**	**546 µg/l**	**3.1 mg/kgdw**	**4.7 mg/kgdw**	**NR**	**NR**	**NR**	**NR**	**NR**	**NR**
Other industries		**38-5813 µg/l**	**148-5923 µg/l**	**0.3-41 mg/kg dw**	**1.9-42.6 mg/kgdw**	**0.8-531 ng/m^3**	**0.8-531 ng/m^3**	**0.0001-0.06 mg/kg dw**	**0.00007-0.04 mg/l**	**5.0-5.1 mg/kg dw**	**3.5 mg/l**

NR: not relevant to calculate PEC due to zero emissions for the particular sector/life cycle stage combination

* It is assumed that no emission reduction measures are applied.

*Generic assessment, marine water**

Industry sector	**Life cycle stage**	**C marine water (µg B/l)**	**PECadd marine water (µg B/l)**	**C marine sediment (mg B/kg dw)**	**PECadd marine sediment (mg B/kg dw)**
Borosilicate	Industrial use	447	465	3.1	3.3
IFG/TFG	Industrial use	475	493	3.3	3.5
Ceramics	Industrial use	581	600	4.1	4.2
Industrial fluids	Industrial use	78	96	0.5	0.7
Metallurgy	Industrial use	33	51	0.2	1.2
Flame retardants	Industrial use	3.8	22	0.03	0.2
Detergents	Private use	30.6	49	0.2	0.4
Cleaners	Private use	5.3	23.5	0.04	0.2
Agriculture (fertilisers)	Industrial use	43.6	61.8	0.3	0.5
Various chemical effects	Industrial use	54.3	72.5	0.4	0.5
Detergents & Cleaners (private use) **Agriculture** **Other industries**		**5.3-30.6 µg/l** **43.6 µg/l** **3.8-581 µg/l**	**23.5-49 µg/l** **61.8 µg/l** **22-600 µg/l**	**0.04-0.2 mg/kg dw** **0.3 mg/kg dw** **0.03-4.1 mg/kg dw**	**0.2-0.4 mg/kg dw** **0.5 mg/kg dw** **0.2-4.2 mg/kg dw**

* It is assumed that no emission reduction measures are applied.

*Specific assessment, freshwater**

Industry sector	**Life cycle stage**	**Cwater (µg B/l)**	**PECwater (µg B/l)**	**Csediment (mg B/kg dw)**	**PECadd sediment (mg B/kg dw)**	**Cair (ng B/m^3)**	**PECadd air (ng B/m^3)**	**Csoil (mg B/kg dw)**	**Cporew Soil (mg B/l)**	**PECtotal soil (mg B/kg dw)**	**PECporew Soil (mg B/l)**
Borosilicate	Industrial use	16167	16278	113	114.6	1798	1798	0.21	0.15	5.21	3.5
IFG/TFG	Industrial use	5744	5850	40.3	41.9	639	639	0.08	0.05	5.08	3.5
Ceramics	Industrial use	9706	9816	68.1	69.7	591	591	0.07	0.05	5.07	3.5
Industrial fluids	Industrial use	511	621	3.6	5.2	0.88	0.88	0.00010	0.00007	5.0	3.5
Metallurgy	Industrial use	135	245	0.9	2.5	NR	NR	NR	NR	NR	NR

Flame retardants	Industrial use	38	148	0.4	2.0	166	166	0.02	0.014	5.02	3.5
Detergents	Private use	/	/	/	/	/	/	/	/	/	/
Cleaners	Private use	/	/	/	/	/	/	/	/	/	/
Agriculture (fertilisers)	Industrial use	/	/	/	/	/	/	/	/	/	/
Various chemical effects	Industrial use	666	776	4.7	6.3	3.5	3.5	0.0004	0.0003	5.0	3.5
Detergents & Cleaners (private use) **Agriculture** **Other industries**		**/** **/** **54-16167 µg/l**	**/** **/** **148-16278 µg/l**	**/** **/** **0.4-113 mg/kg dw**	**/** **/** **2.0-114.6 mg/kgdw**	**NR** **NR** **0.9-1798 ng/m^3**	**NR** **NR** **0.9-1798 ng/m^3**	**NR** **NR** **0.0001-0.2 mg/kg dw**	**NR** **NR** **0.00007-0.15 mg/l**	**NR** **NR** **5.0-5.2 mg/kg dw**	**NR** **NR** **3.5 mg/l**

NR: not relevant to calculate PEC due to zero emissions for the particular sector/life cycle stage combination

It is assumed that no emission reduction measures are applied.

*Specific assessment, marine water**

Industry sector	**Life cycle stage**	**C marine water (µg B/l)**	**PECadd marine water (µg B/l)**	**C marine sediment (mg B/kg dw)**	**PECadd marine sediment (mg B/kg dw)**
Borosilicate	Industrial use	1617	1635	11.3	11.5
IFG/TFG	Industrial use	574	593	4.0	4.2
Ceramics	Industrial use	971	989	6.8	7.0
Industrial fluids	Industrial use	51	69	0.4	0.5
Metallurgy	Industrial use	13.5	32	0.09	0.3
Flame retardants	Industrial use	3.8	22	0.03	0.2
Detergents	Private use	/	/	/	/
Cleaners	Private use	/	/	/	/
Agriculture (fertilisers)	Industrial use	/	/	/	/
Various chemical effects	Industrial use	66.6	84.8	0.5	0.6
Detergents & Cleaners (private use) **Agriculture** **Other industries**		**/** **/** **3.8-1617 µg/l**	**/** **/** **22-1635 µg/l**	**/** **/** **0.03-11.3 mg/kg dw**	**/** **/** **0.2-11.5 mg/kg dw**

* It is assumed that no emission reduction measures are applied.

10.7.1 Recommendations for further work

- From the report, it is clear that exposure concentrations strongly depend on site tonnages and release factors. Considering the conservative default emission factors, and the assumption that no emission reduction measures are taken, these exposure concentrations can not be considered to be very realistic.
- In order to obtain reliable estimates of emissions and exposure, measured local emission and exposure data should be gathered from individual sites, and from other information sources (EC BREF, industry information).
- For the calculation of environmental concentrations some input data are preliminary or not available. These data should be completed or updated.
    - removal efficiency of B in sewage treatment plants;
    - updates of regional monitoring data for water (surface and ground water)
    - monitoring data for sediment, air, soils
- Please note that this report mainly focuses on the local scale exposure assessment (mainly production, formulation and industrial use stages). A regional scale assessment (EUSES 2.0 modelling) was performed on the basis of the life cycle stage approach as outlined in this document (production, formulation, industrial use, private use and waste). This approach has been taken because from the emission inventory analysis it became clear that the availability of emission data on Boron was very limited.

10.8 PECregional derivation (EUSES 2.0)

10.8.1 Input and assumptions

Upscaling from EU-15 to EU-27

Since the tonnage and use fractions derived for different industry sectors and the emissions from the waste stage reported concern the EU-27 Member States (see local exposure chapter 10.2 and waste chapter 10.8.8.8 respectively), the EUSES 2.0 model –used for PECregional determination- will need to be up-scaled to the EU-27. This will be done applying the following input data.

The EUSES 2.0 model will be adjusted to the EU-27. This will be done adjusting the continental area of EU-15 ($3.56x10^6$ km^2) to EU-27 ($4.24x10^6$ km^2) and adjusting the number of inhabitants from the EU-15 to the EU-27 ($4.91x10^8$ inhabitants). The generic region will not be adjusted; it is defined as in the TGD (2003) and in the EUSES 2.0 model (40,000 km^2; 20 million inhabitants).

Table 10-23 gives an overview of general characteristics of the region/continent and EU-15/27.

Tabelle 10.23 Overview of general characteristics of the region/continent/EU

	Region	**Continent (EU-15+Norway)**	**Continent (EU-27)**
Surface are (km^2)	4×10^4	3.56×10^6	$4.24x10^6$
Number of inhabitants	2×10^7	3.7×10^8	$4.91x10^8$
% connection rate to STP	80%	80%	NA

EUSES 2.0 (according to the TGD, 2003) is used for estimating the regional PEC values for each environmental compartment. The boron inputs for the regional assessment are the anthropogenic point and diffuse emissions to air, wastewater, surface water, agricultural soil and industrial/urban soil. Please note that due to the lack of detailed and validated information on Boron sources and emissions (Emission Inventory Report Boric acid and Sodium tetraborates, Arcadis Belgium), regional and continental emissions are estimated as a generic scenario with the EUSES 2.0 model.

The input of chemicals is regarded in the model as continuous and equivalent to continuous diffuse emission. The results from the models are steady-state concentrations, which can be regarded as estimates of long-term average exposure levels (TGD, 2003).

In the continental model, it is assumed that all anthropogenic boron emissions enter into the continental environment. It is also assumed that no inflow of air and water across the boundaries of the continent occurs. Continental exposure concentrations are estimated based on the combined anthropogenic boron emissions from all EU countries (extrapolated) and on the natural/pristine ambient background of boron.

$$PECcontine\,ntal_{total} = PECcontine\,ntal_{add} + natural\ /\ pristineam\,bientbackg\,round$$

The $PECcontinental_{add}$ is the boron concentration at continental scale that is related to boron emissions by man (EUSES 2.0 calculations, see below). Background boron is, by definition, the natural background for surface water and air and is the ambient boron concentration measured in areas away from a point source for soils and sediments.

It should be noted that at present, boron natural background concentrations are available for surface water only (FOREGS maps, median value = 15.6 µg B/l). For this compartment, a PECtotal (incorporating both boron from anthropogenic and natural sources) can be derived. For the sediment, soil and air compartment the reported calculated PEC values do not take into account natural/pristine ambient boron backgrounds (PECadd values: Boron from anthropogenic sources only).

Background boron concentrations in water were taken from the FOREGS Geochemical Baseline Programme (FGBP) database published in March 2004 (http://www.gsf.fi/foregs/geochem/).

FOREGS (Forum of European Geological Surveys) Geochemical Baseline Programme sought to provide high quality environmental geochemical baseline data for Europe based on samples of stream water, stream sediment, floodplain sediment, soil, and humus collected all over Europe. The total number of analysed (ICP-MS, detection limit 0.01 µg/L) water samples was 807. A large spatial variation in baseline boron levels can be noted. Dissolved boron levels ranged between 0.1 and 3030 µg B/L with 50th/90th percentiles of 15.6 and 94.5 µg B/L. The maximum value was determined in Italy. The lowest baseline concentrations are found in the Nordic countries (< 10 µg/L). Regions where relatively high baseline levels of boron are detected (±>30 µg/L), are Italy, South-East England, the lowlands (Belgium/The Netherlands), northern parts of France and Germany, Southern Spain and parts of Eastern Europe. Taking into account the high quality of the data set, the 50th value of 15.6 µg B /L can be accepted as a typical background concentration for B in European surface waters (Europe-regional scale).

The PECregional is calculated from

$$PECregional_{total} = PECregional_{add} + natural / pristine\ ambient\ background$$

The $PECregional_{add}$ is the estimated boron concentration at regional scale that is related to boron emissions by man. PECcontinental and PECregional are calculated with EUSES 2.0. The output of the model gives in fact the predicted added environmental concentrations at continental and regional scale ($PEC_{con,\ add}$ and $PEC_{reg,\ add}$) (anthropogenic boron inputs only).

For modelling the behaviour of boron in the environment, the octanol-water partition coefficient (Kow) is not appropriate. For borates, all individual compounds are assumed to transform into H_3BO_3. For simplicity all values will be expressed as B. In EUSES, the solubility is set to maximum value of $1x10^5$ mg/l. Measured solids-water partition coefficients for sediment, suspended matter and soil (Kp values) are used (TGD Appendix VIII, 2003).

The solids-water distribution coefficient in soil, Kp_{soil}, will be set to 1.5 l/kg. The solids/water partition coefficient, K_p, of suspended matter is set at 3.5 l/kg. The solids/water partition coefficient, Kp, of sediment is set at 2.78 l/kg. Partition coefficients for the distribution of inorganics between water and suspended matter are used to calculate the dissolved concentrations from total concentrations in surface water. Partition coefficients for the partitioning of inorganics between water and sediment are used to calculate the concentration in sediment from the concentration in water. The concentration of suspended solids will be set to 15 mg/l in each scenario, both for the continental and the regional compartment.

Volatilisation is ignored for boron; therefore the Henry-coefficient was set to 0 Pa m^3/mol. Most of the boron present in the atmosphere will be bound to aerosols. The vapour pressure was set to 10^{-10} Pa to ensure that the fraction associated to aerosols was equal to one. Biotic and abiotic degradation rates were considered not to be relevant and have been minimised (TGD Appendix VIII, 2003).

In the TGD model, input sources for soil contamination include direct emission to soil, deposition from the atmosphere and emission of sewage sludge as fertilisers to agricultural soil. The sludge application route is not relevant in this stage of the assessment, since removal of boron is assumed not to take place at a conventional municipal sewage treatment plant (Fwater=1; Fsludge=0). Three types of soil are distinguished: agricultural, natural and industrial. The boron emissions from agricultural practice (fertilisers) are assumed not to affect natural or industrial soil (TGD, 2003). The diffuse boron emissions from atmospheric deposition are distributed between these 3 types of soil proportionally to the surface areas of the three types of soil. According to the TGD (2003) the fraction of surface area that is agricultural soils is 0.60, the fraction natural soil 0.27, and the fraction industrial soil 0.1.

The modelling exercise has been performed for a generic TGD region (regional emisssions: 10% of EU 27; continental emissions: 90% of EU—27 emissions).

10.8.2 Conclusion on regional emissions and PEC regional

Table 10.24 Overview of continental and regional emissions and sources of emissions (industry sector, life cycle stage) (EUSES file)

input continental (anthropogenic): EU$_{total}$ – input$_{regional}$	
amount released to air	1180 T B_20_3/year
amount released to wastewater	90055 T B_20_3/year
amount released to surface water	22903 T B_20_3/year
amount released to agricultural soil	9563 T B_20_3/year
amount released to natural soil	0 T B_20_3/year
amount released to industrial soil	687 T B_20_3/year

Table 10.25 Overview of continental and regional emissions and sources of emissions (industry sector, life cycle stage) (EUSES file)

Industry sector	**Air** (T B_2O_3/year)	**Wastewater & surface water** (T B_2O_3/year)	**Industrial soil** (T B_2O_3/year)	**Agricultural soil** (T B_2O_3/year)
Production	0.00	0.00	0.00	0.00
Agriculture (form)	25.26	30.30	1.01	0.00
Agriculture (ind. use)	0.00	503.7	0.00	9563.00
Flame retardants (form)	16.32	130.31	0.65	0.00
Flame retardants (ind. use)	0.00	6059.00	9.56	0.00
Metallurgy (formulation)	8.94	71.54	0.36	0.00
Metallurgy (ind. use)	872.35	1748.35	174.84	0.00
Industrial fluids (formulation)	10.11	80.67	0.41	0.00
Industrial fluids (ind. use)	0.04	2963.80	3.94	0.00
Chemical synthesis (formulation)	50.01	59.86	1.99	0.00
Chemical synthesis (ind. use)	0.20	138.70	1.98	0.00
Detergency (formulation)	85.41	11.39	3.41	0.00
Detergency (private use)	0.00	32193.00	339.09	0.00
Cleaners & cosmetics (formulation)	0.11	5.07	18.03	0.00
Cleaners & cosmetics (private use)	0.00	5548.00	56.21	0.00
Ceramics (formulation	40.52	121.18	4.05	0.00
Ceramics (industrial use)	0.00	20148.00	20.15	0.00
TFG & IFG (formulation)	55.12	164.98	5.51	0.00
TFG & IFG (ind. use)	0.00	27411.50	27.41	0.00

Industry sector	Air (T B_2O_3/year)	Wastewater & surface water (T B_2O_3/year)	Industrial soil (T B_2O_3/year)	Agricultural soil (T B_2O_3/year)
Borosilicate glass (formulation)	15.55	93.08	3.11	0.00
Borosilicate glass (ind. use)	0.00	15476.00	15.48	0.00
	1180	**112958**	**687**	**9563**

Tabelle 10.26 Overview of input regional (anthropogenic)

input regional (anthropogenic):	
amount released to air	131 T B_20_3/year
amount released to wastewater	10038 T B_20_3/year
amount released to surface water	2566 T B_20_3/year
amount released to agricultural soil(1)	1059 T B_20_3/year
amount released to natural soil(1)	0 T B_20_3/year
amount released to industrial soil(1)	78 T B_20_3/year

Tabelle 10.27 Overview of continental and regional emissions and sources of emissions (industry sector, life cycle stage) (EUSES file)

Industry sector	Air (T B_2O_3/year)	Wastewater & surface water (T B_2O_3/year)	Industrial soil (T B_2O_3/year)	Agricultural soil (T B_2O_3/year)
Production	0.14	43.07	1.44	0.00
Agriculture (form)	2.80	3.36	0.11	0.00
Agriculture (ind. use)	0.00	55.85	0.00	1058.50
Flame retardants (form)	1.81	14.49	0.07	0.00
Flame retardants (ind. use)	0.00	671.60	1.06	0.00
Metallurgy (formulation)	1.00	7.96	0.04	0.00
Metallurgy (ind. use)	97.09	194.55	19.45	0.00
Industrial fluids (formulation)	1.12	8.98	0.04	0.00
Industrial fluids (ind. use)	0.00	329.23	0.44	0.00
Chemical synthesis (formulation)	5.51	6.64	0.22	0.00
Chemical synthesis (ind. use)	0.02	15.37	0.22	0.00
Detergency (formulation)	9.49	11.39	0.38	0.00
Detergency (private use)	0.00	3577.00	37.60	0.00
Cleaners & cosmetics (formulation)	0.01	0.57	2.01	0.00
Cleaners & cosmetics (private use)	0.00	616.85	6.24	0.00
Ceramics (formulation	4.49	13.47	0.45	0.00

Industry sector	Air (T B_2O_3/year)	Wastewater & surface water (T B_2O_3/year)	Industrial soil (T B_2O_3/year)	Agricultural soil (T B_2O_3/year)
Ceramics (industrial use)	0.00	2237.45	2.24	0.00
TFG & IFG (formulation)	6.13	18.36	0.61	0.00
TFG & IFG (ind. use)	0.00	3047.75	3.05	0.00
Borosilicate glass (formulation)	1.73	10.37	0.34	0.00
Borosilicate glass (ind. use)	0.00	1719.15	1.72	0.00
	131	**12603**	**78**	**1059**

The anthropogenic continental and regional emission data and resulting regional PEC estimated values are presented inTable 10-27. Please note that the regional and continental emissions are based on emissions estimated for the major borate sectors (production, formulation and industrial use stages mainly; for detergency and cleaners also private use stages are considered; application of mineral fertilisers on agricultural soils is considered in the industrial use scenario). Although EUSES –in principle- also considers service life and waste stage; the model did not make emission estimates for these life cycle stages –selected IC/UC/MC combinations- due to the lack of appropriate emission factors.

The results in Table 10-28 give an indication of the predicted environmental concentrations in different environmental compartments as a result of emissions from production, formulation, industrial use and private use of boric acid and sodium tetraborates. Emissions from each sector are described in chapter "local environmetal exposure". Please note that with respect to waste emissions, a separate assessment has been made (chapter Waste stream analysis and emissions). The calculated values are averages for a general regional and general continental environment. The PECregional values are reported as 'added' value for the environmental compartments sediment, soil and air. This means that the calculated PEC values for these compartments refer to anthropogenic inputs only (added approach). For water a 'total' value, including natural background is calculated.

Tabelle 10.28 Emission values, total concentration and added/total PEC values for the regional and continental environment (EUSES based: life-cycle stages production, formulation and industrial use mainly; for some uses; private use included)

input continental (anthropogenic): EU_{total} – $input_{regional}$	
Amount released to air	1183 T B_20_3/year
Amount released to wastewater	90155 T B_20_3/year
Amount released to surface water	23032 T B_20_3/year
Amount released to agricultural soil	9563 T B_20_3/year
Amount released to natural soil	0 T B_20_3/year
Amount released to industrial soil	686 T B_20_3/year
input regional (anthropogenic):	
Amount released to air	131 T B_20_3/year
Amount released to wastewater	10038 T B_20_3/year
Amount released to surface water	2566 T B_20_3/year
Amount released to agricultural soil$^{(1)}$	1059 T B_20_3/year
Amount released to natural soil$^{(1)}$	0 T B_20_3/year
Amount released to industrial soil$^{(1)}$	78 T B_20_3/year

Results:		**PEC_{add} continental**	*Natural/pristine ambient background*(2)	**PEC_{add} regional**	*Natural/pristine ambient background*(2)
Concentration in air	mg B/m^3	4.97E-12	NA	**9.57E-11**	NA
Concentration in agricultural soil	mg B/kg_{dwt}	0.007	NA	**0.07**	NA
Concentration porewater agr. Soil	µg B/l	4.2	NA	**41.9**	NA
Concentration in natural soil	mg B/kg_{dwt}	0.0002	NA	**0.005**	NA
Concentration in industrial soil	mg B/kg_{dwt}	0.003	NA	**0.03**	NA
K_p suspended matter = 3.5 l/kg					
Concentration in fresh water (dissolved)	µg B/l	55.0	15.6	176.4	15.6
Concentration in sediment	mg B/kg_{dwt}	0.5	NA	**1.5**	NA
Concentration in sea water (dissolved)	µg B/l	0.64	NA	**17.6**	NA
Concentration in marine sediment	mg B/kg_{dwt}	0.01	NA	**0.15**	NA
PEC values		**PEC_{total} continental**		**PEC_{total} regional**	
PEC air	mg B/m^3	NA		NA	
PEC agricultural soil	mg B/kg_{dwt}	NA		NA	
PEC porewater agr. Soil	µg B/l	NA		NA	
PEC natural soil	mg B/kg_{dwt}	NA		NA	
PEC industrial soil	mg B/kg_{dwt}	NA		NA	
K_p suspended matter = 3.5 l/kg (50P)					
PEC fresh water (dissolved fraction)	µg B/l	70.6		**192.0**	
PEC sediment	mg B/kg_{dwt}	NA		NA	
PEC sea water (dissolved fraction)	µg B/l	NA		NA	
PEC marine sediment	mg B/kg_{dwt}	NA		NA	

*: natural background concentrations: median of monitoring data for surface water (FOREGS programme)

Tabelle 10.29 Emission values, total concentration and added/total PEC values for the regional and continental environment (EUSES based: life-cycle stages production, formulation and industrial use mainly; for some uses; private use included + input from waste assessment analysis (surface water emissions only; incineration, landfiling scenarios EU-27))

input continental (anthropogenic): EU_{total} – $input_{regional}$	
Amount released to air	1183 T B_20_3/year
Amount released to wastewater	90155 T B_20_3/year
Amount released to surface water	26964 T B_20_3/year
Amount released to agricultural soil (1)	9563 T B_20_3/year
amount released to natural soil(1)	0 T B_20_3/year
amount released to industrial soil(1)	686 T B_20_3/year
input regional (anthropogenic):	
amount released to air	131 T B_20_3/year
amount released to wastewater	10038 T B_20_3/year
amount released to surface water	3003 T B_20_3/year
amount released to agricultural soil(1)	1059 T B_20_3/year
amount released to natural soil(1)	0 T B_20_3/year
amount released to industrial soil(1)	78 T B_20_3/year

results:		**PEC_{add} continental**	*Natural/pristine ambient background*$^{(2)}$	**PEC_{add} regional**	*Natural/pristine ambient background*$^{(2)}$
Concentration in air	mg B/m^3	4.99E-12	NA	**9.41E-11**	NA
Concentration in agricultural soil	mg B/kg$_{dwt}$	0.007	NA	**0.07**	NA
Concentration porewater agr. Soil	µg B/l	4.2	NA	**41.9**	NA
Concentration in natural soil	mg B/kg$_{dwt}$	0.0002	NA	**0.005**	NA
Concentration in industrial soil	mg B/kg$_{dwt}$	0.003	NA	**0.03**	NA
K_p suspended matter = 3.5 l/kg					
Concentration in fresh water (dissolved)	µg B/l	56.9	15.6	182	15.6
Concentration in sediment	mg B/kg$_{dwt}$	0.5	NA	**1.58**	NA
Concentration in sea water (dissolved)	µg B/l	0.67	NA	**18.2**	NA
Concentration in marine sediment	mg B/kg$_{dwt}$	0.006	NA	**0.16**	NA
PEC values		**PEC_{total} continental**		**PEC_{total} regional**	
PEC air	mg B/m^3	NA		NA	
PEC agricultural soil	mg B/kg$_{dwt}$	NA		NA	
PEC porewater agr. Soil	µg B/l	NA		NA	
PEC natural soil	mg B/kg$_{dwt}$	NA		NA	
PEC industrial soil	mg B/kg$_{dwt}$	NA		NA	
K_p suspended matter = 3.5 l/kg (50P)					
PEC fresh water (dissolved fraction)	µg B/l	72.5		**197.6**	
PEC sediment	mg B/kg$_{dwt}$	NA		NA	
PEC sea water (dissolved fraction)	µg B/l	NA		NA	
PEC marine sediment	mg B/kg$_{dwt}$	NA		NA	

*: natural background concentrations: median of monitoring data for surface water (FOREGS programme)

10.8.3 Soil

The estimated ***$PECadd_{regional}$ from borates production, formulation, use and end of life emission for agricultural soils is 0.07 mg B/kg dw*** (*natural background not included*). The emission to agricultural soil encompasses direct emissions (10622 T B_20_3; fertiliser application) and indirect emissions (aerial deposition). It should be noted that:

-Sludge applicaton is not considered at this stage, since it is assumed that boron is not removed in a municipal STP (sludge concentration from anthropogenic sources is 0).

-Mineral fertilisers are applied on agricultural soils but it is assumed that the total tonnage is spread equally over the entire surface area. This will lead to an underestimation of the real amount applied as in reality mineral borates fertilisers are applied on agricultural land at a dose of 1-2 kg B/ha resulting in an addition of 0,3-0,6 mg B/kg dw soil (soil effects chapter).The indirect emission, through aerial deposition is calculated as follows: the fraction surface area that is agricultural soil in EU is 0.60, therefore 0.60 x 1314 tonnes B_20_3 (788T B_20_3; EU-27) emitted annually ends up in agricultural soils (aerial deposition). The mixing depth of the agricultural soil is 20 cm. The boron released to natural soil is assumed to consist of atmospheric deposition *from borates production, formulation, use and end of life emission* only. The fraction natural soil (surface based) is 0.27. Emissions to natural soils are therefore 0.27 x 408 1314 tonnes B_20_3 (355 T B_20_3; EU-27). The mixing depth of natural soil is 5 cm. The ***$PECadd_{regional}$ for natural soil is 0.005 mg B/kg dw*** (*natural background not included*).

Boron released to industrial soil consists of direct input and atmospheric deposition *from borates production, formulation, use and end of life emission*. The fraction industrial soil (surface based) is 0.1. Aerial deposition to industrial soils is therefore 0.1 x 1314 tonnes B_20_3 (131T B_20_3; EU-27). The mixing depth of industrial soil is 5 cm.The ***$PECadd_{regional}$ for industrial soil is 0.03 mg B/kg dw*** (*natural background not included*).

10.8.4 Air

Annual atmospheric emissions *from borates production, formulation, use and end of life emission* in the EU amount to 1314 tonnes B_20_3/year. The ***$PECadd_{regional}$ for air is 9.6 $x10^{-11}$ mg B/m^3*** (*natural background not included*). This value does not include burning of coal or wood –both of which (along with forest fires and burning off agricultural waste) contribute significant to air emissions. Park and Schleisinger (2002) estimated forests and forest fires to produce 0.26 to 9.43 Tg B/year – compared with mining activities producing 0.31 Tg B/year. Emissions from coal and wood burning -not really natural sources- but are significant sources of boron loading to the environment.

10.8.5 Aquatic compartment (water and sediment)

Total EU annual emissions to wastewater and surface water *from borates production, formulation, use and end of life emission* amount to 100193 tonnes B_20_3/year and 25597-29967 tonnes B_20_3/year respectively. Wastewater emissions undergo treatment in EUSES (STP treatment). However, as it is assumed that boron is not removed at the STP, these emissions are discharged directly to surface water. Emissions to water through runoff from soil are in principle not accounted for. The anthropogenic part of these emissions is however included in the PECwater calculations because the model (EUSES 2.0) assumes that a fraction of the emissions to soil are released to water.

The ***$PECtotal_{regional}$ for fresh water is 192-198 µg B/l*** (dissolved fraction) (*natural background of 15.6 µg B/l included)*. This value is derived on the basis of a median K_p suspended solids value for B of 3.5 l/kg. The ***$PECadd_{regional}$ for sea water is 17.6-18.2 µg/l*** (dissolved fraction) *(natural background not included since not available)*.

The ***$PECadd_{regional}$ for freshwater sediment*** –determined by using the partitioning methodology – median Kp sediment value of 2.78 l/kg – is ***1.5-1.6 mg B/kg dw)*** (*natural background not included*).

The ***PECadd$_{regional}$* for marine sediment is 0.15-0.16 mg/kg dw** *(natural background not included since not available).*

10.8.6 Measured levels – Ambient concentrations of boron

Rapporteur´s Comment:

The following chapter (10.8.6 Measured levels – Ambient concentrations of boron) is based on the report from Arcadis Belgium – EURAS, 2008. Ambient concentrations of boron in the environment (water, sediment, soil), with emphasis on the European continent. Report 2008. Commissioned by the European Borates Association (EBA).

RWC-ambient PECs were calculated with Risk (Palisade Decision Tools). The outputs of the statistical computer package @Risk (Palisade Decision Tools) (describing the distribution that most likely produced the monitoring data for a specific location, river or region) could not be evaluated, as it is only commercially available.

Aquatic compartment

Boron concentrations in surface water vary widely throughout Europe, from less than 10 µg B/L to concentrations greater than 1000 µg B/L. Such variation is due to both natural and anthropogenic factors (Neal et al, 1998). Extensive environmental monitoring data exists for boron, but the main part of these data has been collected as spot samples rather than as part of a more extensive monitoring programme. For risk assessment purposes only data that can be statistically evaluated should be used.

The ambient regional boron levels that are measured are the sum of different processes and sources, although the extent of their contribution is region-specific:

- ~ There are some areas in Europe where boron levels are high due to local geological conditions, and natural processes like weathering of igneous rocks and leaching of salt deposits which can contribute significantly to concentrations in surface waters (Christ and Harder, 1978). High background levels are found, for instance, in clay-rich marine sediments (Butterwick et al, 1989);
- ~ Rainwater carrying boron from adjacent oceans may contribute boron to surface waters (Chetelat and Gaillardet, 2005);
- ~ Contribution from rainwater, agricultural-affected waters and effluents also contribute to ambient boron levels in surface; waters (Park and Schlesinger, 2002)
- ~ Industrial and commercial effluents arise from *inter alia* glass and ceramic manufacture, insulation products or detergency applications (Gandolfi et al, 2000; Chetelat and Gaillardet, 2005).

The latter authors also compared the ratios of ^{11}B and ^{10}B in the Seine River (France) and in sources (perborate, borax from Turkey, borax from the U.S., fertilizer, rainwater, local rocks). They suggested that about 25% of boron in the Seine in Paris was due to rainwater contribution, 10% was due to agricultural-affected waters, and about 65% due to urban effluents. Mean boron discharge in Paris was 4.6 µmol/L or 50 µg-B/L. In the Seine system, geological sources (dissolution of borate from rocks) appeared to contribute less than 1% of total boron except for spring when it reached 10% of the total.

Three extensive databases were identified containing boron monitoring data in one or several EU countries. These are discussed below.

A first dataset by Wyness et al (2003) describes the distribution of boron in rivers across European Union countries based on data that were collected from national and international monitoring programmes.

Country specific levels were calculated as the mean of the 95 percentile of all national monitoring points. This provides a more conservative estimate of the mean concentration than the recommended 90th percentile (ECB, 2003). An extensive overview of the data availability and the spatial and time-variant coverage is provided in Wyness et al (2003). Table 10-30 gives a data summary of the main country-specific boron levels that were derived in this study.

Tabelle 10.30 Boron Concentration (µg-B/L) – Summary of data (Wyness et al., 2003)

Country	No. of Monitoring Points	Date Coverage	Total No. Values	Arithmetic Mean	Range	Mean of site 95% percentile
Austria	30	1998-2000	712	44	nd-690	80
Belgium	651	1998-2000	5,056	239	25-2,029	410
Denmark				0		
Finland (lakes only)	463	1995	463	3.3	<1-46	44
France	25	1995-2000	1,304	146	nd-2,670	261
Germany	197	1980-95	197	171	nd-1,300	632
Greece	28	1997-99	Not known	144	4-2,330	-
Luxembourg				0		
Ireland	185	1999-2000	185	26	nd-1,630	101
Italy	64	1998-1999	926	114	nd-894	84
Netherlands	9	1986-1999	1,842	111	38-878	218
Portugal	8	1999-2000	129	367	30-3,860	534
Spain	328	1991-2000	4,272	137	nd-7,490	288
Sweden				0		
UK-England	98	1974-2000	22,329	65	nd-1,121	95
UK-Northern Ireland				0		
UK-Scotland	10	1976-1997	3,437	9.7	nd-230	17
UK-Wales	39	1975-1999	4,965	13.0	nd-292	22

A second dataset composed of a substantial amount of boron data were collected within the GREATER project. An overview of these data is presented.

Holt et al (2003) and Fox et al (2000) reported boron concentrations in 4 different rivers or river catchments (Calder catchment, Went catchment, River Aire, and combined data for the Rivers Don and Rother). In the rivers Aire and Calder, the natural upstream and background boron levels are negligible. In the stretch of the river Rother which has been monitored, background boron levels in excess of 100 µg/L are present. These may have resulted from upstream and instream anthropogenic inputs, including leakage from fly ash tipping sites. Background boron levels in excess of 100 µg/L are also present in the river Went, due to exchange with groundwater which contains boron leached from marine sediments exposed to flooded former coal mines. Samples for boron analysis were taken at low water levels, which are used as a reasonable worst case in environmental risk assessment in Europe. The 90th percentiles of boron in the four rivers/river catchments are given in Table 10-31 and are based on site-specific mean values along with the standard deviations which are due to different boron levels at different sites within the catchment. As mentioned before, the means of the 90th percentiles of site-specific concentration levels are recommended for use in regional risk assessment in Europe (ECB, 2003).

Tabelle 10.31 UK Boron monitoring data from the GREATER project (data from Holt et al, 2003; Fox et al, 2000)

River / Catchment	Year	No. of sites (No. of samples per site)	Range of site mean boron conc (µg/L)	RWC-ambient PEC (90th percentile) µg/l
Aire (UK)	1996-1998	16 (3 -38)	20 - 280	283
Calder (UK)	1996-1998	18 (18 -27)	26 -417	324
Rother (UK)	1996-1998	15 (18 -21)	106 -512	441
Went (UK)	1996-1998	7 (19 -24)	203 -530	433

Finally, the most extensive and also most recent dataset was collected by Heijerick and Van Sprang (2004). Recent monitoring data were used to derive the median value of all 90th percentiles from measured data from different sites, rivers/catchments or regions in EU countries. Data on the ambient (background and anthropogenic) water concentration of boron for the different European surface waters were collected from environmental agencies, existing extensive databases and scientific literature.

The procedures that were used by Heijerick and Van Sprang (2004) for the derivation of ambient predicted environmental concentration levels of boron are based on the methods and concepts laid down in the TGD (ECB, 2003) for environmental risk assessment in the European Union and on the Combined Monitoring-based and Modelling-based Priority Setting procedure (COMMPS, 1999). The following selection criteria for the collection of monitoring data from surface waters were applied:

- To increase the relevance of the monitoring data, only the most recent monitoring data were used for PEC derivation (1999-2001): older data were only used if no (or few) recent data are available;
- A data set was fully excluded and not used for the derivation of an ambient PEC-distribution if more than 80% of the measurements fall below the detection limit (COMMPS, 1999). Such information, however, may be useful for risk characterisation purposes;
- With respect to the measurements below the detection limit (DL), it was decided to set those entries <DL to DL/2. These ‘generic’ values are then used for the construction of a distribution function for that specific data set;
- Outliers were identified according to the statistical approach proposed in the TGD (EC, 2003), i.e. $\text{Log10}(Xi) > \text{log10}(p.75) + K(\text{log10}(p.75) - \text{log10}(p.25))$ with Xi being the concentration above which a measured concentration may be considered an outlier, p_i the value of the i^{th} percentile of the distribution and K a scaling factor. A scaling factor K=1.5 is applied, as this value is used in most statistical packages.

It should be stressed that values under the detection limit (set al DL/2) are included for the derivation of ambient PEC distribution, as exclusion of these data points would result in a left-censored data set and an overestimation of the RWC-ambient PEC.

Using the statistical computer package @Risk (Palisade Decision Tools) - a computational tool that allows the selection of the best parametric distribution that fits the input data - the distribution that most likely produced the monitoring data for a specific location, river or region was identified. The goodness-of-fit tests that were used for screening the selected distribution are Chi-Square, Kolgomorov-Smirnov and Anderson-Darling. The latter test is mainly focussing on the goodness-of-fit in the tails of the distribution, and is therefore the most appropriate test when 90th percentiles are considered (ambient PEC). Most frequently used functions for the derivation of 90P-values (after log-transformation of the monitoring data) were the Normal, Logistic and Weibull functions. Non-parametric distributions were used when no parametric distribution could be fitted significantly ($p<0.05$) to the data points. The latter was often the case when many vales below the detection limit were present in the data set.

Country-specific “reasonable-worst-case” (RWC) ambient PEC concentrations were subsequently derived as follows:

RWC-ambient $PEC_{country}$ = median value of all 90th percentiles that have been derived for the different sites within that country.

When an analysis of the monitoring data according to the recommended procedure in the TGD (EC, 2003) could not be performed, a river- or region-specific approach was applied: data for one river, river system or region within a country are grouped and a 90th percentile is calculated (cf. the former recommended methodology).

An overview of the main findings that are reported in Heijerick and Van Sprang (2004**.** A detailed overview of the country-specific datasets and data analysis is outlined in their report. Since then, additional data has been collected. The values derived from theses additional databases are included in Table 10-32 in italics. The databases from which these new data were derived are described here.

Austria

A large amount of data were obtained from the following source: "Erhebung der Wassergüte in Österreich gemäß Hydrographiegesetz i.d.F. des BGBl. Nr. 252/90 (gültig bis Dezember 2006) bzw. Gewässerzustandsüberwachung in Österreich gemäß Wasserrechtsgesetz, BGBl. I Nr. 123/06, i.d.g.F.; BMLFUW, Sektion VII/Abteilung 1; Nationale Wasserwirtschaft; Ämter der Landesregierungen". Monitoring data for more than 50 locations were available, covering the 1993-2007 period. In this evaluation, only the most recent data (i.e., from 2000 onwards) were taken into account, and such data were available for 48 locations. Most reported boron levels represented the total fraction. For the 48 individual locations a site-specific 90th percentile was derived using the Best Fit Software package. These 90P-values were situated between <5 µg/L and 576.5 µg/L. Five locations were identified as an outlier, based on an outlier cut-off value of 127 µg/L, and were not taken into account for the derivation of the country-specific RWC-ambient PEC of 16.4 µg/L. This value represents the median of the site-specific 90th percentiles. Less data were available for the dissolved fraction: information for only six locations was provided. Moreover, the 90th percentiles of these locations ranged from 35.5 µg/L to 216.3 µg/L, i.e. substantially higher than the RWC-ambient PEC that was determined for the total boron fraction. This finding suggests that the locations that were sampled for the determination of dissolved boron levels may not be relevant for Austrian surface waters in general, and may be affected by anthropogenic inputs or by high natural background levels that are not representative for the rest of Austria. Therefore the dissolved RWC ambient PEC of 71.6 µg/L should not be used for the evaluation of regional boron levels in Austria.

Finland:

A data set for the Barentz area was received from the Geological Survey of Finland and contained 337 measurements for boron representing 324 different locations (http://www.gtk.fi/Barents/). As such, no site-specific 90P-values of dissolved boron could be derived and an overall 90P value was considered as best alternative. It is assumed that reported values represent the dissolved fraction as water samples were filtered. Eleven values, ranging between (31.3 and 142.2 µg/L) exceeded the outlier cut-off level of 31.2 µg/L and were therefore discarded from the data set. With the remaining measurements a RWC-ambient PEC of 11.6 µg/L was derived for Finland. As no site- or river-specific approach could be performed, this RWC-ambient PEC represents the 90th percentile of all data.

The Netherlands:

The value that is given for the river Rhine in the Netherlands is an updated value based on newly released monitoring data for 2006, and is based on 53 measurements taken at three different locations (Lobith, Nieuwegein and Nieuwersluis). Values ranged from 34 to 140 µg/L, and site-specific 90th percentiles ranged from 74.3 to 93.9 µg/L. Using this information a RWC-ambient PEC of 83.2 µg/L was derived for the Rhine. An environmental distribution (Log-Weibull) was developed with the different country-specific RWC-ambient PECs and is shown in Figure 10.1. The median value of 111.1 µg B/L is considered as a typical regional ambient PEC for Boron in EU-surface waters.

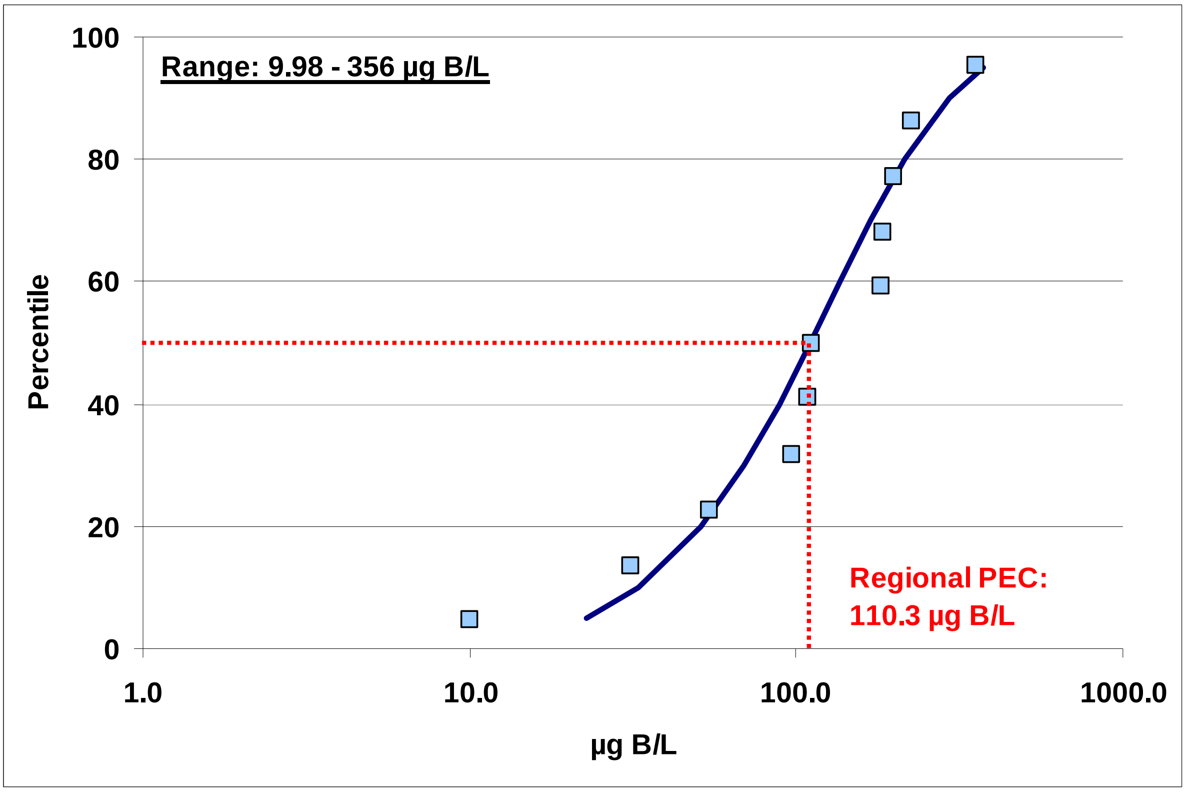

Fig. 10-1 **Environmental distribution of ambient boron levels in the EU**

Tabelle 10.32 Data-derived PECs for European Countries (based on data provided in Heijerick and van Sprang, 2004); country-specific RWC-ambient PECs are indicated in bold.

Country	**Ambient PEC (µg/L)**	**Approach(1)**
Austria	**31.2 µg/L** *16.4 µg B_{total}/L*(2)	Site-specific River-specific
Belgium		
Flanders	447 µg B_{total}/L	Site-specific
Rupel catchment	106 µg B/L	Site-specific
Brussels	347 µg B/L	Site-specific
Walloon Region	95.8 µg B/L	Site-specific
	Mean: 182.9 µg B/L (B_{total} not included)	
Finland	7.4 – 9.3 µg B/L *11.6 µg B_{diss}/L* (1) **Mean: 9.98 µg B/L**	Lake-specific Regional-specifc
France	167 µg B_{total}/L **97.6 µg B_{diss}/L**	Site-specific Site-specific
Germany	General: 125 – 384 µg/L Baden-Wurttemberg: 60 – 132 µg B/L Large rivers - 1997: 226 µg B/L Large rivers – 1998: 216 µg B/L Bavarian rivers: 58 – 270 µg B/L **Mean: 183.9 µg B/L**	Region-specific Region-specific River-specific River-specific River-specific
Greece	191 – 261 µg B/L **(Mean: 226 µg B/L)**	Region-specific
Ireland	47.3 – 62.1 µg B/L **(Mean: 54.7 µg B/L)**	Region-specific
Italy (River Po)	**108.1 µg B/L**	Site-specific
The Netherlands		
River Rhine	*83.2 µg B/L*(1)	Site-specific
River Meuse	140.1 µg B/L	Site-specific
	Mean: 111,7µg B/L	

Portugal	**356 µg B/L**	River-specific
United Kingdom		
England	301 (156 – 405) µg B/L	Site-specific
Wales	19.7 µg B/L	Site-specific
Scotland	125 µg B/L	Site-specific
UK – General	**200 µg B/L**	
Range of country-specific RWC-ambient PECs	**9.98– 356 µg B/L**	
Median (Log-Weibull Distribution)	**110.3 µg B/L**	

(1): site-specific: based on the 90P-values of all data for a specific site; river-specific: based on the 90P-values of all data for a specific river; lake-specific: based on the 90P-values of all data for a specific lake ; regional-specific: RWC-ambient PEC is the 90P-value of all data for a specific region

(1) new additional data, not reported in Heijerick & Van Sprang (2004)

The derived country-specific RWC-ambient PEC values range from 9.98 to 356 µg B/L. In some cases, the 90th percentiles are calculated from data for river systems within a country because full country-wide data were not available. The use of median is seen as more appropriate than the use of mean (average) values because the median value is less influenced when sites with elevated (possibly contaminated) boron concentrations are present in the data set (Heijerick and Van Sprang, 2004). According TGD (2003) the median of these values 110.3 µgB/L will be taken forward in this risk assessment as the EU-PEC-freshwater.

Heijerick and Van Sprang compared their results with those reported by Wyness et al. (2003) and noted that the Wyness results were generally a factor of 2 higher. They suggested several reasons for the systematic differences. The Wyness et al. (2003) analysis;

- included older data in all cases, with no preference for using most recent data set. As the use of borates in detergents has declined considerable over the last 10 years, the use of recent data is recommended.
- was based on 95th percentile values instead of 90th percentile values;
- source that provided monitoring data for a specific country was not always the same for Wyness et al (2003) and Heijerick and Van Sprang 2004)
- used the mean of site-specific 95th percentile values instead of the median values;
- did not perform an evaluation of outliers.

Table 10-33 presents additional surface water monitoring data gathered from a range of sources. However, the data collected by Heijerick and Van Sprang (2004) is the most recent and relevant data set and the probabilistic approach is the most useful in deriving PEC values for surface waters in Europe. The use of this value reflects recent total uses of borates.

Tabelle 10.33 Additional Reports of Boron Concentrations in Surface Waters

Country	**No. sites/ samples**	**Concentration range (µg/L)**	**Year**	**Reference**
Austria		< 20 – 600	1985-1989	Schöller and Bolzer 1989
France	>300	98% < 100	1986-89	DDASS de l'Oise, 1990
Germany	- 7 rivers,17 sites, 360 samples	13 – 372	1991-95	Metzner *et al* 1999
	- 300 samples	100 – 2,000	1974	Graffman et al, 1974 (1)
	- 15 samples	78 – 272	1982	Ruhrverband, 1982 (1)
	- 15 sites (Ruhr)	50P : 175 ; 90P : 317	1980	Mance et al, 1988
Italy	- 19 sites	< 2	1989	Benfenati *et al* 1992
	- 166 sites	< 10 – 500	1983-84	Tartari and Camusso, 1988
	- 5 sites	100 – 200	1997-98	Gandolfi *et al* . 2000
	- 6 samples	400 – 1,000	1975	Manfredu et al, 1975 (1)
	- 17 samples	100 – 330	1972	Brinkman & Dekker, 1972 (1)

Country	No. sites/ samples	Concentration range (µg/L)	Year	Reference
Luxembourg		110 – 390	1993	Unilever 1994
Netherlands		40 – 90	1981	Mance *et al* 1988
	- 22 analyses	90 – 45	1992	Unilever 1994
	- 3 samples	50 – 90	1981	Rijkswaterstaat, 1981 (1)
	- 3 sites	Mean : 66.7	1980	Mance et al, 1988
Spain	5 sites	200 – 3000	1986	Garcia *et al* 1987
Sweden		<5 – 69	1990	Sveriges Geologiska AB Analys, 1991
		<50	1991	KM Lab, 1991
	- 147 samples	1 – 1,046	1972	Ahl & Jonsson, 1972 (1)
	- 20 samples	060 – 650	1978	HMSO, 1980 (1)
	- 14 sites	50P: 23 ; 90P: 68	1980	Mance et al, 1988
England	15 sites	11 – 311 (mean values)	1993-96	Neal *et al,* 1998
Scotland	59 sites (236 samples)	<5 – 35		
England	- 4 sites, 24 samples/site	R.Roding: 448 (mean)	1995	Ashact Ltd, 1996
		R. Ouse: 322 (mean)	1995	
		R.Stour: 222 (mean)	1995	
		Reservoir: 200 (mean)	1995	
	- 63 samples	46 – 822	1980	WRC (unpublished) (1)
UK freshwaters	- 14 sites; Severn	50P: 303 ; 90P: 687	1980	Mance et al, 1988
	- 10 sites; Northumbrian	50P: 97 ; 90P: 198		
	- 10 sites; Thames	50P: 324 ; 90P: 582		
	- 6 sites; Anglian	50P: 290 ; 90P: 400		
	- 6 sites; Welsh	50P: 70 ; 90P: 193		
	- 6 sites; Southern	50P: 158 ; 90P: 241		
	- 11 sites; Forth	50P: 111 ; 90P: 228		
	-27 sites; S-West	50P: 58 : 90P: 136		
Switzerland	8 sites	<4 – 260	1990	EAWAG, 1990

(1): data reported in Butterwick et al, 1989.

Sediment compartment

No monitoring data have been found of boron levels in sediments in the EU.

Some information has been retrieved on boron levels in the sediment compartment in the US. Allen et al (2001) reported a scarce amount of boron levels in US-sediment samples taken in the Neosho River drainage in South-Eastern Kansas. Four locations were monitored, and boron levels were situated between 2 and 6.5 mg/kg dry wt. Compared to concentrations that were determined in sediment samples for other compounds like metals, these levels are relatively low, and possibly reflect the low affinity for boron towards this compartment, as was already suggested by the low distribution coefficient (K_D-values) of 2.78 L/kg that was determined for the sediment compartment. Hooftman et al (2000) indicates that an equilibirium between B concentrations in pore water and overlying water is eventually achieved. Therefore it can be assumed that B concentrations in the sediment are rather constant and no accumulation of B in sediment takes place. No other reliable and relevant data for the sediment compartment were identified in open literature. As no monitoring data have been found of boron levels in sediments in the EU, no EU PEC-sediment based on monitoring data can be proposed.

Soil compartment

Boron occurs naturally in the soil and levels will reflect rock and soil type, weathering and climate. Sedimentary rocks typically have a higher concentration of boron compared to igneous rocks with rock originating from marine sediments containing borate concentrations of 15-300 mg B/kg while the borate concentration in carbonate sediments is around 10 mg B/kg. (ECETOC 1997). Highly concentrated deposits of boron minerals are generally found in arid areas with a history of volcanism or hydrothermal activity (Woods, 1994). There are many reported ranges of boron concentrations the average content of borate in soils range between 10-20 mg B/kg (ECETOC 1997). Boron data for boron were also available for Finland from the Barentz area survey (Geological Survey of Finland, http://www.gtk.fi/Barents/): Boron was measured in the organic top layer (320 data points) and in the mineral layer (97 data points). The mean and median boron concentration in the organic layer are respectively 5.5 mg B/kg dw and 5.24 mg B/kg dw. Most values (98.8%) in the mineral layer were below the detection limit of 5 mg/kg. Therefore it was concluded that boron levels in the mineral layer of Finnish soil samples were below 5 mg/kg dry wt.

Eriksson (2001) determined boron levels in 25 topsoil samples, which were selected according to soil type. Boron levels ranged between 0.5 and 13 mg/kg dry wt, with a mean boron concentration of 5.1 ± 3.2 mg/kg dry wt. The 25th, 50th and 75th percentile were 3.2, 4.8 and 6.6 mg/kg dry wt, respectively. Subsoil boron levels were slightly higher: in these samples the 25th percentile, mean, median and 75th percentile were 4.6, 7.1± 3.6, 7.8 and 10 mg B/kg dry wt, respectively.

Tabelle 10.34 Soil boron levels (mg B/kg dry weight basis)

Region	Range	Mean	Reference
US	10- 300	30	Eisler, 2000
Worldwide	45-124	10-20	Eisler , 2000 ECETOC, 1997 (op cit)
Sweden (topsoil samples)	0.5 – 13	5.1 ± 3.2	Eriksson, 2001
Finland – Organic layer Mineral layer	1.6 – 14.2 <5 – 8.7.1	5,5 90P: <5 Median: 5	Barentz area data set
Conterminous US soils	--	26	Shacklette and Boerngen, 1984; Severson and Tidball, 1979 (in: Allen et al, 2001)
Western US soils	--	23	
Northern Great Plains soils	--	41	

Based on Table 10-34, only data are available for Finland and Sweden. According TGD (2003), the median of these country values, 5 mg B/kg dw will be taken forward in this risk assessment as the EU PEC-soil.

Whetstone et al., 1942, ECETOC (1997) and Weinthal, indicated the high variability in background concentrations in soils, significantly influenced by geological sources, with high background values in Southern Europe. It should be noted that further data across all EU countries are being collected in the framework of the GEMAS project. The EU PEC-soil should be updated using those data when available.

Sewage water

Most boron is not removed by conventional sewage treatment. A review of removal technologies suggested that conventional approaches were not effective at removing boron to sub-parts-per-million concentrations or would be associated with high costs (such as high amounts of sorptive materials, e.g., grams/liter) (Park and Edwards, 2005). While some technologies were seen as meriting further research, none was seen as ready for widespread application.

A limited study looking for evidence of boron removal was done at four water treatment facilities in the UK (Ashact Ltd, 1996). Boron levels were measured each hour for 24 hours at the inlet and outlet of the treatment units such that the same mass of waster was monitored at the inlet and outlet. Boron removal was less than 3% at 3 facilities. This removal is considered not significant since the precision of the ICP analyser is +/-5% At one facility there was significant boron removal (+/-20%). A mechanism for the removal was not identified.

Vengosh et al (1994) determined boron levels in both raw and biologically treated sewage, collected at 3 instances in 1993 from the Dan Region Sewage Reclamation Project (south of Tel Aviv). Boron levels in raw sewage (n=3) varied from 0,49 to 0,60 mg/L and in treated sewage (n=3) from 0,46 mg/L to 1,06mg/L.The boron contents of raw and treated sewage were found to be similar, indicating that the biological treatment has a negligible effect on boron balance. Dietz et al 1975 reported boron concentrations in STP effluents from different STP's in Germany. Concentrations measured range between 1.5-4.5 mg B/L. These data are much higher than the values reported by other authors. The difference can be explained by the period during which these data were collected, this is the seventies. The most important source of boron in waste water is use of borates in detergent. This use has however declined significantly over the last years. Fox et al (2002) and Hes (2003) demonstrated a reduction of 50% in Germany during the nineties. As more recent data are available on boron concentrations in sewage water for Germany, the data by Dietz et al (1975) will not be further used.

Monitoring studies under the GREATER project (Fox et al., 2000; Holt et al 2003; Gandolfi et al., 2000) show 90th Percentile-STP effluent concentrations in the range 0.67 to 1.14 mg B/L. Older reviews (Butterwick et al., 1989) suggested typical effluent values of 2 mg-B/L with levels up to 3 to 5 mg-B/L in European sewage.

Tabelle 10.35 Examples of boron concentrations in sewage waters; country-specific RWC-PECs are indicated in bold.

Country	No. sites /samples	Conc range (µg/L)	Mean (µg/L)	Year	Reference
Austria	4	< 20 – 800	-		Schöller and Bolzer, 1989; Schöller, 1990
	4		780		Zessner et al (2003)
			850 (filtered)		UBA (2000)
			RWC: 836		
Germany	1 STP	500		1993	Metzner *et al*, 1999
	1 STP/15	335		1993	Fox et al, 2002
	1 STP	900		1996-1999	
	1 STP	240-640			Beier, 2008
			RWC: 780		
Italy	7 STPs		1,000		Mezzanotte *et al*, 1995
	1 STP	230 – 660	420		Gandolfi *et al*, 2000
	1 STP	670 – 1,260	1,000		Gandolfi *et al*, 2000
	1 STP	730 – 2,860	1,900		Gandolfi *et al*, 2000
			RWC: 1630		
Netherlands	1 STP	390 – 750		1994	Feijtel *et al*, 1997
	7 STP/21	450-970	720	1994	Matthijs et al, 1999
			RWC: 696		
Spain	2 STPs		1,450 – 3,000		Navarro *et al*, 1992
			RWC: 2845		
Sweden	1 STP		400		Ahl and Jönssen 1972
UK-Aire	8 STPs/228	427 – 837	90P: 673	1996-1998	Holt *et al* 2003
UK-Calder	15 STPs/310	161 – 1,116	90P : 768		
UK-Went	7 STPs/140	720 – 1,157	90P : 1,144		
UK-Rother/Don	6 STPs/153	704 – 1,057	90P : 1,115		
UK	3 STP/72	212, 322, 448	Mean : 262	1995	Ashact, 1996

			RWC : 861		
Range **Median**			**696-2845** **849**		

The derived country-specific RWC- PEC values (the 90-percentile for each country) range from 696 to 2845 µg B/L. According TGD (2003), the median of these values, 849 µg B/L will be taken forward in this risk assessment as the EU PEC-STP.

There are some restrictions in using these data as an estimate for the emission of B through discharge of domestic wastewater:

- from the information on the uses of boric acid and sodium tetraborates, it can be seen that the use in detergents has declined significantly. It can therefore be expected that current exposure values in water are lower. However, no recent monitoring data are available to substantiate this;
- it is unknown whether the data only reflect concentrations from STP exclusively treating household wastewaters.

As more recent data is not available at this moment, a boron concentration of 849 µg B/L –based on the data - will be further used for this assessment as the EU PEC-STP. To improve the accuracy of the above estimation and to ensure they reflect current uses and emissions, it is recommended to collect more recent data on boron concentrations in sewage water.

Sewage sludge

There has always been an assumption that boron is not significantly removed during the sewage treatment process. Nevertheless, some boron is associated with sewage sludge although data is scarce. Results of boron concentrations in sewage sludge from a study of 48 sewage treatment plants in Sweden (Eriksson, 2001) are detailed in Table 10-36. All sewage works in Stockholm, Gothenburg and Malmö, the three largest cities in Sweden, were included. As the final stage in the selection process, sewage works from three different size categories were selected to be, as far as possible, representative of the division of these size categories of all Sweden's sewage treatment works.

Tabelle 10.36 Concentration of boron (mg B/kg dw) in sewage sludge (data from Eriksson, 2001)

Number of samples	Mean	SD	Min	Percentile					Max
				10%	25%	Median	75%	90%	
48	61	81	2	8	18	32	58	150	392

UBA (2000) reported boron concentrations in sludge in Vienna between 40,9 and 63 mg B/kg dw. Fujita et al. (2005) investigated boron adsorption onto activated sludge using bench-scale reactors under simulated wastewater treatment conditions. Two experiments, continuous flow and batch, were performed. The results of the continuous-flow experiment indicated that a small amount of boron accumulated on the activated sludge and its concentration in the sludge depended on the nature of the biota in the sludge. They reported boron adsorption reaching sludge concentrations of 40 to 600 mg-B/kg-sludge (dry weight) when influent concentrations ranged from 0.3 to 30 mg-B/L. The Freundlich constants k and 1/n for activated sludge were determined to be 26 mg/kg and 0.87. They found that activated sludge has a limited capacity for boron adsorption. They suggested that at typical wastewater concentrations in Japan of less than 0.1 mg-B/L, sludge concentrations would likely range from 20 to 60 mg-B/kg. This is in reasonable agreement with the results reported by Eriksson (2001). As only data were available for Sweden, the 90-percentile value from the Swedish data, 150 mg B/kg dw sewage sludge will be used as the EU-PEC-sewage sludge.

Groundwater

The same source (i.e., Erhebung der Wassergüte in Österreich gemäß Hydrographiegesetz i.d.F. des BGBl. Nr. 252/90 (gültig bis Dezember 2006) bzw. Gewässerzustandsüberwachung in Österreich gemäß Wasserrechtsgesetz, BGBl. I Nr. 123/06, i.d.g.F.; BMLFUW, Sektion VII/Abteilung 1; Nationale Wasserwirtschaft; Ämter der Landesregierungen) that provided total boron concentrations in Austrian surface waters also supplied numerous data of total boron for the 1991-2007 period. Due to the large amount of measurements (> 100,000 values), it was decided to perform the analysis with the most recent collected data (2007-data). The total amount of data points for 2007 was 7,635, representing 2,022 different locations. Due to the low number of data points for each specific location (i.e., in most cases ranging between 1 and 4), derivation of the site-specific 90P values according the approach described above was not feasible. Alternatively, a 90P-value was calculated for each of the 4 data sets that contained B-levels and the mean of those 4 90P-values was considered as a relevant typical value for total boron levels in Austrian groundwater. A summary of the different values is provided in Table 10-37. No further information on the content and origin of the database in available. Based on the information in these datasets a typical ambient PEC for total boron levels in Austrian groundwater is 85.6 µg/L. Zessner et al (2003) reported an average boron concentration in groundwater of 60-70 µg B/L at 2 locations in Austria.

Tabelle 10.37 Total boron levels in Austrian groundwater samples (Detection limit: 20 µg/L) (Nationale Wasserwirtschaft)

Database	No. of data points 2007	No. of sampling sites	RWC-ambient PEC (µg/L)
TG-dataset	52	26	159.6
PG1-dataset	2,106	544	91.5
PG2-dataset	4,170	1,109	79.1
KK-dataset	1,307	343	12 (DL: 20)
Total dataset	***7,635***	***2,022***	***Mean: 85.6***

The BOREMED project (Weinthal, year not specified)) has produced a first transnational overview of boron concentrations in the ground waters of the Mediterranean region. Data were collected in for EU-countries, i.e., France, Italy, Greece and Cyprus. Main findings are discussed below, but as the report did not provide the raw monitoring data, no region- or country-specific ambient groundwater levels could be calculated.

France:

Sources of the data are described in the BOREMED-report. The data set contained 11,499 data points representing 1,589 locations. The majority of the boron values were below the former and present WHO recommended limit value of 0.3 mg/L and 0.5 mg/L, respectively. Clearly identifiable boron anomalies were found in urban areas in northern France. Maximum levels up to 1.3 mg/L were observed in the Lille area, and are related to both the geochemical background and human influence.

Italy:

Sources of the data are described in the BOREMED-report. The data set contained 3,158 data points representing 2,632 locations. The distribution of boron shows a strong contrast between low boron levels in northern Italy, whereas levels up to more than 10 mg/L are recorded on the eastern side of the Italian peninsula. High boron contents are also reported in middle-western Sicily, but exact values are not provided in the BOREMED report.

Greece:

The data set for Greece contained 622 data points representing 484 locations. The BOREMED report stated that very high levels of boron in groundwater were mainly observed in the volcanic arch of South Aegean and in the peninsula of Chalkidiki, but no levels were specified.

Cyprus:

A total number of 1,016 measurements, representing 734 locations, were available for Cyprus. High concentrations, related to the presence of igneous rocks containing glassy lavas and the presence of sedimentary rocks (chalks, chalky marls and gypsum), range between 1-9 ppm and 2-8 ppm, respectively.

It is clear from the above data that ambient concentrations of boron in groundwater are highly variable and significantly influenced by geological sources. As only raw data were available for Austria, the RWC value for Austria, 85,6 µg B/L groundwater will be used as the EU-PEC-groundwater.

Background concentrations of boron in Europe

INTRODUCTION

In order to interpret ambient boron concentrations that are measured in the environment, boron being a natural element, it is important to evaluate the data in view of background reference concentrations. Background concentrations are required in EUSES-modelling of regional exposure levels, as the final modelled concentration - which is compared with measured data – is the sum of the anthropogenic input (calculated with EUSES) and a typical background level for a specific region. “True” natural background concentrations can hardly be found in the European environment as a result of historical and current anthropogenic input from diffuse sources (Salminen, 2005). For the aquatic compartment this issue was discussed for the EU Water Framework Directive and the following definition was agreed by a Group of experts in 2004: “The background concentration of target metals in the aquatic ecosystems of a river basin, river sub-basin or river basin management area is that concentration in the present or past corresponding to very low anthropogenic pressure” (De Vos and Tarvainen, 2006). The methodologies proposed for setting the background concentrations were: (1) trace metal concentrations in groundwater (shallow and/or deep); (2) analysed values for trace metal concentrations in pristine areas (with assurance that river basin is pristine or nearly so) (3) expert judgment (incl. international agreements; river basin commissions). A draft working document discussed further the approach and stated that the first step in this process is to elucidate default background concentrations applicable to a large part of Europe. It was agreed that the most important database is the FOREGS Geochemical Baseline Programme (FGBP) published in March 2004 (http://www.gsf.fi/foregs/geochem/). FOREGS (Forum of European Geological Surveys) Geochemical Baseline Programme sought to provide high quality environmental geochemical baseline data for Europe based on samples of stream water, stream sediment, floodplain sediment, soil, and humus collected all over Europe.

In order to interpret the FOREGS data in an adequate way, three definitions are given here explaining the difference between natural background, baseline and ambient concentrations, and which were also used in the accepted compulsory and voluntary metal EU-risk assessments. These definitions are based on information that is provided in Tarvainen and De Vos (2005, In: Salminen et al, 2005), and in the TGD (ECB, 2003):

- natural background concentration: the natural concentration of an element in the environment that reflects the situation before any human activity disturbed the natural equilibrium (e.g., the situation a few thousands year ago). As a result of historical and current anthropogenic input from diffuse sources the direct measurement of natural background concentrations is not feasible in the European environment.

- baseline background concentration: the concentration of an element in the present or past corresponding to very low anthropogenic pressure (i.e., close to the natural background). The data that are provided in the FOREGS dataset are considered to represent such baseline levels.
- ambient concentration: the sum of the natural background of an element with diffuse anthropogenic input in the past or present (i.e., influence of point sources not included). Reasonable worst case (RWC) ambient concentration levels are used for the regional risk

The overall objective of this section is to give an overview of baseline boron concentrations in the aquatic environment. Raw monitoring data from the FOREGS-website were downloaded and country-specific baseline levels (50th and 90th percentiles) were derived for the water compartment. FOREGS did not provide any data on baseline boron levels in the sediment or terrestrial compartment.

FOREGS-DATABASE

The FOREGS Geochemical Baseline Mapping Programme's main aim was to provide high quality, multi-purpose environmental geochemical baseline data for Europe. Subsequent compilation of inventories of existing regional geochemical databases in Europe revealed the existence of some 120 separate geochemical databases based on up to seven different sample media. Although a wide range of element concentrations were determined by 13 different analytical methods, many environmentally essential elements were, however, not measured. (Plant and Ridgeway, 1990; Plant et al. 1996, 1997). Because it was impossible to compile a homogeneous data set for the whole of Europe from these data, it was clear that the establishment of a harmonised European wide geochemical database was essential. This database could then be used for levelling older national geochemical databases in order to produce more detailed European wide maps to satisfy the needs of present day national and European Union legislation.

A detailed description of sampling methodology, sampling preparation and analysis is given by Salminen et al. (2005). High quality and consistency of the obtained data were ensured by using standardised sampling methods and by treating and analysing all samples in the same laboratories. Sampling was carried out in each country by national teams. Normally, one team sampled all sites in each country during one field season between 1997 and 2001. However, in some cases the work was divided in two field seasons. Therefore, it can be stated that the FOREGS geochemical baselines mapping programme represents the end twentieth century state of the surficial environment in Europe.

Five random points were selected in each Global Terrestrial Network cell (160*160 km2), one point in each quadrant and one point random in the cell. The points were used to select the five nearest small drainage basins of <100 km2. The sampling sites selected for stream water analyses of dissolved elements were typical of locally unimpacted or slightly impacted areas. As a consequence, the element concentrations that are determined in these samples can be considered as relevant baseline concentrations. These concentrations are fundamentally different from the values that were used for the derivation of a regional RWC-ambient PEC: the sampling locations that were used for the regional RWC-ambient PEC did not represent pristine areas, but only excluded locations that were directly impacted by local point sources, as recommended by the TGD (2003).

The following criteria and recommendations were formulated for the selection of sampling sites and sample collection:

- running stream water was collected form small, second order drainage basins (<100 km^2);
- whenever possible, sampling was performed during winter and early spring months, and was avoided during rainy periods and flood events;
- a full description of sampling materials and sampling volumes is provided, and all materials were rinsed twice with unfiltered or filtered stream water (depending on the type of water sample);
- all potential contaminating factors were reduced during the sampling period (wearing of gloves, no smoking in the area allowed, no hand jewelry was allowed , running vehicles during sampling was prohibited, etc..)

DATA TREATMENT

The procedures used for the evaluation of B-baseline levels in the environment are based on the methods and concepts laid down in the TGD (EC, 1996; 2003) for environmental risk assessment in the European Union and on the Combined Monitoring-based and Modeling-based Priority Setting procedure (COMMPS, 1999). Using the statistical computer package @Risk (Palisade Decision Tools) - a computational tool that allows selection of the best parametric distribution that fits the input data - the distribution that most likely produced the baseline environmental monitoring data is identified. The goodness-of-fit tests that are used for screening the selected distribution are Chi-Square, Kolgomorov-Smirnov and Anderson-Darling. The former test is mainly focussing on the goodness-of-fit in the centre of the distribution, and is therefore the most appropriate test when 50th percentiles are considered (typical baseline levels). Non-parametric distributions were used when no parametric distribution could be fitted significantly ($p<0.05$) to the data points. In this study, baseline B-levels for each country were grouped separately, and country-specific distributions were developed. From these distributions typical, country-specific baseline levels were derived.

The programme resulted in 807 stream water samples spread over Europe. The data that were acquired from the FOREGS monitoring program for boron are shown in Figure 10-2, which presents the currently most extensive, robust and spatially-relevant data set of dissolved baseline boron concentrations on the European scale. This map shows the great spatial importance of the boron baseline levels, likely related to local geochemical characteristics.

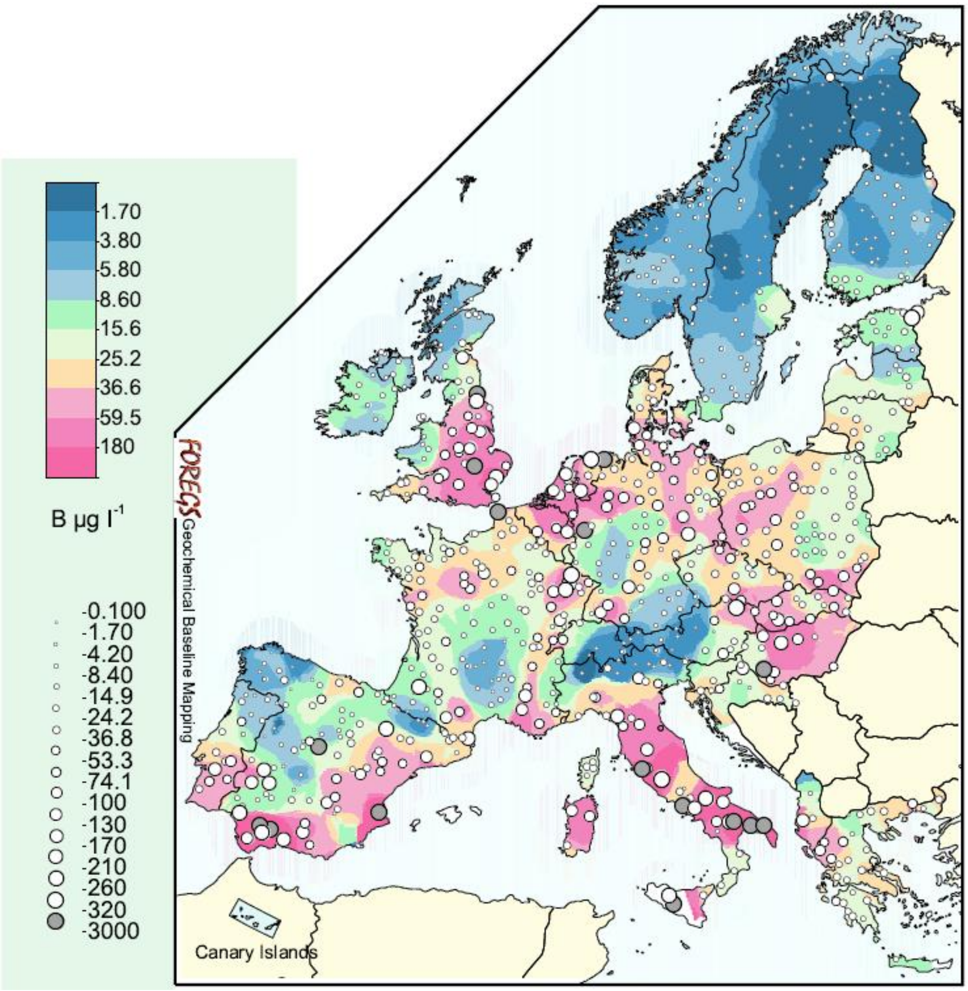

Fig. 10-2 Baseline B-levels (dissolved) in European surface waters (figure taken from FOREGS Geochemical Baseline Programme)

The total number of analysed (ICP-MS, detection limit 0.01 µg/L) water samples was 807. A large spatial variation in baseline boron levels can be noted. Dissolved boron levels ranged between 0.1 and 3030 µg B/L with 50th/90th percentiles of 15.6 and 94.5 µg B/L. The maximum value was determined in Italy. The lowest baseline concentrations are found in the Nordic countries (< 10 µg/L). Regions where relatively high baseline levels of boron are detected (± > 30 µg/L), are Italy, South-East England, the lowlands (Belgium/The Netherlands), northern parts of France and Germany, Southern Spain and parts of Eastern Europe. Taking into account the high quality of the data set, the median value (i.e., the 50th percentile value) of 15,6 µg B /L that was presented by Salminen et al (2005) can be accepted as a typical background concentration for B in European surface waters (Europe-regional scale).

Table 10-38 presents the country-specific 50th and 90th percentiles of dissolved baseline B-levels in surface waters. The table also reports the fitted distribution, the number of data points, and the minimum and maximum measured baseline level in each country. A negative value was recorded for one data point (United Kingdom). As it is not clear from the original data sheet whether the B-level at this location was not measured or simply was below detection limit, this entry was discarded from the data set and was not used for the derivation of country-specific baseline levels.

Tabelle 10.38 General description of country-specific B-surface water concentrations (µg/L) in Europe (data from FOREGS Geochemical Baseline Programme)

Country	No. of data µg/L	Minimum	Maximum	50th percentile	90th percentile	Log-Distribution
All data	807	0.1	3030	15.6	94.5	---
Albania	3	5	140	56 (1)	---	---
Austria	20	2	275	7	103	Erlang
Belgium	5	19	142	58	129	Weibull
Switzerland	10	2	120	19	138	Normal
Czech R.	10	8	54	23	49	Normal
Germany	74	2	485	21	105	Weibull
Denmark	5	10	34	19	38	Normal
Estonia	11	5	275	15	94	Pearson V
Spain	87	0.1	806	18	146	Logistic
Finland	65	1	54	4	16	Weibull
France	119	2	448	21	69	Logistic
Greece	27	2	99	23	60	Logistic
Croatia	10	3	77	19	57	Logistic
Hungary	10	10	327	54	262	Normal
Ireland	11	5	15	9	14	Normal
Italy	48	1	3030	41	516	Normal
Lithuania	14	8	41	22	35	Weibull
Latvia	7	7	34	15	32	Uniform
The Netherlands	9	29	278	78	232	Normal
Norway	58	1	16	5	9	Logistic
Poland	56	10	92	26	60	Gamma
Portugal	19	2	133	16	79	Normal
Sweden	51	0.3	22	3	10	Erlang
Slovakia	15	11	136	40	94	Weibull
Slovenia	4	12	43	27 (1)	---	---
United Kingdom	59	3	445	17	131	Erlang
EU27 + Norway	794 (3)	0.1	3030	Median: 19.7	Median: 69.5	Weibull

(1): average value ; (2): insufficient data for a reliable/relevant fitting ; (3): Albania, Switzerland not included

Typical baseline levels are situated between ± 3-10 µg B/L (Scandinavian countries) and higher than 50 µg B/L (Lowlands, Hungary). For some countries the 90th percentile was an extrapolated value, i.e., higher than the highest measured data (e.g., Switzerland, Denmark). Such findings are typical for small data sets where the number of data points is 10 or less. The median of all typical country-specific baseline levels is 19.7 µg B/L (EU-27+Norway), a value that is slightly higher than the reported median of all raw data for Europe (Albania, Switzerland included), i.e., 15.6 µg B/L.

10.8.7 Comparison of modelled and measured data

Table 10-39 summarises the typical regional boron concentrations in air, soils, water and sediment and shows natural/pristine ambient backgrounds, continental and regional PECs for the default scenarios (life cycle approach & life cycle approach + waste; current incineration and landfilling scenario) (EU-27) in these various compartments.

Tabelle 10.39 Comparison of measured versus modelled environmental concentrations

	Natural/ pristine ambient back-ground FOREGS	**Modelled (EUSES 2.0) EU-27 Life cycle stages**		**Modelled (EUSES 2.0) EU-27 Life cycle stages + waste assessment**		**Measured Monitoring report**
	EU	**Continental scale**	**Regional scale**	**Continental scale**	**Regional scale**	**EU-15**
Air PEC$_{add}$(mg/m^3)	NA	4.97E-12	9.57E-11	4.99E-12	9.41E-11	NA
agricultural soil PEC$_{addl}$ (mg/kg dw)	NA	0.007	0.07	0.007	0.07	5 (0.5-13)
Porewater agr. Soil (µg/l)	NA	4.2	41.9	4.2	41.9	85.6
natural soil PEC$_{add}$ (mg/kg dw)	NA	0.0002	0.005	0.0002	0.005	NA
Industrial soil PEC$_{add}$ (mg/kg dw)	NA	0.003	0.03	0.003	0.03	NA
freshwater PEC$_{total}$ $_{l}$(dissolved; µg/l)	15.6	55	192	56.9	197.6	110.3 (10-356)
Sea water; PEC$_{add}$ (dissolved; µg/l)	NA	0.64	17.6	0.67	18.2	NA
sediment PEC$_{add}$ (mg/kg dw)	NA	0.5	1.5	0.5	1.58	NA (US<6.5 mg/kg dw)
Marine sediment PEC$_{add}$ (mg/kg dw)	NA	0.01	0.15	0.006	0.16	NA

NA: not available *: natural background concentrations: median of monitoring data for surface water (FOREGS programme)

10.8.7.1 Soil

Comparison of modelled and measured values for **agricultural soil** clearly shows that the modelled regional PEC$_{add}$ of 0.08 mg B/kg dw -calculated at steady state- is 60-fold below the reported levels of the measured (total) soil concentrations in agricultural soil of 5 mg B/kg dw. Note that information on pristine background concentrations is not available for the soil compartment, hence a PEC$_{total}$ level could not be derived.

Predicted **added pore water concentrations** under agricultural soils are 42 µg B/l, this is 50% of the reported value for groundwaters i.e. 86 µg B/l based on monitoring data.

The modelled regional PEC_{added} of 0.006 mg B/kg dw for **natural soil** is 3 orders of magnitude below the reported measurements for ambient background levels in soils of 5 mg B/kg dw. Monitoring data on natural background concentrations of boron in natural soils are not available.

10.8.7.2 Aquatic compartment (water and sediment)

The typical calculated PEC_{total} **freshwater** in the TGD-region of 192-198 µg B/l is almost twofold the median of 90percentile boron concentrations in the aquatic compartment for different EU-countries (i.e. 110,3 µg B/l). Real emission data needs to be collected to replace the TGD default values and to improve the estimation of the PEC_{total} **freshwater**. It should be noted that in order to derive the PEC total an ambient pristine background for water of 15.6 µg B/l is added to the modelled PEC (FOREGS database).

No European monitoring data are available for the **sediment compartment**. The only reported levels are for the US, where typical boron levels below 6.5 mg/kg dw are reported. The typical regional modelled PEC_{add} for the TGD region is 1.5-1.6 mg/kg dw. As this value is derived from the PECadded freshwater, it is expected that also this value is an overestimation of the addition from borates production formulation, use and end of life. Note that no monitoring data are available on boron concentrations in pristine sediments, hence a PEC_{total} level could not be estimated.

Care should be taken when comparing modelled and measured data. As already stated; the regional modelling exercise focuses merely on production, formulation industrial and private uses of boric acid and borax substances. Service life is not included in the assessment. Model parameters are set to “typical” values for European conditions. The model calculates steady state concentrations –after thousands of years- using constant emission levels for one selected year; while measured data are a result of variable use and release patterns in time.

Not all portions of the biogeochemical cycle of boron are represented in the standard model – for example combustion of coal and wood and forest fires are estimated to involve about 0.26 to 0.43 Tg B/y, about the same magnitude as global borate mining production (0.31 Tg B/yr, Park & Schleisinger, 2002). The model was set to exclude sludge application and volatilization. Data on existing soil and sediment concentrations are not available, so models of added boron have little context for comparison with backgrounds.

Both the measured and modelled PECregional for the aquatic compartment will be taken forward to the regional risk characterisation section. For soil and sediment, only modelled data are available and can be taken forward. Further work is needed to improve the monitoring and modelling assessments before any final conclusions can be drawn.

10.8.8 Emission inventory

10.8.8.1 Derivation of anthropogenic B input data: regional/continental point and diffuse emissions

So the aim of this chapter is to quantify the releases to the environment during the life cycle stages of boric acid and sodium tetraborates, taking into account the different types of uses during these life cycles stages, the different emission pathways and receiving environmental compartments and the spatial scale of the emissions. As boron is a natural element, besides these intentional sources there are also unintentional emission sources of boron. Where relevant these are also considered.

Emissions need to be considered for all life-cycle stages:

- Point source emissions
- Diffuse emissions

Point sources are regarded as sources which are easy to locate and can be tracked back to a single source or origin, e.g. stack emissions. Looking at the life-cycle stages, they include industrial emissions from manufacture, formulation or industrial/professional use in an industrial environment. Diffuse or non-point sources are regarded as sources that are not easy to locate and for which emission can only be estimated on an area-basis, e.g. emissions from traffic. In the framework of this inventory "diffuse" sources will include the emissions from private use, service life and waste disposal.

Diffuse emissions will be divided in:

- Emissions from private use;
- Emissions during service life: this relates to type of use and type of article. It refers to the degree of release (low, high, intended) related to the type of article and use during service life:
  - Intended release (technical performance of product is geared to release of substances)
  - Unintended release (technical quality of product includes limitation or prevention of substance or material losses)
  - Unintentional releases not related to the production and use of boric acid and sodium tetraborates.

10.8.8.2 Available emission data in the EU27 Member States

All European Union member countries (EU-27[12]) were in order to gather the most recent available boric acid and sodium tetraborates emission data and their quantification methods. The availability of data through official international registers like EPER (European Pollutant Emission Register)[13], WebDab - EMEP[14] activity data and emission database was also checked. The emissions from point and diffuse sources are assigned to the different environmental compartments (air, surface water and soil). Neither the EPER norWebDab contain any Boron emission data.

The following information was gathered:

<u>Belgium (Flanders)</u>

Due to the fact that in Belgium, the regions are responsible for environmental issues, the emission inventory systems are different for the three regions (Flanders, Walloon, Brussels).

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[12] EU-27=Austria, Belgium, Germany, Denmark, Ireland, Greece, Spain, France, Italy, Luxembourg, the Netherlands, Portugal, Finland, Sweden, UK, Bulgaria, Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Romania, Slovania, Slovakia

[13] EPER is the first European-wide register of industrial emissions into air and water

[14] EMEP: Co-operative programme for monitoring and evaluation of long range transmission of air pollutants in Europe (CLRTAP)

Answers were only received from Flanders. Through the reporting of emissions by big companies in their annual environmental report, some data on emissions to surface water are available. These are only emissions from point sources. Emissions from diffuse sources are not estimated, neither are emissions to air available (point nor diffuse air emission sources). The emissions to surface water from some industrial sources are given in Table 10-34. This gives an overview of the emissions to surface water for 2004, 2005 and 2006. These are the reported emissions from individual companies through their environmental report (called "IMJV"). B-emissions only have to be reported if total annual emissions exceed 1000 kg. So, companies emitting less than 1000 kg B/annum are not included. Data are provided by the individual companies and can be the result of measurements in the effluent or estimations based on emission factors, activities (e.g. amount of production) and other assumptions. It is not known which values are based on actual measurements or on estimates. The table gives a distinction between "direct" emissions, directly discharged to the surface water and "indirect" emissions, which are emitted to a sewage system and in most cases treated in a community STP before entering the surface water. Direct emissions are thus emitted to surface water in the vicinity of the plant (sometimes after treatment on-site). Indirect emissions are emitted to a sewage system and thus the data shown for 'indirect emissions' are not simply the amounts entering the surface water.

Tabelle 10.40 Overview of the emissions to surface water in Flanders by industry (VMM, 2008)

NaceCode	Sector	Emissions (in kg B/annum)					
		water direct			water indirect (1)		
		2004	2005	2006	2004	2005	2006
15.42	**Manufacture of refined oils and fats**	**938**					
17	**Manufacture of textiles**	**2,065**	**1,948**	**2,360**	**2,396**	**1,652**	**0**
17.00	Manufacture of textiles					335	
17.10	Preparation and spinning of textile fibres	223	136				
17.11	Preparation and spinning of cotton-type fibres	1,740	1,250	2,360	344		
17.30	Finishing of textiles	102			855	754	
17.51	Manufacture of carpets and rugs		562		1,197	563	
23.20	**Manufacture of refined petroleum products**	809	1,016				
24	**Manufacture of chemicals and chemical products**	**270,001**	**274,217**	**221,810**	**1,445**	**742**	**174,930**
24.10	Manufacture of basic chemicals	830	1,070	1,100			
24.13	Manufacture of other inorganic basic chemicals	330	459	6,750			
24.14	Manufacture of other organic basic chemicals	268,043	271,560	213,960			173,000
24.16	Manufacture of plastics in primary forms	362	244		89	77	
24.41	Manufacture of basic pharmaceutical products					163	
24.42	Manufacture of pharmaceutical preparations	77					
24.51	Manufacture of soap and detergents, cleaning and polishing preparations				55		
24.64	Manufacture of photographic chemical material				510	436	
24.66	Manufacture of other chemical products	359	884		791	66	1,930
27	**Manufacture of basic metals**	**19,321**	**15,829**	**18,530**	**1,120**	**4,620**	**2,280**
27.10	Manufacture of basic iron and steel and ferro-alloys	1,551	378				
27.33	Cold forming or folding	98	53				
27.34	Wire drawing	9,253	9,283	11,030	1,120	1,210	
27.40	Manufacture of basic precious and non-ferro metals	2,050	2,040	2,680			
27.42	Aluminium production	1,220	620			3,410	2,280
27.44	Copper production	123	154				
27.45	Other non-ferrous metal production	5,026	3,301	4,820			
28	**Manufacture of fabricated metal products, except machinery and equ**	**29**	**424**	**0**	**998**	**492**	**0**
28.22	Manufacture of central heating radiators and boilers		258				
28.51	Treatment and coating of metals		166		998	492	
28.52	General mechanical engineering	29					
29	**Manufacture of machinery and equipment**	**1,210**	**1,040**	**0**	**265**	**304**	**0**
29.31	Manufacture of agricultural tractors	1,210	1,040				
29.32	Manufacture of otehr agricultural and forestry machinery				265	304	
31.50	**Manufacture of lighting equipment and electric lamps**	**344**	**375**				
34.10	**Manufacture of motor vehicles**	**7,460**	**6,590**	**6,390**			
35.30	**Manufacture of aircraft and spacecraft**				**160**		
37.20	**Recycling of non-metal waste and scrap**				**293**	**333**	
40.10	**Production and distribution of electricity**	**7,236**	**14,002**	**11,180**			
40.30	Steam and hot water supply		39				
74.70	**Industrial cleaning**	**785**	**588**				
90.00	**Sewage and refuse disposal, sanitation and similar activities**	**7,551**	**6,660**	**7,650**	**76**		
TOTAL EMISSIONS		**317,749**	**322,727**	**267,920**	**6,754**	**8,144**	**177,210**

(1) discharged to a sewage system and in most cases treated in a community Sewage Treatment Plant

According to Table 10-40 the sector, responsible for the biggest share in total emissions is “Manufacture of other organic basic chemicals”.

United Kingdom

The Pollution Inventory (PI) is an annual record of pollution to the air in England and Wales from selected activities they regulate. The PI now includes seven years of data from major industrial sites. Results from the UK Pollution Inventory Data Trends Spreadsheet (UK Environment Agency, 2008) are shown in the table below. For B, the emission data are limited to the air compartment.

Tabelle 10.41 Total releases to air (in kg B) from industrial sites in England and Wales regulated by the Environment Agency (IPC, PPC, WML, RAS and WIA) (UK Environment Agency, October 2008)

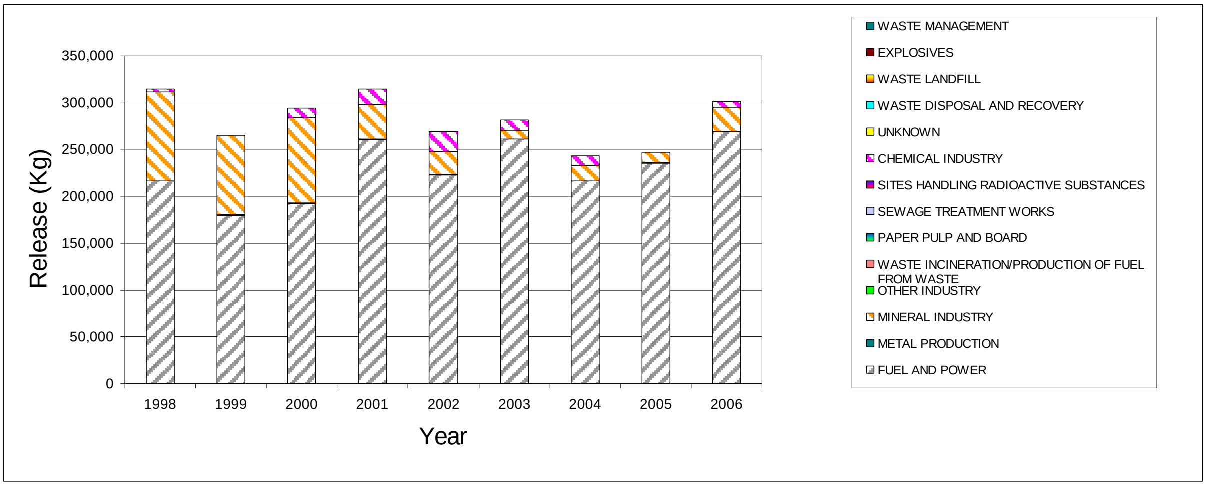
	1998	1999	2000	2001	2002	2003	2004	2005	2006
Animal, vegetable and food	0	0	0	0	0	0	0	0	0
Explosives									0
Fuel and power	216594	179712	192479	260847	222891	261310	216925	235780	269122
Metal production	231	693	449	526	808	0	19	113	2
Mineral Industry	94955	84735	91394	36946	24597	9191	15751	10924	25669
Other industry	0	0	0	0	0	0	0	0	0
Paper pulp and board	0	0	0	0	0	0	0	0	0
Sewage treatment works			0	0	0	0	0	0	0
Sites handling radio-active substances			0	0	0	0	0	0	0
Chemical industry	2523	355	9762	16402	20700	10900	10400	0	6692
Unknown						0	0	0	0
Waste disposal and recovery	0	0	0	0	0	0	0	0	0
Waste incineration/Production of fuel from waste	0	0	0	0	0	0	0	0	0
Waste landfill					0	0	0	0	0
Waste management								0	0
TOTAL - ALL INDUSTRIES	314303	265495	294083	314722	268996	281401	243095	246816	301486

The sectors, responsible for the biggest share in total emissions are:

- Fuel and power: presumably from coal fly ash (unintended source)
- Mineral industry: presumably from glass and glass fibres manufacturers, falling under this industry sector (cf NACE code 26)

Fig. **10-3.3** shows the share of the different activities mentioned in the PI in total releases to air reported in this PI.

Fig. 10-3 Share of different activities in total releases to air from industrial sites in England and Wales regulated by the Environment Agency (IPC, PPC, WML, RAS and WIA) (UK Environment Agency, October 2008)



10.8.8.3 Identification of sources

For the B emission inventory, in fact within the ESR, emissions for different B compounds need to be reported. In line with the existing RAR, the following B-compounds will be focussed on:

- Boric acid (H3BO3)
- Disodium tetraborate decahydrate (Na2B4O7.10H2O)
- Disodium tetraborate pentahydrate (Na2B4O7.5H2O)
- Disodium tetraborate anhydrous (Na2B4O7)

Emission inventories however are not split into the different borate compounds but only refer to B. Therefore, it will not be possible to report emissions for each compound individually. Attempts will be made, based on the uses/applications of different B-compounds to allocate the emissions to different B-compounds.

Coal contains significant amounts of boron, reflecting its plant material origins. Consequently, combustion of coal may release boron as part of the coal ash. Eisler (1990) reports coal ash contains from 5 to 200 mg B/kg-dry weight, depending on the type of coal. As much as 71% of the boron in coal may be released to air (Eisler, 1990). It is likely that emission inventories will report such emissions of boron. However, these releases are unintentional. As already indicated, emission sources need to be divided in point and diffuse sources. The selection or identification of sources will therefore be reported as such.

10.8.8.4 Emissions estimation from point sources

As already indicated, “point sources” are regarded as sources which are easy to locate and can be tracked back to a single source or origin, e.g. stack emissions. Looking at the life-cycle stages, they include industrial emissions from manufacture, formulation or industrial/professional use in an industrial environment

Manufacture

Emissions from the production of:

- Boric acid (H3BO3)
- Disodium tetraborate decahydrate (Na2B4O7.10H2O)
- Disodium tetraborate pentahydrate (Na2B4O7.5H2O)
- Disodium tetraborate anhydrous (Na2B4O7)

Emissions from manufacturers are covered in the local environmental exposure chapter.

Formulation

“Formulation” is the use of a substance as such or in preparations for making preparations (mixing, blending), including filling into containers and re-packaging of substances or preparations. Information on these point sources are estimated in the local assessment.

Industrial/professional use

This is the use of a substance as such or in preparations in any kind of process, including production of articles:

Substance is used as an intermediate and hence consumed in the synthesis of another substance

Substance (as such or in a preparation) is used as processing aid in manufacturing processes, service processes or as a household product. The life cycle ends with reaction on use (e.g. heat stabilizers, reaction promoters, reactive resins), emissions to the environment via air and waste water or at waste life stage;

Substance becomes part of an article (articles service life and the corresponding waste life stage to be considered as additional life cycle stages);

Based on the information from MS and literature, individual companies in different industrial sectors can be identified as point sources (see list below). Note that this list of activities/industrial sectors is much more extensive than the sectors quantified in the local exposure assessment. This is due to the fact that in the underlying emission inventory chapter of the report, all emission sources are taken into account, meaning emissions from intentional as well as unintentional sources. Based on the uses of different boron compounds, sectors in which boron emissions occur due to "intentional sources" are indicated with "(INT)" and a indication of the possible intentional use of B is given.

- Manufacture of refined oils and fats
- Manufacture of textiles (INT – flame retardants)
    - Preparation and spinning of textile fibres
    - Preparation and spinning of cotton-type fibres
    - Finishing of textiles
    - Manufacture of carpets and rugs
- Manufacture of refined petroleum products (INT – antifreeze, brake fluids, motor oil)
- Manufacture of chemicals and chemical products (INT – detergency (perborate),)
    - Manufacture of basic chemicals
    - Manufacture of other inorganic basic chemicals
    - Manufacture of other organic basic chemicals
    - Manufacture of plastics in primary forms
    - Manufacture of basic pharmaceutical products
    - Manufacture of pharmaceutical preparations
    - Manufacture of soap and detergents, cleaning and polishing preparations
    - Manufacture of photographic chemical material
    - Manufacture of other chemical products
- Manufacture of basic metals (INT – metallurgy)
    - Manufacture of basic iron and steel and ferro-alloys
    - Cold forming or folding
    - Wire drawing
    - Manufacture of basic precious and non-ferro metals
    - Aluminium production
    - Copper production
    - Other non-ferrous metal production
- Manufacture of fabricated metal products, except machinery and equipment (INT – metallugry (metalworking fluids)
    - Manufacture of central heating radiators and boilers
    - Treatment and coating of metals
    - General mechanical engineering
- Manufacture of machinery and equipment (INT – metallugry (metalworking fluids)
    - Manufacture of agricultural tractors
    - Manufacture of other agricultural and forestry machinery
- Manufacture of lighting equipment and electric lamps (INT – glass)
- Manufacture of motor vehicles (INT- metallurgy)
- Manufacture of aircraft and spacecraft (INT- metal treatment)
- Recycling of non-metal waste and scrap
- Production and distribution of electricity (INT- nuclear application)
- Steam and hot water supply
- Industrial cleaning (INT - detergency)

The EPER and WebDab databases were screened for boron emissions. Boron is not included in these databases and therefore not useful to estimate emissions from industry. Only Flanders (Belgium) and the UK provided us with national emission data from industrial point sources, which thus only shows a minor part of total industrial emissions. For the estimation of emissions from point sources an extensive literature search should be performed (e.g. based on IPPC BREF documents) to look for representative emission factors per type of industry. This is not included in the current assessment.

10.8.8.5 Emission estimation from diffuse sources

As already indicated, “diffuse or non-point” sources are regarded as sources that are not easy to locate and for which emissions can only be estimated on an area-basis, e.g. emissions from domestic wastewater, emissions from traffic, etc. “Diffuse” sources will include the emissions from private use, service life and waste disposal. It must be noted that the treatment of wastewater and waste on community level is seen as a diffuse source, since emissions cannot be allocated specifically to the primary source. Potential diffuse sources are identified based on literature search and the MS questionnaires:

- Agricultural use, mainly from the use of borate-containing fertilizers and the use of sewage sludge
- Burning of domestic waste, crop residues and wood fuel, as boron is present in many plants being necessary for their growth
- Combustion of fossil fuels (power plants, disposal sites of ash and fly ash)
- Discharge of domestic wastewater: The use of borates and perborates in household products
- Exhaust fumes from motor vehicles (+ windblown dust from paved/unpaved roads)

10.8.8.6 Domestic wastewater

The chapter on “10.8 Measured levels – Ambient concentrations of boron” contains a literature review on boron concentrations in sewage waters. Table 10-42 gives an overview of examples of boron concentrations in sewage water.

Tabelle 10.42 Examples of boron concentrations in sewage waters; country-specific RWC-PECs are indicated in bold.

Country	No. sites /samples	Conc range (µg/L)	Mean (µg/L)	Year	Reference
Austria	4	< 20 – 800	-		Schöller and Bolzer, 1989; Schöller, 1990
	4		780		Zessner et al (2003)
			850 (filtered)		UBA (2000)
			RWC: 836		
Germany	1 STP	500		1993	Metzner *et al,* 1999
	1 STP/15	335		1993	Fox et al, 2002
	1 STP	900		1996-1999	
	1 STP	240-640			Beier, 2008
			RWC: 780		
Italy	7 STPs		1,000		Mezzanotte *et al,* 1995
	1 STP	230 – 660	420		Gandolfi *et al,* 2000
	1 STP	*670 – 1,260*	1,000		Gandolfi *et al,* 2000
	1 STP	730 – 2,860	1,900		Gandolfi *et al,* 2000
			RWC: 1630		
Netherlands	1 STP	390 – 750		1994	Feijtel *et al,* 1997
	7 STP/21	450-970	720	1994	Matthijs et al, 1999
			RWC: 696		
Spain	2 STPs		1,450 – 3,000		Navarro *et al*, 1992
			RWC: 2845		
Sweden	1 STP		400		Ahl and Jönssen 1972
UK-Aire	8 STPs/228	427 – 837	90P: 673	1996-1998	Holt *et al* 2003
UK-Calder	15 STPs/310	161 – 1,116	90P : 768		
UK-Went	7 STPs/140	720 – 1,157	90P : 1,144		
UK-Rother/Don	6 STPs/153	704 – 1,057	90P : 1,115		

UK	3 STP/72	212, 322, 448	Mean : 262 **RWC : 861**	1995	Ashact, 1996
Range **Median**			**696-2845** **849**		

The derived country-specific RWC- PEC values (the 90-percentile for each country) range from 696 to 2845 µg B/L. According TGD (2003), the median of these values, 849 µg B/L will be taken forward in this risk assessment as the EU PEC-STP.

There are some restrictions in using these data as an estimation for the emission of B through discharge of domestic wastewater:

- No more recent monitoring data are available;
- the data refer to effluents of sewage treatment plants and not influents. However, since the removal rate of B by conventional treatment is very low, it can be assumed that influent concentrations are quite similar to effluent concentrations;
- it is unknown whether the data referred only reflect concentrations from STP exclusively treating household wastewaters.

Based on the produced amount of wastewater and the connection rate to sewage systems and sewage treatment plants in each Member State, a B-emission to surface water can only estimated preliminarily.

Tabelle 10.43 Inhabitants, water consumption and connection rate of households to STP and to sewage systems (EWA, 2005 and Eurostat, 2008)

	Sewage system connection rate (%) (EWA, 2005)	STP connection rate (%) (EWA, 2005)	Number of inhabitants 2006 (Eurostat, 2008)	water consumption (l/person/day) (EWA, 2005)	Not to sewage system (Mm^3/year) (1)	Sewage system not to STP (Mm^3/year) (2)
Austria	86.6	86.6	8265925	125	51	0
Belgium	84.6	55.1	10511382	107	63	121
Bulgaria	80.2	72.6	7718750	130	72	28
Czech Republic	77.4	72.5	10251079	103	87	19
Germany	95.0	93.0	82437995	127	191	76
Denmark	88.8	90.0	5427459	130	29	0
Estonia	72.0	71.0	1344684	100	14	0
Ireland	88.8	72.0	4209019	130	22	34
Greece	88.8	55.0	11125179	130	59	178
Spain	86.0	83.0	43758250	265	593	127
France	93.0	87.5	62998773	164	264	207
Italy	88.8	70.0	58751711	130	311	524
Cyprus	68.3	59.7	766414	130	12	3
Latvia	84.0	59.7	2294590	132	18	27
Lithuania	65.0	65.0	3403284	97	42	0
Luxembourg	99.0	94.0	469086	150	0	1
Hungary	59.0	51.0	10076581	151	228	44
Malta	68.3	59.7	405006	130	6	2
Netherlands	98.0	98.0	16334210	126	15	0
Poland	68.3	52.0	38157055	130	573	295
Portugal	71.0	50.0	10569592	161	180	130
Romania	68.3	59.7	21610213	130	325	88
Slovenia	53.0	35.5	2003358	146	50	19
Slovakia	55.9	50.5	5389180	109	95	12
Finland	81.0	81.0	5255580	150	55	0
Sweden	68.3	85.0	9047752	130	136	0
United Kingdom	94.0	94.0	60393100	343	454	0
Norway	80.0	77.0	4640219	130	44	7
Average (EU27+N)	80.2	72.6		130		
Average (EU15)	88.8	80.2				
Average (EU12+)	68.3	59.7				
TOTAL EU27					3943	1936
TOTAL EU27+N					3987	1943

(1) Total discharge of wastewater not to sewage system = (100-sewage system connection rate)/100*number of inhabitants*water consumption/day*365days/year/1000000000L/Mm^3

(2) Total discharge of wastewater from sewage system not connected to STP = (sewage system connection rate - STP connection rate)/100*number of inhabitants*water consumption/day*365days/year/1000000000L/Mm^3

EU-27+N= EU-27 + Norway
EU-15=Austria, Belgium, Germany, Denmark, Ireland, Greece, Spain, France, Italy, Luxembourg, the Netherlands, Portugal, Finland, Sweden, UK
EU12+=Bulgaria, Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Romania, Slovania, Slovakia

Based on the calculations, we estimate a discharge of wastewater from households directly at the source (to soil or surface water in the vicinity of homes not connected to a sewage system) of 3943 Mm³. B. A B-concentration of 849 µg/L was assumed The combination of both sources brings us to a B-emission to surface water directly at the source of about 3.3 ktonnes B. Taken into account that not all sewage systems are connected to an STP, then another 1936 Mm³ of wastewater will be emitted from the sewage systems not connected to STPs. Also here a B-concentration of 849 µg/L was assumed, resulting in a B-emission of about 1.6 ktonnes B, emitted to the surface water from those unconnected sewage systems.

10.8.8.7 Use of fertilisers and sewage sludge on agricultural land

Fertilisers

Boric acid as well as sodium tetraborates are used as fertilisers. These compounds are used on several agricultural sites - next to non-agricultural sites like residential, commercial, medical, veterinary, industrial, forestry and food/feed handling areas. Due to this activity, boron can be released from run-off and leaching where boron-containing fertilisers are used.
The local assessment chaptert of the regional exposure, reports end use volumes for all borate compounds (as B2O3) (EBA, 2008). This table indicates a use of about 79% of 11 257 T B_2O_3 as mineral fertilisers, which is about 9000 Tonnes (8892 T). This 9000 Tonnes is thus a direct input to agricultural soil, but is not an emission to soil or surface water. The leached part can be seen as direct emission to groundwater/surface water. Total input, diminished by leaching and uptake by crops can be seen as emission to soil. Since there is not enough information on uptake by crops, emissions cannot be estimated at this time.

Sewage sludge

Since boron is not substantially absorbed during processing, there is almost no removal during the sewage treatment process (Park and Edwards, 2005). The following on B-concentrations in sewage sludge is reported in Eriksson, 2001: "There has always been an assumption that boron is not significantly removed during the sewage treatment process. Nevertheless, some boron is associated with sewage sludge although data is scarce. Results of boron concentrations in sewage sludge from a study of 48 sewage treatment plants in Sweden are detailed in Table 10-44. "

Tabelle 10.44 Concentration of boron (mg B/kg dw) in sewage sludge (data from Eriksson, 2001)

Number of Samples	MEAN	SD	Min	Percentile					Max
				10%	25%	Median	75%	90%	
48	61	81	2	8	18	32	58	150	390

Fujita et al. (2005) reported boron adsorption reaching sludge concentrations of 40 to 600 mg-B/kg-sludge (dry weight) when influent concentrations ranged from 0.3 to 30 mg-B/L. They suggested that at typical wastewater concentrations in Japan of less than 0.1 mg-B/L, sludge concentrations would likely range from 20 to 60 mg-B/kg. This is in reasonable agreement with the results reported by Eriksson (2001).

A first very rough estimation of the input of B to soil through the use of sewage sludge as a fertiliser is based on an extrapolation of data from the EU-15:

- In the EU-15 8.2 Mtonnes sewage sludge is produced (CEC, 2003) for a total of 22166 Mm³ sewage water treated (based on connection rates and water use per inhabitant in EWA, 2005), which is about 298 g sewage sludge per m³ sewage water treated (based on EWA, 2005; and CEC, 2003);

- In the EU-15 about 3.5 Mtonnes of the sewage sludge is used on agricultural soil (based on CEC, 2003). The usage on agricultural soil ranges between 9% and 66% of the production in the different EU15 MS, with P50 of 43% and a P90 of 63%.

Since no detailed information for EU-27 are available, it is assumed that these data, referring to EU-15, would be representative for the EU-27. Based on the EWA (2005) report, it can be estimated a total amount of sewage water treated in the EU-27 of 25050 Mm³.

If it is assumed (referring to the EU-15) that 298 g sewage sludge per m³ sewage water treated is produced, that about 43% of the sewage sludge is used in agriculture and that the mean B-concentration (Eriksson, 2001) in sewage sludge is 150 mg B/kg DW, a total input in agricultural soil in EU-27 of about 489 tonnes B can be estimated. The importance of this and, since boron in waste water is not substantially absorbed during processing; the source of boron in sludge should be further assessed.

10.8.8.8 Boron emissions from waste management stragegies

Rapporteurs Comment: The following chapter is based on the report of Arcadis Belgium – EURAS, Waste stream analysis and emission assessment. Progress report – Oktober 2008. Commissioned by the European Borate Association (EBA).

Introduction

The aim of this chapter is to quantify the associated boron emissions from end of life to the environment. Guidance on how to estimate the emissions from the waste disposal stage, however, is not provided within the Technical Guidance Document (TGD, 1996). The revised TGD (TGD, 2003) includes some sections on waste disposal and was taken as the starting point for the approach developed by the contractors in the framework of the Targeted Risk Assessment on nickel in Ni-Cd batteries (TRAR, 2005) to assess emissions from Municipal Solid Waste (MSW). The latter approach was discussed in depth and the methodology was agreed by the Member States at the technical meeting level. This methodology has been used as a starting point for the calculation of the boron emissions associated with the waste management of MSW. Current emissions are estimated based on an overall European situation. However, since waste management strategies may differ considerably between the Member States, due consideration is given to these differences by means of including several scenarios (with the extremes: 100 % landfilling and 100 % incineration). Emissions of boron from incineration of MSW are expected to occur through air if no adequate flue gas treatment is in place and through the discharge of incinerator effluents. The major environmental concerns associated with MSW landfills are usually related to the generation and eventual discharge of leachate into the environment. Therefore the aforementioned emissions routes of the management of MSW are the focal point of this report. In the Waste Incineration Directive 2000/76/EC Boron Emissions are not regulated for the air and water pathway. Due to lack of methodology no attempt has been made to address the boron emissions from the other waste streams. Overall data on boron in waste streams are extremely scarce. Hence, a large uncertainty is surrounding the release estimates. The results should therefore be interpreted as semi quantitave.

Boron emissions from Waste Management Strategies

MSW-Waste management practices in Europe

Waste management practices[15] vary considerably among different countries and regions in the EU. The current status of waste management strategies for the different EU countries is presented the following tables. Data were extracted from the OECD/EUROSTAT joint questionnaire "waste"databank.

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[15] Only incineration and landfill practices are being considered in this progress report.

Tabelle 10.45 Landfilling and incineration of MSW (in ktonnes wet weight) in EU-27 for the period 2001-2003

Country	Year	MSW landfilled (ktonnes wet wt.)	MSW incinerated (ktonnes wet wt.)
Austria	2002	1,500	490
Belgium	2003	582	1,646
Denmark	2003	181	1,955
Finland	2003	1,482	213
France	2002	12,991	11,110
Germany	2003	10,474	12,239
Greece	2003	4,328	0
Ireland	2002	1,967	0
Italy	2002	18,500	2,698
Luxembourg	2001	58	121
Netherlands	2003	261	3,192
Portugal	2003	3,518	1,028
Spain	2002	14,723	1,567
Sweden	2003	575	1,893
UK	2002	27,545	2,681
Bulgaria	2003	3,194	0
Czech Republic	2003	2,049	401
Estonia	2003	371	0
Cyprus	2003	467	0
Latvia	2003	579	23
Lithuania	2003	909	0
Hungary	2003	3,958	245
Malta	2003	218	0
Poland	2003	9, 609	42
Romania	2003	6,268	0
Slovenia	2002	699	5
Slovakia	2002	1,192	156
Total EU-27	**169,903**	**128,198**	**41,705**

The calculation of the share (%) of MSW waste being landfilled or incinerated is calculated using only the ratio between incineration and landfilling in the different Member States.

Tabelle 10.46 Landfilling and incineration practices (in %) in EU-27 for the period 2001-2003

Country	Year	% of MSW landfilled	% of MSW incinerated
Austria	2002	75.4	24.6
Belgium	2003	26.1	73.9
Denmark	2003	8.5	91.5
Finland	2003	87.4	12.6
France	2002	53.9	46.1
Germany	2003	46.1	53.9
Greece	2003	100.0	0.0
Ireland	2002	100.0	0.0
Italy	2002	87.3	12.7
Luxembourg	2001	32.4	67.6
Netherlands	2003	7.6	92.4
Portugal	2003	77.4	22.6
Spain	2002	90.4	9.6
Sweden	2003	23.3	76.7
UK	2002	91.1	8.9
Bulgaria	2003	100.0	0.0
Czech Republic	2003	83.6	16.4
Estonia	2003	100.0	0.0
Cyprus	2003	100.0	0.0
Latvia	2003	96.2	3.8
Lithuania	2003	100.0	0.0
Hungary	2003	94.2	5.8
Malta	2003	100.0	0.0

Poland	2003	99.6	0.4
Romania	2003	100.0	0.0
Slovenia	2002	99.3	0.7
Slovakia	2002	88.4	11.6
Total EU-27		**75.5**	**24.5**

Overall it can be concluded that landfilling remains the predominant disposal route for waste while there is a growing trend towards increased incineration (EEA, 2000). The overall ratio between incineration and landfilling of MSW within the European Union is 24.5 to 75.5 (situation 2001-2003).

Inherent to the quantification of boron emissions caused by landfills or incineration is the fact that available data on landfill and incineration emissions always represent the total emissions of boron containing materials present in the waste stream. The overall boron emissions may vary considerably depending on the used Flue Gas Cleaning System or the presence of a leachate treating system/protective lining in the case of landfills. The scenario based on the European average situation (24.5 % incineration and 75.5 % landfill) is compared with two extreme scenarios: 100 % sent to landfill or 100 % incinerated. These shall allow a rudimentary sensitivity analysis to reflect the extremes in waste management option.

Releases to the environment

Current boron emissions from incineration MSW

Boron entering into standard MSW incineration will be distributed among various output fractions such as stack emissions (flue gas), wastewater, fly ash, bottom ash and slag. The distribution pattern of boron over these incineration residues depends on the physical-chemical properties of boron, the gas cleaning technology and the operation and maintenance conditions. While the flue gas and wastewater emissions are immediate, emissions of the incineration residues (via disposal and/or re-use) are delayed.

Flue gas emissions

Approximately 5,000-6,000 Nm^3 (Nm^3 stands for normal cubic metre. Normal refers to the gas volume being measured at 0 °C and at a pressure of 1 atm (= 760 mm Hg)) dry flue gas is generated per ton waste (wet wt.) incinerated (Van De Wijdeven, 1991). Today, almost all waste incineration plants have some kind of flue gas cleaning system (FGCS) in place. The amounts of household waste incinerated per flue gas cleaning system in use by the different Member States are presented in the table below and were extracted from the national data collected by ISWA (2002). It should be noted that not all countries or incinerators present in a country have been covered. The analysis is restricted to the countries mentioned in Table 10-47. The distribution of the FGCS in percent (based on a weight basis) is presented below.

Tabelle 10.47 Amounts of household waste (ktonnes WW) treated per Type of Flue gas Cleaning System (reference year 1999 unless specified) (ISWA, 2002)

Country	Dry	SD	WET	Dry + WET	SD	ESP	FF	O	Total
Austria	0	0	437	0	0	0	0	0	437
Belgium[a]	38	304	208	0	203	0	0	0	753
Denmark[d]	44.3	137	258.5	0	0	0	0	0	440
France	803	0	6,465	0	0	706	0	351	8,326
Germany	155	1,117	5,024	272	1,656	0	0	0	8,225
UK	150	488	0	0	0	0	0	0	639
Netherlands	0	20	1,876	0	917	0	0	0	2,813
Norway	0	11	305	0	0	0	0	0	316
Portugal[c]	0	1,060	0	0	0	0	0	0	1,060
Spain[b]	21	991	320	0	0	0	0	0	1,332
Sweden	322	0	645	283	0	0	53	0	1,303

Total	**1,535**	**4,128**	**15,538**	**555**	**2,776**	**706**	**53**	**351**	**25,642**

Dry: Dry scrubbing; SD: Semi dry scrubbing; WET: Wet scrubbing; FF: Fabric Filter; ESP: Electrostatic precipitator; O: other)

a updated figures for Flanders (OVAM: Peter Loncke, Personal communication)

b updated figures for Spain (MMA, 2002)

c updated figures for Portugal (LIPOR II, Calheiros JM and Almeida A., pers. com., 2002)

d based on updated figures for Denmark (Riber et al, 2002)

Tabelle 10.48 Distribution (%) of Flue Gas Cleaning Systems for different Member States

Country	Dry	SD	WET	Dry + Wet	SD+Wet	ESP	FF	O	Total
Austria	0	0	100	0	0	0	0	0	100
Belgium	5	40.4	27.6	0	27	0	0	0	100
Denmark	10.1	31.2	58.8	0	0	0	0	0	100
France	9.7	0	77.6	0	0	8.5	0	4.2	100
Germany	1.9	13.6	61.1	3.3	20.1	0	0	0	100
UK	23.5	76.5	0	0	0	0	0	0	100
Netherlands	0	0.7	66.7	0	32.6	0	0	0	100
Norway	0	3.4	96.6	0	0	0	0	0	100
Portugal	0	100	0	0	0	0	0	0	100
Spain	1.6	74.4	24.0	0	0	0	0	0	100
Sweden	24.7	0	49.5	21.7	0	0	4.1	0	100
Total	**6.0**	**16.1**	**60.6**	**2.2**	**10.8**	**2.8**	**0.2**	**1.4**	**100**

Source: ISWA, 2002. Dry: Dry scrubbing; SD: Semi dry scrubbing; WET: Wet scrubbing; FF: Fabric Filter; ESP: Electrostatic precipitator; O: other

It can be concluded that approximately 22 % of all the household waste incinerated in Europe is followed by dry and semi-dry flue gas cleaning. Wet flue gas cleaning accounts for 73,6 %. Three percent of the household waste incinerated is followed by ESP or FF only. Actual measured air emissions of boron by Municipal Solid Waste incinerators were not available. So air emissions can not be quantified at this stage.

Emissions from wastewater

Emissions to water results essentially from the discharge of wastewater from incineration plants with wet flue gas cleaning systems. Wastewaters have been shown to contain metals and inorganic salts, and may exhibit wide pH ranges (Reimann, 1987). The main sources of wastewater from incinerators are from flue gas treatment as flue gas scrubber water, e.g. alkaline scrubbing of the gases to remove acid gases, and the quenching of incinerator ash (wet slag discharge system).Typical a limited amount of wastewater generated in the order of 0.5-2.5 m^3 per tonne of municipal waste incinerated (Williams, 1998). Reimann (2002a and b) reported a water consumption of 1.1 m^3/tonnes for the FGCS and 0.25 m^3/tonne as boiler water. Stubenvoll et al (2002) reported amounts of waste water between 0.3-0.4 m^3/tonne. As a worst case assumption the highest volume of wastewater generated (i.e. 2.5 m^3) is used to calculate the regional contributions. For the local assessment both the lower limit (i.e. ± 0.5 m^3) and the higher limit will be used to calculate the dilution factors.

Discharge of wastewater results only from incineration plants equipped with wet flue gas cleaning systems. Dry and semi-dry sytems have no water emissions. Overall 74 % of the incinerated MSW is followed by some kind of wet FGCS. In future this figure is likely to decrease since more and more incinerators are being equipped with a semi-dry FGCS eliminating the emissions to water (Personal communication with Bert Gielen, ECOLAS). For the calculation of the water emissions per country only the percentage of waste incinerated in incinerator plants with wet flue gas cleaning systems has been taken into account. Furthermore as a worst case scenario it is assumed that for all countries the total incinerator process produced 2.5 m^3 wastewater/tonne wet wt. of MSW (Williams, 1998). Only one English abstract has been identified that reported boron concentrations in the effluent of a garbage incinerator (before treatment). Effluents from the Osaka City garbage incinerators contained between 0.9-4.3 mg/L boron (Fukunaga and Minoru (2001). The 4.3 mg/L value has been used as a default value for the calculation of the emissions through waste water for the other countries. According to the Osaka Environment bureau incineration plants (e.g. Maishima plant) is equiped with a bug filter and moist cleaning equipment.

As an example, the emission for France is calculated as follows:

- Amount incinerated each year = 11,110 ktonnes wet wt.
- Fraction of incinerators equipped with WET FGCS: 11,110 x 0,776 = 8,621 ktonnes
- Volume influent per year = 8,621 ktonnes x 2,500 m^3/ktonnes = 21,553,400 m^3
- Total B load in effluent per year = 21,553,400 m^3 x 4.3 10^{-3} kg B/m^3 = 92,680 kg
- B load to surface water = 92,680 kg

As indicated above for the regional emissions it has been assumed as a worst case estimate that 2.5 m^3 waste water per tonne wet wt. of MSW is generated. For the regional and local calculations the default boron concentration of 4.3 mg/L will be used

Tabelle 10.49 Overall boron emissions to water (modelled data) (in kg/year) in EU-27 due to incineration of MSW. Scenario current incineration 24.5 %.

Country	MSW incinerated (ktonnes wet wt.)	Wet flue gas cleaning (%)*	Emissions to water (kg/year) Scenario 24.5 %
Austria	490	100	5,268
Belgium	1,646	54,6	9,661
Denmark	1,955	58,8	12,358
Finland	213	73,6	1,685
France	11,110	77,6	92,680
Germany	12,239	84,5	111,176
Greece	0	0	0
Ireland	0	0	0
Italy	2,698	73,6	21,347
Luxembourg	121	73,6	957
Netherlands	3,192	99,3	34,074
Portugal	1,028	0	0
Spain	1,567	24	4,043
Sweden	1,893	71,2	14,489
UK	2,681	0	0
Bulgaria	0	0	0
Czech Republic	401	73,6	3,173
Estonia	0	73,6	0
Cyprus	0	73,6	0
Latvia	23	73,6	182
Lithuania	0	73,6	0
Hungary	245	73,6	1,938
Malta	0	73,6	0
Poland	42	73,6	332
Romania	0	73,6	0
Slovenia	5	73,6	40
Slovakia	156	73,6	1,234
Total EU-27	**41,705**		**314,636**

*: Country specific value used where available. In absence of country specific data, the EU value of 73,6 % has been used.

Based on the calculations above the boron emission due to incineration of MSW is approximately 315 tonnes B/year to water in the EU-27.

Overall boron emissions from landfilling MSW

Release of pollutants from a landfill can occur over an indefinite period. Hence, the daily or annual release may result in a very small PEC and does not reflect the long-term emissions of a landfill. No specific guidance is provided by the TGD (2003) on how to quantify the current and future landfill emissions**.** Due to the large uncertainties associated with this subject, the analysis that is should be considered as a semi-quantitative approach. Both regional and local emissions of landfilling will be addressed. Only for the local scenario the issue of dilution in time (long term emissions) will be analysed. The local emissions associated with landfilling MSW will be given for three separate time horizons beginning from waste placement:

- Short term time frame (20 years) corresponding roughly to the landfill's period of active decomposition.
- Intermediate term time frame (100 years) corresponding roughly to the life span of a given generation.
- Long term time frame (500 years) corresponding to an indefinite time reference where emissions of any given environmental flow have reached or nearly reached their theoretical yield.

Here only the regional emissions are given.

Leachate generation

Emissions of landfills can occur primarily by generation of landfill gasses and leaching of contaminants. In the case of metals, emissions by generation of landfill gas are negligible in all cases except for Hg and possibly Cd (Baccini et al, 1987, Finnveden, 1996). However, in this document the pollution via leachate release is being considered as the most important long term flux impacting the environment. Leachate is generated as a result of the expulsion of liquid from the waste due to its own weight or compaction loading (termed primary leachate) and the percolation of water through a landfill (termed secondary leachate). The source of percolating water could be precipitation, irrigation, groundwater or leachate recirculated through the landfill.

Leachate quality

An overview of reported boron concentrations in MSW landfill leachates is given in Table 10-50. Again the data for boron concentrations are very limited.

Tabelle 10.50 Overview of total boron concentrations (mg/L) in leachates of MSW landfills

N° of landfills	Type/origin	Min	Max	Mean	Percentiles	Reference
41 (10 data points)	• 31 Switzerland • 7 Italy • 4 France				P50: 2 P90: 7	Looser et al (1996) and Looser et al (1999)
1	• Canada: mixed landfill			10.2		Sarta and Fernandes (2005)
	Austria:					Watzinger et al (2003)
11 (155 data points)	• Survey period: 1990-2000	0	58	10.1		
7 (33 data points	• Survey period: 1999-2000	0.1	58	10.3		
41 landfill total	Germany					Krümpelbeck (1999)
5 landf/15 measurement points	• 1-5 years	0.4	15	5.9		
13/2	• 6-10 years	0.3	43	6		
18/91	• 11-20 years	0.4	18	5.6		
5/20	• 21-30 years	1	58	9.1		

Reported boron concentrations range from 0.3 to 58 mg/L. The large range is partly due to the heterogeneity of the composition of the investigated landfills (ranging from landfills with primarily domestic waste inputs to co-disposal landfills) but also the choice of sampling sites can be influential. In case waste layers are unsaturated underlying aquifers are often sampled. Most of the prevailing evidence give average boron concentrations between 5 and 10 mg/L. In this report the a concentration of 10 mg/L boron, has been chosen. This value is the 90th percentile of the current database and as such this value can be considered as representative for a realistic worst case situation.

The measured concentration value represents the boron leached out from all boron sources present in the MSW. Since data on leachability of boron in specific applications is limited it is very difficult to assess the individual contributions. The default value of 10 mg B/L is taken forward in the calculations.

Leachate quantity

Leachate production is highly depended on the landfill design and local climatic conditions. Precipitation represents the largest single contribution to the production of leachate. There is some variation in the potential generation of leachate within the EU because precipitation and evapotranspiration depends on geographical location. In Mediterranean areas (Greece, Spain, Italy) leachate generation is smallest during summer season and leachate generation occurs principally during the colder, wet season (i.e. from October to April). For example an annual leachate production, expressed as height of water of 40-80 mm/year has been calculated for a landfill site near Athens (Greece, rainfall: 387 mm/y, Kouzeli-Katsiri et al, 1993). In a landfill site near Madrid (Gössele, 1993) the leachate production was calculated to be 7 mm/year and in a landfill near Pavia (Italy, Baldi et al, 1993) it was 82 mm/year. Leachate quantities tend to be higher in the north of the EU than the south. In Sweden an average leachate volume of 250-300 mm/year is reported during operation

(Nilsson, 1993). In Denmark similar figures have been reported: 320-400 mm during operation and 56-89 mm/year (Hjelmar, 1988-1989). But equally large variations can be found from east to west and over relatively short distances within Member States (Hjelmar et al, 1994). Reported leachate volumes vary from 25 m3 to 3,000 m3 per hectare (Flyhammer, 1995, Qiang et al, 2002). The results of various empirical studies indicate that the average percentage of precipitation that result in leachate production depends on the age of the landfill and is largely controlled by the presence and type of cover. In general it has been noted that the amount of leachate produced is between 15 and 50 % of the respective rainfall, depending mainly on the final landfill cover type and the manner of waste compaction (Canziani and Cossu, 1989). As a realistic worst case scenario in this report the water balances has been calculated for a relatively high precipitation rate (800 mm/year) for different scenarios representative for landfill practices that are currently common.

Regional emissions of landfilling MSW

The regional emissions of boron per year from MSW landfills in the EU can be calculated with the following formula.

Boron flux (kg/year) = Landfill surface (ha) x leachate generation (m^3/ha.y) x boron concentration in the leachate (10,000 10^{-6}.kg/L)

In this report a concentration of 10,0000 µg B/L is taken as a realistic worst case value for MSW landfill leachate. A maximum leachate volume of 2,500 m^3/ha.y (was derived for an average rainfall of 7,999 m^3/ha.y (TRAR, 2003). The only unknown in the equation is the total surface area of the landfills. Reported landfill areas range between < 1 ha to > 10 ha while new established landfills are assumed to be reasonably large (average 20 ha, Hjelmar et al, 1994). However, almost no reliable data on the total number of MSW landfills or their landfill surface were found for most of the Member States. The values that have been reported for operational landfills for some countries are listed in Table 10-51. The boron flux has been calculated with the equation described above.

Tabelle 10.51 General parameters of operational MSW landfills for some countries.

Country[a]	**MSW landfilled (ktonnes)**	**Number of landfills**	**ktonne MSW/y per landfill**	**Average surface area /landfill (ha)**	**Total surface area (ha)**	**Reference**
Finland	1,610	/	/	9.3	/	Asmutt (1992)
Sweden	1,300	270-280	4.8	10	2,800	Flyhammar (1995) and RVF (2002)
UK	26,860	764 + 796	17.2	18.9 9.1	14,482 + 7,300	Mc. Mellin (2002)
Germany	16,000	376	42.5	10[a]	3,760	UBA (2001)
The Netherlands	800	30	19.7	30.7	921	AOO (2002-2004)
Weighted Average			**20**	**13**		

[a] *very rough approximation on the average landfill area*

Boron fluxes are directly related to the landfill surface area and the annual precipitation. Since the total landfill surface area for most of the Member States is unknown an indirect approach had to be developed in order to assess the overall boron emissions for these countries. The weighted average landfill surface of 13 ha can be calculated. Furthermore approximately 20 ktonne MSW (wet wt.) is landfilled per landfill each year The latter information can be used to translate the amount of MSW landfilled (ktonnes) in each year per country into a number of landfills. Assuming that each landfill has a surface area of 13 ha the total landfill surface can be calculated. For those country where actual data were available these data were used by preference. Finally the boron flux is calculated with the equation mentioned above.

As an example the emission for France is calculated as follows:

- Amount landfilled each year = 12,991 ktonnes wet wt..

- Number of landfills = 12,991 ktonnes/20 ktonnes per landfill = 649
- Total landfill surface = 649 landfills x 13 ha/landfill = 8,437 ha
- Total boron flux (kg/y) = 8,437 ha x 2,500,000 L/ha.y x $10{,}000.10^{-9}$.kg B/L = 210,925 kg/y

The generated flux (leachate) may either be discharged to an off-site municipal sewage plant, discharged directly to surface water or enter into the groundwater compartment. Collection and discharge to a Sewage Treatment Plant (STP) is by far the most common discharge route for leachates from municipal waste landfills. A smaller proportion of leachate is discharged directly to surface waters (Hjelmar, 1994). The highest proportion of landfills discharging directly to surface water is Germany (23 %) with less than 10 % in other Member States (Hjelmar et al, 1994).

Discharge to surface waters is only allowed if the leachate quality fulfil certain requirements (sometimes pre-treatment, e.g aerated lagoons, is needed). Most often this quality is governed by the presence of increased levels of BOD, COD and ammonium.

Tabelle 10.52 Detailed analysis of leachate sample taken at Chapel Farm landfill, Swindon, Wiltshire, 1990-1991 (Robinson, 1995)

Parameter	Concentration (mg/L)
COD	850-10,600
BOD_5	239-4,100
Ammoniacal-N	283-531
Chloride	834-4,670

Permitted discharge to groundwater is uncommon for modern MSW landfills but may occur by old landfills or in the framework of an engineered leachate attenuation site (Robinson, 1995).

Since the number of sites designed with bottom liners and on-site leachate treatment plants is currently increasing it is proposed to use the following regional allocation key for landfills:

- 10 % direct discharge to groundwater (attenuation/dilution sites) (Hjelmar et al, 1994)
- 10 % direct discharge to surface water (sometimes an on site pre-treatment step is included)
- 80 % collected and discharged via public sewerage systems or transported via tankers to a STP. Boron removal efficiencies in a STP are very low. As a worst case it is assumed that no boron is removed.. It should be clear that a direct discharge to groundwater or surface water is only possible when the leachate quality is considered suitable. If the quality is insufficient a form of pre-treatment is needed.

The above regional scenario was validated with the data presented in the extensive report of Robinson (1995). The semi-quantitative and qualitative information on leachate management in the EU reported on a country by country basis also give support to the aforementioned allocation key (Hjelmar, 1994).

An overview of the overall boron emissions to groundwater/surface water (in kg/year) in Europe due to landfilling of MSW is presented in the tables below. The overall boron flux was calculated with the methodology described in previous paragraphs.

Tabelle 10.53 Overall boron emissions to groundwater/surface water and sludge (in kg/year) in EU-27 due to landfilling of MSW (operational landfills only). Current scenario: 75.5 % landfilling

Country	MSW landfilled (ktonnes wet wt.)	Total boron flux (kg/y)	Fugitive emissions to surface water (kg/year)	Fugitive emissions to groundwater (kg/year)	Collected leachate and discharged to surface water
Allocation key			10 %	10 %	80 %
Austria	1,500	24,375	2,438	2,438	19,500
Belgium	582	9,458	946	946	7,566
Denmark	181	2,941	294	294	2,353
Finland*	1,482	17,228	1,723	1,723	13,783

France	12,991	211,104	21,110	21,110	168,883
Germany*	10,474	94,000	9,400	9,400	75,200
Greece	4,328	70,330	7,033	7,033	56,264
Ireland	1,967	31,964	3,196	3,196	25,571
Italy	18,500	300,625	30,063	30,063	240,500
Luxembourg	58	943	94	94	754
Netherlands*	261	23,025	2,303	2,303	18,420
Portugal	3,518	57,168	5,717	5,717	45,734
Spain	14,723	239,249	23,925	23,925	191,399
Sweden	575	68,750	6,875	6,875	55,000
UK*	27,545	544,550	54,455	54,455	435,640
Bulgaria	3,194	51,903	5,190	5,190	41,522
Czech Republic	2,049	33,296	3,330	3,330	26,637
Estonia	371	6,029	603	603	4,823
Cyprus	467	7,589	759	759	6,071
Latvia	579	9,409	941	941	7,527
Lithuania	909	14,771	1,477	1,477	11,817
Hungary	3,958	64,318	6,432	6,432	51,454
Malta	218	3,543	354	354	2,834
Poland	9, 609	156,146	15,615	15,615	124,917
Romania	6,268	101,855	10,186	10,186	81,484
Slovenia	699	11,359	1,136	1,136	9,087
Slovakia	1,192	19,370	1,937	1,937	15,496
Total EU-27	**128,198**	**2,175,295**	**217,530**	**217,530**	**1,740,236**

*Using country specific data reported

The total amount of MSW being landfilled in 2001-2003 for the EU-27 was 128,198 ktonnes wet wt. corresponding with an overall EU landfilling share of 75.5 %. A total yearly boron flux of 2,175 tonnes has been calculated. Based on the calculations above the boron emission to the groundwater compartment due to landfilling MSW is 218 tonnes B/year. An additional 1,958 tonnes is emitted to surface water.

10.8.8.9 Exhaust fumes from motor vehicles

Boron emissions from on-road mobile sources are rarely reported. No information was found in European Emission inventories. The emissions inventory of New South Wales in Australia (DECC, 2003) reports boron emissions from exhaust fumes of motor vehicles. A specific emission factor was not found in publicly available reports. The currently available information is insufficient neither to assess the importance of this source nor to estimate the relevant emissions.

10.8.8.10 Total regional/continental emissions

Due to the lack of more, detailed and validated information on Boron sources and emissions, regional and continental emissions, also from diffuse sources, will be estimated as a generic scenario with the EUSES 2.0 model.

11 RISK CHARACTERISATION

11.1 Risk characterisation for Human Health

Risk characterisation ratios (RCRs) for the human health section are derived by comparing exposure levels to derived no-effect levels (DNELs) and express the risk to man due to the extent of exposure. In this case, following formula is used.

$$RCR = \frac{Exposure\ to\ Boron}{DNEL}$$

RCRs are positive and dimensionless values (>0). Control of risk for a substance is demonstrated when the RCRs for all exposures from all exposure scenarios, all endpoints, all timescales and all exposed populations are below one (Exposure < DNEL).

11.1.1 Risk characterization for workers

Occupational exposure has been estimated for a variety of exposure scenarios related to the manufacturing, import and use of boric acid and the anhydrous, pentahydrate and the decahydrate species of disodium tetraborate. As no monitoring data was available, only a first tier exposure assessment could be made using the EASE model without taking into account the attenuating effects of any personal protective equipment (PPE).

Some exposure scenarios for workers have been identified which are not covered in this dossier and need to be further specified (esp. scenarios for DUs and the use of boron containing products by workers). The RCRs from these missing exposure scenarios are not considered here and need to be covered later in the registration dossier from industry. Furthermore, "mixed exposure"-scenarios basing on typical worker's day shift referring to different industries need to be validated respectively developed by more detailed information.

Worker RCR long term inhalation for single tasks

Table 11.1 reveals the derived typical and reasonable worst case (RWC) boron concentrations in air released by the given tasks. The boron concentrations refer to boric acid and to the three sodium tetraborates, as derived and already described in chapter 9. It is assumed as a worst assumption that the released aerosol consists to 100% of one of the four substances. Applying the Worker DNEL- long term inhalation of 1,2mgB/m^3 (chapter 5.11), results in the given Worker RCRs- long term inhalation.

The presented RCRs demonstrate that risk (exposure to boron) depends on the boron content of the substance, assuming a constant dust generation for all substances due to the same task. As sodium tetraboratate anhydrous reveals the highest boron content among these four substance (21,49%), this results also in the highest RCR for the same task ($RCR_{Na2B4O7}$>$RCR_{B(OH)3}$> $RCR_{Na2B4O7\cdot5H2O}$>$RCR_{Na2B4O7\cdot10H2O}$). But it should be also borne in mind that boric acid and sodium tetraborate penthahydrate represent the largest part of the total use volumes (table 2.3) and therefore exposure to them is more likely than to sodium tetraborate anhydrous and sodium tetraborate decahydrate.

As the Worker-DNEL long term inhalation refers to a workers whole day shift, the presented RCRs in table 11.1 are not applicable for most cases, because in general operatives don't carry out only a single task per day considering the information gained via the visits of sites and the receipt of completed questionnaires. A workers shift often consists of more than one activity and includes also activities which reveal no exposure to one of these substances. Therefore a better picture of the risk characterisation of worker should be given by mixed exposures (i.e; combination of tasks) (chapter 9.1.5.10-11). Despite of that, the RCRs of the single tasks are presented as they identify the scenarios revealing the greatest risk potential, which is also relevant for the mixed exposures.

Most single tasks reveal RCRs below 1 for the reasonable worst case (RWC) and for the typical case for each of the four substances. Control of risk is demonstrated for these single tasks. Scenario “Discharging borates from ships” and “Cleaning by sweeping” reveal significantly higher values than 1 for the typical and reasonable worst case for all four substances. Referring to these results, no control of risk is demonstrated for any substance, if the relevant task is carried out for a whole shift.

Based on the experience and estimation of industry, the used airborne particle concentrations calculated with EASE 2.1 and the resulting RCRs are too high and overestimate boron exposure at the work place especially for the scenarios “Discharging borates from ships” and “Cleaning by sweeping”. However, it is necessary to support this assumption with more advanced descriptions of the scenarios basing on measurements at the sites, more detailed models and/or the application of LEV resp. PPE, where it’s not already applied (2nd Tier).

Table 11.1: Worker-RCR-long term inhalation for single tasks
(Worker-DNEL long-term inhalation: 1,2mg B/m^3)

Single tasks	Substance	Inhal. exposure to boron [mg B/m^3]		RCR- long term inhalation [ ]	
		Typ.	RWC	Typ.	RWC
Discharging borates from ships	$B(OH)_3$	4,81	8,74	4,01	7,28
	$Na_2B_4O_7$	5,91	10,75	4,93	8,96
	$Na_2B_4O_7 \cdot 5H_2O$	4,08	7,43	3,40	6,19
	$Na_2B_4O_7 \cdot 10H_2O$	NR	NR	NR	NR
Discharging borates from big bags	$B(OH)_3$	0,61	0,88	0,51	0,73
	$Na_2B_4O_7$	0,75	1,08	0,63	0,89
	$Na_2B_4O_7 \cdot 5H_2O$	0,52	0,74	0,43	0,62
	$Na_2B_4O_7 \cdot 10H_2O$	0,40	0,57	0,33	0,48
(Un)loading borates into/from tankers	$B(OH)_3$	0,35	0,61	0,29	0,51
	$Na_2B_4O_7$	0,42	0,75	0,36	0,63
	$Na_2B_4O_7 \cdot 5H_2O$	0,30	0,52	0,25	0,43
	$Na_2B_4O_7 \cdot 10H_2O$	NR	NR	NR	NR
Packaging into bulk bags	$B(OH)_3$	0,61	0,88	0,51	0,73
	$Na_2B_4O_7$	0,75	1,08	0,63	0,89
	$Na_2B_4O_7 \cdot 5H_2O$	0,52	0,74	0,43	0,62
	$Na_2B_4O_7 \cdot 10H_2O$	0,40	0,57	0,33	0,47
Packaging into 25kg bags	$B(OH)_3$	0,61	0,79	0,51	0,66
	$Na_2B_4O_7$	0,75	0,97	0,63	0,81
	$Na_2B_4O_7 \cdot 5H_2O$	0,52	0,67	0,43	0,56
	$Na_2B_4O_7 \cdot 10H_2O$	0,40	0,51	0,33	0,43
Discharging 25kg bags or similar	$B(OH)_3$	0,61	0,79	0,51	0,66
	$Na_2B_4O_7$	0,75	0,97	0,63	0,81
	$Na_2B_4O_7 \cdot 5H_2O$	0,52	0,67	0,43	0,56
	$Na_2B_4O_7 \cdot 10H_2O$	0,40	0,51	0,33	0,43
Packaging liquids containing borates	$B(OH)_3$	NR	NR	NR	NR
	$Na_2B_4O_7$	NR	NR	NR	NR
	$Na_2B_4O_7 \cdot 5H_2O$	NR	NR	NR	NR
	$Na_2B_4O_7 \cdot 10H_2O$	NR	NR	NR	NR
Cleaning (i) Sweeping	$B(OH)_3$	1,75	7,87	1,46	6,56
	$Na_2B_4O_7$	2,15	9,67	1,79	8,06
	$Na_2B_4O_7 \cdot 5H_2O$	1,48	6,68	1,24	5,57
	$Na_2B_4O_7 \cdot 10H_2O$	1,13	5,10	0,94	4,25
Cleaning (ii) Vacuuming	$B(OH)_3$	0,02	0,09	0,02	0,08
	$Na_2B_4O_7$	0,02	0,11	0,02	0,09

	$Na_2B_4O_7 \cdot 5H_2O$	0,01	0,07	0,01	0,06
	$Na_2B_4O_7 \cdot 10H_2O$	0,01	0,06	0,01	0,05
Installation of glass fibre insulation	B	0,002	0,008	0,00	0,01

$B(OH)_3$ Boric acid; **$Na_2B_4O_7$** Sodium tetraborate anhydrous; **$Na_2B_4O_7 \cdot 5H_2O$** Sodium tetraborate pentahydrate; **$Na_2B_4O_7 \cdot 10H_2O$** Sodium tetraborate decahydrate; **NR: Not Relevant**

Worker RCR long term dermal for single tasks

Table 11.2 presents the calculated Worker RCRs long term dermal for single tasks. The given dermal exposure levels to boron (mgB/d) are derived from EASE-calculated dermal dust exposures and refer to the boron content of the applied substance and 960cm^2 exposed skin area (default, hands, face and upper surface of forearms; Guidance on IR and CSA, chapter R. 14, table R. 14-4). It is also considered for the calculation of the dermal RCRs that only a small amount of the deposited boron penetrates the skin and is available for the human body. (A dermal absorption of 0,5% is applied for risk characterization calculations (chapter 5.1). The RCRs refer to a Worker DNEL-long term dermal of 16,1mgB/d (70kg body weight, default for worker; which is equal to 0,23mgB/kg bw/d).

As already mentioned in the section before, the Worker DNEL-long term dermal refers to an activity taking the whole day shift of worker, therefore the RCRs might not be applicable for workers carrying out several tasks per days- in this case, the results from the mixed exposures should be preferred- but identify the scenarios revealing the greatest potential for risk.

The Worker RCRs-long term dermal for all scenarios and substances reported in table 11.2 are well below 1. Considering only this fact, control of risk is demonstrated for dermal exposure of workers, but it must be borne in mind, that inhalation and dermal exposures occur together during each of these scenarios. As inhalation exposure is significant for some scenarios, the derived dermal exposures contribute also an important part to the total amount of exposure. The combined Worker RCR long term inh. + derm., which considers both uptake routes can be calculated by summation of the relevant RCRs (table 11.1 and 11.2) for the same task and substance.

The assumed dermal exposure levels and the referring RCRs for the given tasks are probably too high as the exposure values base only on a first tier exposure assessment. Protection through gloves was not considered for the EASE derived values and gloves are a common PPE for these tasks. This would result in a significant reduction of the given RCRs as exposure of these tasks is estimated to occur especially via hands.

Table 11.2: Worker-RCR-long term dermal for single tasks (Worker-DNEL long-term dermal: 16,1mg B/d (0,23mg B/kg bw/d; 70kg bw default))

Single tasks	Substance	Derm. exposure to B (Exp. to 960 cm^2, default) [mgB/d]		B- intake (0,5% derm. absorption) [mg B/d]		RCR- long term dermal [ ]	
		Typ.	RWC	Typ.	RWC	Typ.	RWC
Discharging borates from ships	$B(OH)_3$	92,3	167,8	0,46	0,84	0,03	0,05
	$Na_2B_4O_7$	113,5	206,4	0,57	1,03	0,04	0,06
	$Na_2B_4O_7 \cdot 5H_2O$	78,1	142,0	0,39	0,71	0,02	0,04
	$Na_2B_4O_7 \cdot 10H_2O$	NR	NR	NR	NR	NR	NR
Discharging borates from big bags	$B(OH)_3$	92,4	168,0	0,46	0,84	0,03	0,05
	$Na_2B_4O_7$	113,5	206,4	0,57	1,03	0,04	0,06
	$Na_2B_4O_7 \cdot 5H_2O$	78,1	142,0	0,39	0,71	0,02	0,04
	$Na_2B_4O_7 \cdot 10H_2O$	59,7	105,6	0,30	0,54	0,02	0,03
(Un)loading borates into/from tankers	$B(OH)_3$	16,8	92,4	0,08	0,46	0,01	0,03
	$Na_2B_4O_7$	20,6	113,5	0,10	0,57	0,01	0,04
	$Na_2B_4O_7 \cdot 5H_2O$	14,2	78,4	0,07	0,39	0,00	0,02
	$Na_2B_4O_7 \cdot 10H_2O$	NR	NR	NR	NR	NR	NR
Packaging into bulk bags	$B(OH)_3$	16,8	168,0	0,08	0,84	0,01	0,05
	$Na_2B_4O_7$	20,6	206,0	0,10	1,03	0,01	0,06
	$Na_2B_4O_7 \cdot 5H_2O$	14,2	142,0	0,07	0,71	0,00	0,04
	$Na_2B_4O_7 \cdot 10H_2O$	10,8	108,0	0,05	0,54	0,00	0,03

$B(OH)_3$ Boric acid; **$Na_2B_4O_7$** Sodium tetraborate anhydrous; **$Na_2B_4O_7 \cdot 5H_2O$** Sodium tetraborate pentahydrate; **$Na_2B_4O_7 \cdot 10H_2O$** Sodium tetraborate decahydrate; **NR: Not Relevant**

Table 11.2: Worker-RCR-long term dermal for single tasks (Worker-DNEL long-term dermal: 13,8mg B/d (0,23mg B/kg bw/d; 70kg bw default))

Single tasks	Substance	Derm. exposure to B (Exp. to 960 cm^2, default) [mgB/d]		B- intake (0,5% derm. absorption) [mgB/d]		RCR- long term dermal [ ]	
		Typ.	RWC	Typ.	RWC	Typ.	RWC
Packaging into 25kg bags	$B(OH)_3$	92,4	151,2	0,46	0,76	0,03	0,05
	$Na_2B_4O_7$	113,5	185,8	0,57	0,93	0,04	0,06
	$Na_2B_4O_7{\cdot}5H_2O$	78,1	127,9	0,39	0,64	0,02	0,04
	$Na_2B_4O_7{\cdot}10H_2O$	59,7	97,6	0,30	0,49	0,02	0,03
Discharging 25kg bags or similar	$B(OH)_3$	92,4	151,2	0,46	0,76	0,03	0,05
	$Na_2B_4O_7$	113,5	185,7	0,57	0,93	0,04	0,06
	$Na_2B_4O_7{\cdot}5H_2O$	78,1	127,9	0,39	0,64	0,02	0,04
	$Na_2B_4O_7{\cdot}10H_2O$	59,7	97,6	0,30	0,49	0,02	0,03
Packaging liquids containing borates	$B(OH)_3$	5,0	9,1	0,03	0,05	0,00	0,00
	$Na_2B_4O_7$	6,2	11,1	0,03	0,06	0,00	0,00
	$Na_2B_4O_7{\cdot}5H_2O$	4,3	7,7	0,02	0,04	0,00	0,00
	$Na_2B_4O_7{\cdot}10H_2O$	3,3	5,9	0,02	0,03	0,00	0,00
Cleaning (i) Sweeping	$B(OH)_3$	33,6	151,0	0,17	0,76	0,01	0,05
	$Na_2B_4O_7$	41,3	185,8	0,21	0,93	0,01	0,06
	$Na_2B_4O_7{\cdot}5H_2O$	28,4	128,0	0,14	0,64	0,01	0,04
	$Na_2B_4O_7{\cdot}10H_2O$	21,7	97,6	0,11	0,49	0,01	0,03
Cleaning (ii) Vacuuming	$B(OH)_3$	1,7	15,1	0,01	0,08	0,00	0,00
	$Na_2B_4O_7$	2,1	18,6	0,01	0,09	0,00	0,01
	$Na_2B_4O_7{\cdot}5H_2O$	1,4	12,8	0,01	0,06	0,00	0,00
	$Na_2B_4O_7{\cdot}10H_2O$	1,1	9,8	0,01	0,05	0,00	0,00

Worker RCR long term inhalation for “Mixed Exposures”

The term “Mixed Exposures” relates to a worker’s day shift, which consists of several different tasks handling one specific compound and also tasks with no exposure to boron. Typical “Mixed Exposure”-scenarios for the concerned industries have been developed base on the results of the questionnaires and are considered to be more representative for day shift of a worker than single tasks. The composition of these scenarios and the EASE derived exposure estimations are given in chapter 9.1.5.10-11. The Worker RCRs- long term inhalation for mixed exposures are presented in table 11.3 and refer to a Worker DNEL long term inhalation of 1,2mg B/m^3 (chapter 5.11).

The reasonable worst case RCRs for scenario “M/I 2” are significantly above 1 and the typical RCR are close to 1 for sodium tetraborate anhydrous and boric acid, therefore no general control of risk is demonstrated for this scenario. “M/I 1” reveals lower RCRs in comparison with “M/I “, The RWC-values of “M/I 1” are above 1 for tetraborate anhydrous and boric acid and below 1 for sodium tetraborate pentahydrate and sodium tetraborate decahydrate. Therefore, control of risk is demonstrated for at least two of the four substances. A major reason for these high RCR-values base on the scenario “Cleaning by sweeping”, which is part of the mixed exposures “M/I 1” and “M/I 2“. Furthermore, “M/I 2“ includes “Discharging borates from ships”, which is also a scenario with a high calculated exposure level.

The “Mixed Exposure”-scenarios “Glass and Ceramics DU” and “Industrial Fluids DU” are based on a smaller number of questionnaires than the two other scenarios, therefore it’s not validated, if they are representative for these industries. Despite of that, it seems to be obvious and reasonable that the level of exposure is smaller than for the M/I-scenarios, which is indicated by significantly lower RCRs. All of these scenarios are below 1 for all substances.

Table 11.3: Worker-RCR-long term inhalation for “mixed exposure”-scenarios (Worker-DNEL long-term inhalation: 1,2mg B/m^3)

Mixed Exposures	Substance	Inhal. exposure to boron [mgB/m^3]		RCR- long term inhalation [ ]	
		Typ.	RWC	Typ.	RWC
M/I 1	$B(OH)_3$	0,49	1,36	0,41	1,14
	$Na_2B_4O_7$	0,60	1,68	0,50	1,40
	$Na_2B_4O_7 \cdot 5H_2O$	0,41	1,15	0,35	0,97
	$Na_2B_4O_7 \cdot 10H_2O$	0,32	0,88	0,26	0,74
M/I 2	$B(OH)_3$	0,98	2,25	0,82	1,88
	$Na_2B_4O_7$	1,20	2,77	1,00	2,31
	$Na_2B_4O_7 \cdot 5H_2O$	0,83	1,92	0,69	1,60
	$Na_2B_4O_7 \cdot 10H_2O$	0,64	1,46	0,53	1,22
Glass and Ceramics DU	$B(OH)_3$	0,11	0,66	0,09	0,55
	$Na_2B_4O_7$	0,14	0,81	0,11	0,68
	$Na_2B_4O_7 \cdot 5H_2O$	0,09	0,56	0,08	0,47
	$Na_2B_4O_7 \cdot 10H_2O$	0,07	0,43	0,06	0,36
Industrial Fluids DU	$B(OH)_3$	0,15	0,54	0,12	0,45
	$Na_2B_4O_7$	0,18	0,67	0,15	0,56
	$Na_2B_4O_7 \cdot 5H_2O$	0,12	0,46	0,10	0,38
	$Na_2B_4O_7 \cdot 10H_2O$	0,10	0,35	0,08	0,29

Worker RCR long term dermal for “Mixed Exposures”

The Worker RCRs long term dermal for “Mixed Exposures” (table 11.4) are calculated like for the single tasks. The presented RCRs are well below 1 for all scenarios and substances. Despite of that, it is assumed that the dermal exposure levels and the referring RCRs for the given tasks are too high, because the effect of gloves was not considered for the EUSES derived values and gloves are a common PPE for these industries. This would result in a significant reduction of the given RCRs as exposure of these tasks is estimated to occur especially to the hands.

Table 11.4: Worker-RCR-long term dermal for mixed exposures (Worker-DNEL long-term dermal: 16,1mg B/d (0,23mg B/kg bw/d; 70kg bw default))

Mixed exposures	Substance	Derm. exposure to B (Exp. to 960 cm^2, default) [mgB/d]		B- intake (0,5% derm. absorption) [mg B/d]		RCR- long term dermal [ ]	
		Typ.	RWC	Typ.	RWC	Typ.	RWC
M/I 1	$B(OH)_3$	83,90	172,84	0,42	0,86	0,03	0,05
	$Na_2B_4O_7$	103,15	212,49	0,52	1,06	0,03	0,07
	$Na_2B_4O_7\cdot5H_2O$	71,28	146,84	0,36	0,73	0,02	0,05
	$Na_2B_4O_7\cdot10H_2O$	54,43	112,13	0,27	0,56	0,02	0,03
M/I 2	$B(OH)_3$	90,62	209,76	0,45	1,05	0,03	0,07
	$Na_2B_4O_7$	111,40	257,88	0,56	1,29	0,03	0,08
	$Na_2B_4O_7\cdot5H_2O$	76,98	178,20	0,38	0,89	0,02	0,06
	$Na_2B_4O_7\cdot10H_2O$	58,79	136,08	0,29	0,68	0,02	0,04
Glass & Ceramics DU	$B(OH)_3$	8,39	20,14	0,04	0,10	0,00	0,01
	$Na_2B_4O_7$	10,32	24,76	0,05	0,12	0,00	0,01
	$Na_2B_4O_7\cdot5H_2O$	7,13	17,11	0,04	0,09	0,00	0,01
	$Na_2B_4O_7\cdot10H_2O$	5,44	13,06	0,03	0,07	0,00	0,00
Industrial Fluids DU	$B(OH)_3$	11,75	63,77	0,06	0,32	0,00	0,02
	$Na_2B_4O_7$	14,44	78,40	0,07	0,39	0,00	0,02
	$Na_2B_4O_7\cdot5H_2O$	9,98	54,17	0,05	0,27	0,00	0,02
	$Na_2B_4O_7\cdot10H_2O$	7,62	41,37	0,04	0,21	0,00	0,01

Combination of “Mixed Exposure”-scenarios for occupational exposure

The described scenarios reveal exposure to workers via inhalational and dermal route at the same time. Therefore, Worker RCRs-long term systemic (resp. Worker RCRs-long term (inh. + derm.) are derived by addition of the relevant inhalational and dermal RCRs. These values describe the total risk due to inhalational and dermal exposure of a scenario. The results for mixed exposures are presented in table 11.5 as they are more representative for the day shift of a worker than the single tasks. The Worker RCRs-long term systemic for single tasks can be easily derived by addition of the relevant inhalational and dermal Worker RCRs long term (table 11.1-2). Futhermore, it should be considered that boric acid and sodium tetraborate penthahydrate represent the largest part of the total use volumes (table 2.2) and therefore exposure to them is more likely and likely to occur more often than to sodium tetraborate anhydrous and sodium tetraborate decahydrate.

Most presented RCRs-long term systemic are higher than 1 or at least close to 1 for the “M/I”-scenarios for the reasonable worst cases. The relevant typical values are below 1. Being conservative no control of risk is demonstrated except for sodium tetraborate decahydrate applied according to scenario “M/I 1”. As already mentioned in the previous discussion, these values are expected to be overestimating exposure and need to be reduced by an advanced assessment and higher tier approach. The derived “Mixed Exposure”-scenarios for downstream users (DU) reveal control of risk for all four substances without any exception.

Table 11.5: Worker-RCR-long term systemic for mixed exposures

Mixed Exposures	Substance	Worker RCR long term (inh. + derm.) [ ]	
		Typical	RWC
M/I 1	$B(OH)_3$	0,43	1,19
	$Na_2B_4O_7$	0,53	1,46
	$Na_2B_4O_7{\cdot}5H_2O$	0,37	1,01
	$Na_2B_4O_7{\cdot}10H_2O$	0,28	0,77
M/I 2	$B(OH)_3$	0,84	1,94
	$Na_2B_4O_7$	1,04	2,39
	$Na_2B_4O_7{\cdot}5H_2O$	0,72	1,65
	$Na_2B_4O_7{\cdot}10H_2O$	0,55	1,26
Glass & Ceramics DU	$B(OH)_3$	0,09	0,56
	$Na_2B_4O_7$	0,12	0,68
	$Na_2B_4O_7{\cdot}5H_2O$	0,08	0,47
	$Na_2B_4O_7{\cdot}10H_2O$	0,06	0,36
Industrial Fluids DU	$B(OH)_3$	0,13	0,47
	$Na_2B_4O_7$	0,15	0,58
	$Na_2B_4O_7{\cdot}5H_2O$	0,11	0,40
	$Na_2B_4O_7{\cdot}10H_2O$	0,08	0,31

Worker RCR short term inhalation for single tasks

The worker RCRs- short term inhalation refer to a worker DNEL- short term inhalation of 0,8 mgB/m^3. The given concentrations of boron in air for the different scenarios are derived from the EASE-derived airborne particle concentrations (table 11.6). Short term exposure refers to a duration of 15min, the average concentration within this period of time should not exeed the given DNEL. All presented tasks are likely to take longer than 15min and are within the scope. Most RCR- values for the typical- and RWC cases are close to, higher or significantly higher. Some tasks demonstrate control of risk for each of the four substances. Other tasks reveal control of risk only for some of the presented substances and “Discharging borates from ships” and “Cleaning by sweeping show no control of risk at all. It is assumed by industry that the EASE-derived concentrations are overestimating exposure. Therefore a further refinement (tier 2) of the exposure scenarios is needed to support this assumption as already described for the worker RCRs- long term inhalation (2nd Tier approach).

Table 11.6: Worker-RCR-short term inhalation for single tasks
(Worker-DNEL short-term inhalation: 0,8mg B/m^3)

Single tasks	Substance	Inhal. exposure to boron [mgB/m^3]		RCR- short term inhalation [ ]	
		Typ.	RWC	Typ.	RWC
Discharging borates from ships	$B(OH)_3$	4,81	8,74	6,01	10,93
	$Na_2B_4O_7$	5,91	10,75	7,39	13,43
	$Na_2B_4O_7 \cdot 5H_2O$	4,08	7,43	5,10	9,28
	$Na_2B_4O_7 \cdot 10H_2O$	NR	NR	NR	NR
Discharging borates from big bags	$B(OH)_3$	0,61	0,87	0,76	1,09
	$Na_2B_4O_7$	0,75	1,07	0,94	1,34
	$Na_2B_4O_7 \cdot 5H_2O$	0,52	0,74	0,65	0,93
	$Na_2B_4O_7 \cdot 10H_2O$	0,40	0,57	0,50	0,71
(Un)loading borates into/from tankers	$B(OH)_3$	0,35	0,61	0,44	0,76
	$Na_2B_4O_7$	0,43	0,75	0,54	0,94
	$Na_2B_4O_7 \cdot 5H_2O$	0,30	0,52	0,37	0,65
	$Na_2B_4O_7 \cdot 10H_2O$	NR	NR	NR	NR
Packaging into bulk bags	$B(OH)_3$	0,61	0,87	0,76	1,09
	$Na_2B_4O_7$	0,75	1,07	0,94	1,34
	$Na_2B_4O_7 \cdot 5H_2O$	0,52	0,74	0,65	0,93
	$Na_2B_4O_7 \cdot 10H_2O$	0,40	0,57	0,50	0,71
Packaging into 25kg bags	$B(OH)_3$	0,61	0,79	0,76	0,98
	$Na_2B_4O_7$	0,75	0,97	0,94	1,21
	$Na_2B_4O_7 \cdot 5H_2O$	0,52	0,67	0,65	0,84
	$Na_2B_4O_7 \cdot 10H_2O$	0,40	0,51	0,50	0,64
Discharging 25kg bags or similar	$B(OH)_3$	0,61	0,79	0,76	0,98
	$Na_2B_4O_7$	0,75	0,97	0,94	1,21
	$Na_2B_4O_7 \cdot 5H_2O$	0,52	0,67	0,65	0,84
	$Na_2B_4O_7 \cdot 10H_2O$	0,40	0,51	0,50	0,64
Packaging liquids containing borates	$B(OH)_3$	NR	NR	NR	NR
	$Na_2B_4O_7$	NR	NR	NR	NR
	$Na_2B_4O_7 \cdot 5H_2O$	NR	NR	NR	NR
	$Na_2B_4O_7 \cdot 10H_2O$	NR	NR	NR	NR
Cleaning (i) Sweeping	$B(OH)_3$	1,75	7,87	2,19	9,83
	$Na_2B_4O_7$	2,15	9,67	2,69	12,09
	$Na_2B_4O_7 \cdot 5H_2O$	1,49	6,68	1,86	8,35
	$Na_2B_4O_7 \cdot 10H_2O$	1,13	5,10	1,42	6,38
Cleaning (ii) Vacuuming	B(OH)3	0,02	0,09	0,02	0,11
	$Na_2B_4O_7$	0,02	0,11	0,03	0,13
	$Na_2B_4O_7 \cdot 5H_2O$	0,01	0,07	0,02	0,09
	$Na_2B_4O_7 \cdot 10H_2O$	0,01	0,06	0,01	0,07
Installation of glass fibre insulation	B	0,00	0,01	0,00	0,01

$B(OH)_3$ Boric acid; **$Na_2B_4O_7$** Sodium tetraborate anhydrous; **$Na_2B_4O_7 \cdot 5H_2O$** Sodium tetraborate pentahydrate; **$Na_2B_4O_7 \cdot 10H_2O$** Sodium tetraborate decahydrate; **NR: Not Relevant**

11.1.2 Risk characterization for indirect exposure via the environment

The RCRs- long term systemic for general public via local and regional environment are presented in the tables 11.7 and 11.8. The derivation of the boron uptake is described in chapter 9.3 and refers to the uptake of an adult. The DNEL- long term systemic for the general public is 0,12mg B/kg bw/day. For comparing this value with the boron uptake of an adult (mg B/day), a default value of 60kg body weight is assumed, resulting in a DNEL-long term systemic for an adult of 7,2mg B/day.

The tables reveal that the inhalation of air and the ingestion of soil lead to a negligible uptake of boron in comparison with the uptake of boron via food respectively water consumption. The regional RCRs for general population range from 0,32 to 0,55 for the regional environment and from 0,65 to 0,66 for the local values. No risk is identified under these circumstances for the general population. Despite of that the uptake via the environment mainly food and drinking water is significant: 32% to 55% and. 65% to 66% of the DNEL (7,2mg B/day) for respectively the regional and the local environment. It should however be noted that the higher exposure value for the regional environment is not based on monitoring data for drinking water but on the EU drinking water limit for boron, a limit which is 2,5 times the reported average concentration in the EU. On the other hand, there is no limit for boron in mineral water. As it usually contains more boron than drinking water and its consumption instead of drinking water is widespread, the EU drinking water limit was chosen. This assumption was also made for the local environment. In addition for the local environment, boron concentrations in food were derived from literature data for a mining area where boron concentrations in soil and air are much higher than those found at local environments around plants in the EU and using the food basket described in the TGD (2003).

As already mentioned in the man via environment section, boron concentration in food and water can differ significantly, depending on their origin and the diet habits of individuals. Therefore it can’t be excluded that even higher uptakes of boron can occur. The boron uptake of children and infants is not considered.

Table 11.7: Regional- Man via environment

Source	Boron uptake [mgB/day]		RCR-long term systemic for general population [ ]	
	Range		Range	
Air		**0,00**	**0,00**	**0,00**
Soil	**0,00**	**0,00**	**0,00**	**0,00**
Dietary intake	**1,50**	**1,94**	**0,21**	**0,27**
Drinking resp. mineral water	**0,80**	**2,00**	**0,11**	**0,28**
Daily uptake via environment	**2,30**	**3,94**	**0,32**	**0,55**

Table 11.8: Local- Man via environment

Source	Boron uptake [mgB/day]		General population RCR-long term systemic [ ]	
	Range		Range	
Air		**0,04**	**0,00**	**0,01**
Soil	**0,00**	**0,00**	**0,00**	**0,00**
Dietary intake	**2,70**	**2,70**	**0,38**	**0,38**
Drinking resp. mineral water	**2,00**	**2,00**	**0,28**	**0,28**
Daily uptake via environment	**4,70**	**4,74**	**0,65**	**0,66**

11.1.3 Risk characterization for exposure via consumer products

The risk-characterisation assessment for boron exposure via consumer products was not derived due to the lack of information on all possible applications. Referring to the consumer exposure section, exposure to man via glass and ceramics is small and negligible in comparison with other sources. A study on borates in consumer products was carried out on behalf of the commission. The results will be publicly available on the commission's website. However, they were not available at the time when this dossier was finalized.

11.1.4 Aggregated exposure (combination of occupational exposure and exposure of man via environment)

As boron is a natural occurring element and is contained to a significant extent in food and drinking water, these natural boron sources must be considered for the exposure estimation of workers due to boron. Table 11.9 and 11.10 reveal the aggregated RCRs for workers via occupational and natural exposure. The values are derived by summing up the relevant Worker RCR- long term (inh. + derm.) of a "mixed exposure"-scenario and the General population RCR-long term systemic of interest (regional resp. local).

Table 11.9 contains the aggregated RCRs for boric acid and sodium tetraborate pentahydrate as these two substances represent the major total use volumes. Therefore, exposure to them is most likely. The derived values refer to the typical Worker RCR-long term (inhal. + derm.) values and are partially below but mainly above 1 for the M/I- mixed scenarios and below 1 without exception for the DU-scenarios "Glass and Ceramics" and "Industrial Fluids".

Table 11.10 presents the aggregated RCRs for the reasonable worst case Worker RCRs long term (inhal. + derm.) which have been derived for the given "Mixed Exposure"-scenarios. At least one of the values of a scenario is above 1. This is valid for boric acid and sodium tetraborate pnethydrate. Therefore no control of risk is demonstrated for all "mixed exposure"-scenarios considering these results.

The exposure of boron via consumer products is not considered for this calculation, as little information about the scenarios and the referring total uptake is available for this transitional dossier. This needs to be covered by industry in their registration dossier.

Table 11.9: Aggregated RCRs for worker via environment (typical exposure of workers)

"Mixed Exposure"-scenarios for workers		Aggregated RCRs-worker and general population (Worker RCR-long term (inhal. + derm.) + General population RCR-long term systemic)			
Mixed Exposures	**Substance**	**Man via environment Regional [ ]**		**Man via environment Local [ ]**	
M/I 1	$B(OH)_3$	0,75	0,98	1,09	1,09
M/I 1	$Na_2B_4O_7 \cdot 5H_2O$	0,69	0,92	1,02	1,03
M/I 2	$B(OH)_3$	1,16	1,39	1,50	1,50
M/I 2	$Na_2B_4O_7 \cdot 5H_2O$	1,04	1,26	1,37	1,37
Glass & Ceramics DU	$B(OH)_3$	0,41	0,64	0,75	0,75
Glass & Ceramics DU	$Na_2B_4O_7 \cdot 5H_2O$	0,40	0,63	0,73	0,74
Ind. Fluids DU	$B(OH)_3$	0,45	0,67	0,78	0,78
Ind. Fluids DU	$Na_2B_4O_7 \cdot 5H_2O$	0,43	0,65	0,76	0,76

Table 11.10: Aggregated RCRs for worker via environment (RWC exposure of workers)

“Mixed Exposure”-scenarios for workers		Aggregated RCRs-worker and general population (Worker RCR-long term (inhal. + derm.) + General population RCR-long term systemic)			
Mixed Exposures	**Substance**	**Man via environment Regional [ ]**		**Man via environment Local [ ]**	
M/I 1	$B(OH)_3$	1,51	1,74	1,84	1,85
M/I 1	$Na_2B_4O_7 \cdot 5H_2O$	1,33	1,56	1,66	1,67
M/I 2	$B(OH)_3$	2,26	2,49	2,60	2,60
M/I 2	$Na_2B_4O_7 \cdot 5H_2O$	1,97	2,20	2,30	2,31
Glass & Ceramics DU	$B(OH)_3$	0,88	1,10	1,21	1,21
Glass & Ceramics DU	$Na_2B_4O_7 \cdot 5H_2O$	0,79	1,02	1,13	1,13
Ind. Fluids DU	$B(OH)_3$	0,79	1,02	1,12	1,13
Ind. Fluids DU	$Na_2B_4O_7 \cdot 5H_2O$	0,72	0,95	1,05	1,06

11.1.5 Overall conclusion

Conclusion (i) is reached because:

- There is a need for better information to adequately characterize the risks to workers and consumers from boron exposure via boric acid and sodium tetraborates.

The information requirements are:

- Information on occupational exposure for producing/importing processing sites, downstream user and consumer applications.

11.2 Environment

11.2.1 Methodology

B is a naturally occurring element, and B concentrations differ, depending on geography, climate and parent material. In order to deal with the presence of a natural background, various concepts have been developed, such as the *Added Risk approach (Added RA) and the Total Risk approach (Total RA)* concepts. In essence the Added RA assumes that species are fully adapted to the natural background concentration and therefore that only the anthropogenic added fraction should be regulated or controlled. The Total RA assumes that "exposure" and "effects" should be compared on the combination of the natural background and the added anthropogenic concentrations. The decision for using one of them is based on how the background level relates to the derived PNEC value (Guidance on IR and CSA, Chapter R.7 APPENDIX R.7.13-2 – METALS).

Sufficient information is not available to describe quantitatively the natural background concentration. Therefore no scientific based decision for using neither the Added RA nor the Total RA could be made. There is inadequate knowledge of the natural Boron concentration in water, sediment and soil in Europe. Due to the lack of data on background concentrations the Added RA was chosen in the following Risk Characterisation. There is also insufficient knowledge to incorporate bioavailability.

In the Added RA both the "Predicted Environmental Concentration" (PEC) and the "Predicted No Effect Concentration" (PNEC) are expressed as B added by man, resulting in an "added Predicted environmental Concentration" (PECadd) and "added Predicted No Effect Concentration" (PNEC add), respectively. The use of the Added RA implies that only the anthropogenic amount of a substance, i.e. the amount added to the natural background concentration, is considered to be relevant for the risk characterisation of that substance.

At the current stage exposure data are not sufficient. The exposure assessment is only a first Tier assessment based on information collected by Industry through questionnaires on tonnages and process descriptions of manufacturers and users. As no data were available on emission factors and as no local monitoring was available, local environmental concentrations were calculated using EUSES and the default emission factors from the TGD A-tables. A further Tier risk assessment needs to be performed before any decisive conclusions can be made whether there are risks for the environment related to the production or use of borates.

Therefore it is foreseen that industry will collect extensive monitoring data as well as information on anthropogenic input and further hazard data for their registration dossier under REACH. For more information on the work planned by industry. For these reasons the present risk characterisation can only be seen as a preliminarily version.

11.2.2 Spatial scales

For most environmental endpoints, a RCR is calculated at both the regional and the local spatial scale. For STP micro-organisms, however, only the local scale is assessed since these organisms are exposed to the concentration in the STP.

11.2.3 Local Scale

The PECadd local (PECadd local = PECadd regional + C local) value is compared to the derived PNECadd for the local risk characterisation and the paired PECadd/PNECadd ratio are derived.

Aquatic compartment

Inland

STP

The PNECadd-stp for sewage treatment plants (STP) was determined to be 1.75 mg B/l. This value is used for risk assessment in STP's. The calculation of the different PEC values can be found in the local environmental exposure part. PEC/PNEC ratios in the STP are presented intable 11.11 from different uses for generic and specific assessment. It is assumed that 0% Boron is removed in the STP: PECadd stp = Ceffluent (default fractions: Fsludge = 0; Fwater = 1)

Table 11.11 **Summary of calculated PECadd/PNECadd ratios for generic and specific assessment**

PNECadd stp = 1.75 mg B/l		**Generic assessment Default Tonnage**		**Specific assessment Individual Site Tonnage**	
Industry sector	**Life cycle stage**	**PECadd stp = Ceffluent [mg/l]**	**PECadd/PNECadd**	**PECadd stp = Ceffluent [mg/l]**	**PECadd/PNECadd**
Producers	Production/import	22.31	12.75	18.38 - 31.07	10.5 - 17.75
Borosilicate	Formulation	3.75 - 5.36	2.14 -3.06	2.81 - 9.7	1.61 - 5.54
IFG/TFG	Formulation	3.8 - 7.6	2.17- 4.34	0.89 - 3.45	0.51 - 1.97
Ceramics	Formulation	4.88 - 6.98	2.79 - 3.99	1.75 - 5.82	1.00 -3.33
Industrial fluids	Formulation	4.65	2.66	2.35 - 5.11	1.34 - 2.92
Metallurgy	Formulation	4.12	2.35	0.73 - 1.35	0.42 - 0.77
Flame retardants	Formulation	7.51	4.29	10.87	6.21
Detergents	Formulation	4.71	2.69	*	*
Cleaners	Formulation	0.29	0.17	*	*
Agriculture (fertilisers)	Formulation	1.74	0.99	0.52 - 1.93	0.30 - 1.10
Various chemical effects	Formulation	3.44	1.97	0.95 - 2.85	0.54 - 1.63
Borosilicate	Industrial use	44.67	25.53	161.67	92.38
IFG/TFG	Industrial use	47.5	27.14	57.44	32.82
Ceramics	Industrial use	58.13	33.22	97.06	55.46
Industrial fluids	Industrial use	7.75	4.43	5.11	2.92
Metallurgy	Industrial use	3.3	1.89	1.35	0.77
Flame retardants	Industrial use	0.375	0.21	0.38	0.22
Detergents	Private use	3.06	1.75	*	*
Cleaners	Private use	0.53	0.30	*	*
Agriculture (fertilisers)	Industrial use	4.36	2.49	*	*
Various chemical effects	Industrial use	5.43	3.10	6.66	3.81

*No site specific information available

Preliminary Conclusion: Nearly all PECadd/PNECadd ratios are >1, indicating a potential risk to micro-organisms in STP's. This section will have to be refined by industry for the registration dossier. Further work includes both improvement of the PEClocal and PNEC derivations.

Conclusion (i) is reached because:

- There is a need for better information to adequately characterize the risks to the STP system from the releases of boric acid and sodium tetraborates.

The information requirements are:

- Information on local exposure and emissions to the STPs for producing/importing and processing sites

- Good quality data, e.g. current boron concentrations of well functioning STPs and laboratory ecotoxicity data to improve the PNEC

Surface water

A PNECadd-freshwater of 180 µg B/L was derived. This value is used for the risk assessment in surface waters. $PEC_{add,water}/PNEC_{add,water}$ ratios in surface water are presented in Table.
As no local monitoring data are available at this stage, PECadds were calculated using EUSES 2.0.3 (EC, 2004) and default emission factors from the TGD A-tables, which assumes that concentrations in surface water are a factor 10 lower than in the STP due to dilution in the receiving surface water body. For surface water boron natural background concentrations are available (FOREGS maps, median value 15.6 µg B/l).

Table 11.12 Summary of calculated PECadd/PNECadd ratios for generic and specific assessment

PNECadd-water = 180 µg B/l		**Generic assessment Default Tonnage**		**Specific assessment Individual Site Tonnage**	
Industry sector	**Life cycle stage**	**PECadd-water [µg/l]****	**PECadd/PNECadd**	**PECadd-water [µg/l]****	**PECadd/PNECadd**
Producers	Production/import	2325.4	12.92	1933.4 - 3201.4	10.74 - 17.79
Borosilicate	Formulation	470.4 - 630.4	2.61 - 3.50	375.4 - 1064.4	2.09 - 5.91
IFG/TFG	Formulation	474.4 - 854.4	2.64 - 4.75	174.4 - 439.4	0.97 - .44
Ceramics	Formulation	582.4 - 791.4	3.24 - 4.40	269.4 - 677.4	1.50 - 3.76
Industrial fluids	Formulation	558.4	3.10	329.4 - 605.4	1.83 - 3.36
Metallurgy	Formulation	506.4	2.81	167.4 - 229.4	0.93 - 1.27
Flame retardants	Formulation	845.4	4.70	1181.4	6.56
Detergents	Formulation	565.4	3.14	*	*
Cleaners	Formulation	124.4	0.69	*	*
Agriculture (fertilisers)	Formulation	269.4	1.50	146.4 - 288.4	0.81 - 1.60
Various chemical effects	Formulation	438.4	2.44	189.4 - 380.4	1.05 - 2.11
Borosilicate	Industrial use	4561.4	25.34	16262.4	90.35
IFG/TFG	Industrial use	4834.4	26.86	5834.4	32.41
Ceramics	Industrial use	5907.4	32.82	9800.4	54.45
Industrial fluids	Industrial use	856.4	4.76	605.4	3.36
Metallurgy	Industrial use	425.4	2.36	229.4	1.27
Flame retardants	Industrial use	132.4	0.74	132.4	0.74
Detergents	Private use	401.4	2.23	*	0.00
Cleaners	Private use	147.4	0.82	*	0.00
Agriculture (fertilisers)	Industrial use	530.4	2.95	*	0.00
Various chemical effects	Industrial use	637.4	3.54	760.4	4.22

*No site specific information available **PECadd = PECadd regional + Clocal

Preliminary Conclusion: Nearly all PEC/PNEC ratios are >1, indicating a potential risk to organisms in surface water. This section will have to be refined by industry for the registration dossier. Further work includes both improvement of the PEClocal and PNEC derivations.

Conclusion (i) is reached because:

- There is a need for better information to adequately characterize the risks to the aquatic ecosystem from the releases of boric acid and sodium tetraborates.

The information requirements are:

- Information on local exposure and emissions to the aquatic compartment for producing/importing and processing sites
- Information on insects to improve the PNEC

Sediment

A PNECadd-sediment of 1.8 mg B/kg was derived from ecotoxicity data. This value is used for the risk assessment in the sediment compartment. As no local monitoring data are available at this stage, PECadds were calculated using EUSES 2.0.3 (EC, 2004) and default emission factors from the TGD A-tables.$PEC_{add\text{-}sediment}/PNEC_{add\text{-}sediment}$ ratios in sediment are presented in table 11.13.

Table 11.13 Summary of calculated PECadd/PNECadd ratios for generic and specific assessment

PNECadd-sediment = 1.8 mg B/kg dw		**Generic assessment Default Tonnage**		**Specific assessment Individual Site Tonnage**	
Industry sector	**Life cycle stage**	**PECadd-sediment [mg/kg dw]**	**PECadd/PNECadd**	**PECadd-sediment [mg/l dw]**	**PECadd/PNECadd**
Producers	Production/import	17.3	9.61	14.5 - 23.4	8.06 - 13
Borosilicate	Formulation	4.2 - 5.4	2.33 - 3.00	3.6 - 8.4	2.00 - 4.67
IFG/TFG	Formulation	4.3 - 6.9	2.39 - 3.83	2.2 - 4	1.22 - 2.22
Ceramics	Formulation	5 - 6.5	2.78 - 3.61	2.8 - 4	1.56 - 2.22
Industrial fluids	Formulation	4.9	2.72	3.3 - 5.2	1.83 - 2.89
Metallurgy	Formulation	4.5	2.50	2.1 - 2.5	1.17 - 1.39
Flame retardants	Formulation	6.9	3.83	9.2	5.11
Detergents	Formulation	4.9	2.72	*	*
Cleaners	Formulation	1.8	1.00	*	*
Agriculture (fertilisers)	Formulation	2.8	1.56	2 - 3	1.11 - 1.67
Various chemical effects	Formulation	4	2.22	*3.4*	1.28 - 1.89
Borosilicate	Industrial use	32.6	18.11	114.6	63.67
IFG/TFG	Industrial use	34.6	19.22	41.9	23.28
Ceramics	Industrial use	42.6	23.67	69.7	38.72
Industrial fluids	Industrial use	7	3.89	5.2	2.89
Metallurgy	Industrial use	3.9	2.17	2.5	1.39
Flame retardants	Industrial use	1.9	1.06	2	1.11
Detergents	Private use	3.8	2.11	*	*
Cleaners	Private use	2	1.11	*	*
Agriculture (fertilisers)	Industrial use	4.7	2.61	*	*
Various chemical effects	Industrial use	5.4	3.00	6.3	3.50

*No site specific information available

Preliminary Conclusion: Nearly all PEC/PNEC ratios are >1, indicating a potential risk to organisms in sediment. This section will have to be refined by industry for the registration dossier. Further work includes both improvement of the PEClocal and PNEC derivations.

Conclusion (i) is reached because:

- There is a need for better information to adequately characterize the risks to the sediment ecosystem from the releases of boric acid and sodium tetraborates.

The information requirements are:

- Information on local exposure and emissions to the sediment compartment for producing/importing and processing sites
- Good quality chronic data for the improvement of the PNEC are preferable.

Marine

A PNECmarine could not be estimated on the basis of marine species. Due to the high natural boron background of ~5mg B/L in the marine environment, it is likely that marine species are less sensitive than freshwater species. Derived PECmarine values are based on default emission values from the TGD A-tables and EUSES and no natural background concentrations have been considered. Therefore at this preliminary stage no risk characterisation can be performed.

Conclusion (i) is reached because:

- There is a need for better information to adequately characterize the risks to the marine ecosystem (including sediment), from the releases of boric acid and sodium tetraborates.

The information requirements are:

- Information on local exposure and emissions to the marine compartment (including sediment) for producing/importing and processing sites
- Good quality chronic data to derive a reliable PNEC as outlined in the according section.

Atmosphere

Due to the low volatility of the inorganic borates, emissions to air will be very low. Furthermore, no ecotoxicity data are available based on atmosphere so a PECadd-air/PNECadd-air for air cannot be calculated.

Terrestrial compartment

Confidence in this PECsoil values is limited. Monitoring data on natural background concentrations of boron in soils is needed for drawing a final conclusion. For future risk characterications, results from the ongoing GEMAS project should be taken into account.

Conclusion (i) is reached because:

- There is a need for better information to adequately characterize the risks to the terrestrial environment from the releases of boric acid and sodium tetraborates.

The information requirements are:

- Information on local exposure and emissions to the atmosphere for producing/importing and processing sites
- Good quality chronic data to improve the PNEC as outlined in the according section.

Secondary Poisoning

The potential for secondary poisoning is not significant (see PBT-chapter). Therefore a risk characterisation is not necessary.

11.2.4 Regional Scale

At this preliminary stage no regional risk characterization can be performed.

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C. AVAILABLE INFORMATION ON ALTERNATIVES

Section not relevant for this dossier

D. JUSTIFICATION FOR ACTION ON A COMMUNITY-WIDE BASIS

Section not relevant for this dossier

E. JUSTIFICATION WHY A RESTRICTION IS THE MOST APPROPRIATE COMMUNITY-WIDE MEASURE

Section not relevant for this dossier

F. SOCIO-ECONOMIC ASSESSMENT OF PROPOSED RESTRICTION(S)

Section not relevant for this dossier

G. STAKEHOLDER CONSULTATION

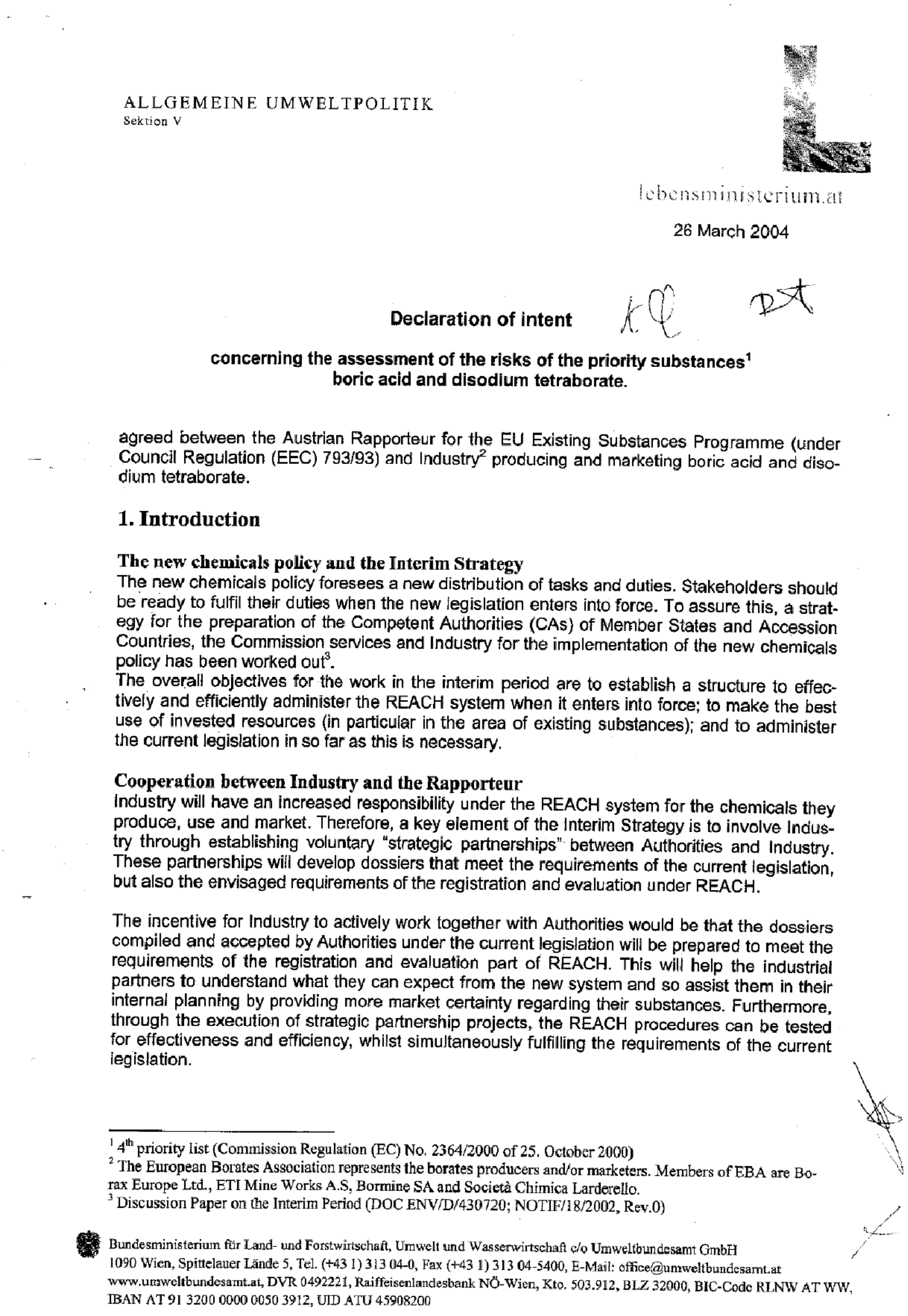
Section not relevant for this dossier

H. OTHER CONSULTATION

Section not relevant for this dossier

ANNEXES

Annex I: Declaration of intent



ALLGEMEINE UMWELTPOLITIK
Sektion V

lebensministerium.at

26 March 2004

Declaration of intent

concerning the assessment of the risks of the priority substances[1]
boric acid and disodium tetraborate.

agreed between the Austrian Rapporteur for the EU Existing Substances Programme (under Council Regulation (EEC) 793/93) and Industry[2] producing and marketing boric acid and disodium tetraborate.

1. Introduction

The new chemicals policy and the Interim Strategy
The new chemicals policy foresees a new distribution of tasks and duties. Stakeholders should be ready to fulfil their duties when the new legislation enters into force. To assure this, a strategy for the preparation of the Competent Authorities (CAs) of Member States and Accession Countries, the Commission services and Industry for the implementation of the new chemicals policy has been worked out[3].
The overall objectives for the work in the interim period are to establish a structure to effectively and efficiently administer the REACH system when it enters into force; to make the best use of invested resources (in particular in the area of existing substances); and to administer the current legislation in so far as this is necessary.

Cooperation between Industry and the Rapporteur
Industry will have an increased responsibility under the REACH system for the chemicals they produce, use and market. Therefore, a key element of the Interim Strategy is to involve Industry through establishing voluntary "strategic partnerships" between Authorities and Industry. These partnerships will develop dossiers that meet the requirements of the current legislation, but also the envisaged requirements of the registration and evaluation under REACH.

The incentive for Industry to actively work together with Authorities would be that the dossiers compiled and accepted by Authorities under the current legislation will be prepared to meet the requirements of the registration and evaluation part of REACH. This will help the industrial partners to understand what they can expect from the new system and so assist them in their internal planning by providing more market certainty regarding their substances. Furthermore, through the execution of strategic partnership projects, the REACH procedures can be tested for effectiveness and efficiency, whilst simultaneously fulfilling the requirements of the current legislation.

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[1] 4th priority list (Commission Regulation (EC) No. 2364/2000 of 25. October 2000)
[2] The European Borates Association represents the borates producers and/or marketers. Members of EBA are Borax Europe Ltd., ETI Mine Works A.S, Bormine SA and Società Chimica Larderello.
[3] Discussion Paper on the Interim Period (DOC ENV/D/430720; NOTIF/18/2002, Rev.0)

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For those priority high production volume chemicals that are in the current existing substances regulation process, the data requirements, testing strategies and derogation procedures can be tested.

The advantage for the Authorities will be to efficiently use and maintain the experience and knowledge of their experts in the interim period as well as to prepare themselves for their new role in the REACH system.

The Austrian Rapporteur intends to establish a strategic partnership with Industry representing the producers and marketers of boric acid and borax. It is proposed to apply the procedure of the future REACH system[2] taking into account the requirements of the current legislation. Doing so, the registration and evaluation part of REACH can be tested.

The declaration of intent on hand, describes the tasks and responsibilities of the Austrian Rapporteur and Industry in detail and will be agreed by both parties.

2. Tasks and responsibilities of Industry

Industry shall compile all information required for the registration and evaluation under REACH and required in the current legislation. Industry will submit a registration dossier consisting of a technical dossier and the Chemical Safety Report as defined in title II, Article 9, 11 and 13 in the REACH proposal[4].

The Austrian Rapporteur may ask for original study reports or reports on monitoring programs and other relevant activities in addition to those documents that have already been submitted.

Technical dossier

An updated IUCLID datafile will be accepted as technical dossier (including robust study summaries) for registration under REACH. Besides information in IUCLID, additional information on all uses of the substances as well as information on currently running or planned testing shall be submitted to the Rapporteur.

Chemical Safety Report

The Chemical Safety Report shall be prepared in accordance with the standards required for Risk Assessment under the current legislation (Council Regulation (EEC) 793/93) and shall include the following sections:

1. Substance identification and physico-chemical properties
2. Human health hazard assessment
3. Human health hazard assessment of physicochemical properties
4. Environmental hazard assessment
5. PBT and vPvB assessment
6. Exposure assessment
7. Risk characterisation
8. Appropriate measures to adequately control the risks identified in the Chemical Safety Report.

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[4] Proposal concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), presented by the European Commission; 29th October 2003)

According to the REACH proposal the Chemical Safety Report would only include the exposure assessment and the risk characteration in the case the substance meets the criteria for classification as dangerous (according to Directive 67/548/EEC) or it is considered to be a PBT or vPvB.
Nevertheless, in this exercise also the actual requirements for risk assessment shall be taken into account. Therefore, the exposure assessment and the risk characteration shall be performed regardless of the substances classification.

The Chemical Safety Report shall at least address those issues described in the Rapporteur's proposal for a TRA of boric acid and disodium tetraborate.

Industry may develop and submit parts of the risk assessment separately to the Rapporteur (the Exposure Assessment, Effect Assessment and Risk Characterisation for both the Environmental and the Human Health part).

For reporting the format currently used under the Existing Substances Programme shall be used.

3. Tasks and responsibilities of the Austrian Rapporteur

After submission of the registration dossier required under REACH, the Austrian Rapporteur shall perform the evaluation as defined in title VI, chapter 2 and 3, of the REACH proposal.
The Rapporteur will accept separate submission of parts of the Chemical Safety Report and may in this case evaluate the parts separately.

The Rapporteur may request additional information from Industry if needed for the evaluation process. The Rapporteur may ask Industry to revise specific chapters of the report if this is considered necessary. He will present the Chemical Safety Report in the relevant working group after agreement on all sections of the report with Industry.

In case of disagreement between the Rapporteur and Industry, the Rapporteur will submit to all Member States CAs:

- the Chemical Safety Report indicating the issues of discussion,
- the position of the Rapporteur, and
- the position of Industry.

Issues of disagreement shall be discussed within the relevant working groups. The Technical Meeting under 793/93/EEC shall take the place of the Member State Committee foreseen under REACH.

The final Chemical Safety Report may be published as foreseen under the current legislation.

4. Signature

for the Rapporteur:

Federal Ministry of Agriculture, Forestry, Environment and Water Management
Mr. Thomas Jakl

for Industry: (all EBA Members listed below)

BORAX EUROPE LTD
Mr. Kieran Quill

ETI MINE WORKS AS
Mr. Recep Akgündüz

BORMINE SA
Mr. Peter Treichler

SOCIETA CHIMICA LARDERELLO SPA
Mr. Paolo Bonini

Annex II: Identified data gaps and further work options to be considered during the preparation of the REACH dossiers for boric acid and sodium tetraborates

Grey areas indicate different points of view between rapporteur and industry

Human Health

Conclusion (i) is reached because:

There is a need for further information using newer techniques to:

- adequately characterize the risks to workers from the exposure to boric acid and sodium tetraborates;
- adequately characterize the risks to consumers from exposure to boric acid and sodium tetraborates in consumer products;
- address data gaps in fertility effects exposed to boric acid and sodium tetraborates; and
- adequately address relevance to humans of developmental effects observed in animal tests of boric acid.

Issue	**Section of RAR**	**Identified information data gaps**	**Comment**
Nasal irritation - Alarie Assay	Respiratory	• Determination of the RD_{50} value in the Alarie Assay is beneficial for providing additional information on sensory irritation of boric acid and sodium tetraborates for use in setting protective levels for the health of workers. • The rapporteur disagrees	The Alarie test was adopted in 1984 as a standard test by the American Society for Testing and Materials (E 981-04), and uses 0.03 * RD50 for setting OELs (ASTM 2004). RD50s are a basis, at least partially, for a number of OELs by ACGIH (Kuwarbara et al 2007). The rapporteur does not support a new Alarie-test. The applicability for the derivation of human OELs is not sufficiently supported, which is stated in Chapter R.8 and 7A of the guidance document on IR and CSA, as well as in Bos et al. (2002) and Bos et al. (1992) The above mentioned factor of 0,03 has no scientific basis as outlined in the draft guidance by Bos et al. (2007): “The mouse sensory irritation bioassay (Alarie-test): Its relevance for AEGL-derivation. SIR-advisory report 11449 A00”. RIVM, De Bilt, The Netherlands, cited by Chapter R.8 of the guidance on IR and CSA: If however an Alarie-test would be carried out it should follow the

Issue	Section of RAR	Identified information data gaps	Comment
NOEC		- Good quality epidemiological studies to define the NOEC for work-related acute irritant effects .	recommendations of the above mentioned guidance, Bos et al. (2007). Inter alia: - The use of an RD10 value is recommended as point of departure (POD) for extrapolation to a human threshold for sensory irritation mediated by trigeminal nerve stimulation. Its appropriateness as POD for sensory irritation should be carefully weighed against all available data - The choice of interspecies and intraspecies assessment factors can be made according to the cited guidance. Acute irritant effects are documented in human workers exposed to borates. Although there is concentration-response information from the study used for the DNEL derivation, due to the limitations of the study, it is not possible to identify where in the exposure spectrum symptoms occurred (Wegman et al. 1991). Studies by Cain et al (2004, 2008) were conducted in response to these uncertainties and were intended to evaluate sensory response to borate dust exposure with more precision. However, study limitations and disagreement on the interpretation of the results limited the relevance of the studies.

Inhalation and dermal occupational exposure	Occupational Exposure	- Information on occupational exposure by inhalation for all producing/importing sites
		- Information on occupational exposure by inhalation for processing sites
		- Information on occupational exposure by dermal contact for all producing/importing sites:
		  - Either read-across from metal compounds;
		  - Or collection of actual dermal data
		- Information on occupational exposure by dermal contact for processing sites:
		  - Either read-across from metal compounds;
		  - Or collection of actual dermal data
		- Address scenarios estimated in screening tier assessment which pose risk (RCR > 1)
		- Identify scenarios not included in screening tier assessment to evaluate exposures and risk
			Minimal occupational exposure measurements have been collected for producing and importing sites.
			Little or no information is available for downstream users.
			Occupational monitoring data representative of the activities and the materials being handled would allow accurate identification of the risks.

Consumer Exposure	Consumer Exposure	- Information on consumer exposure data from RPA study - Information on end uses not identified in RPA study - Identify scenarios not included in screening tier assessment to evaluate exposures and risk	The RPA report was not available at the time of the submission of this dossier. This report is expected to provide information on consumer exposure. Therefore, minimal data are available on consumer exposure. In the event that the RPA report does not contain sufficient information, additional consumer exposure information and data will be required if those uses are to be supported by the REACH registration dossier.

Issue	Section of RAR	Identified information data gaps	Comment
Fertility Effects	Reproductive Toxicity	• Information on data gaps identified in animal studies for female fertility effects. • Good quality epidemiological studies to identify effects on male and female fertility in humans	Industry disagrees on the need for an additional assessment factor based on the uncertainty described for effects on female fertility. Males have been shown to be the more sensitive gender with respect to fertility effects of borates. Establishing exposure levels that protect against male fertility effects will therefore prevent female fertility effects.
Developmental Effects	Reproductive Toxicity	• Information on developmental effects in humans from epidemiological studies of populations exposed to high concentrations of boron. • Good quality epdidemiological studies	Relevance of the developmental effects observed in rodents has not been established in humans. Epidemiological studies were not sufficient to clarify the relevance of developmental effects in humans.

Environment

Conclusion (i) is reached because:

There is a need for further information to adequately characterize the risks to:

- the aquatic ecosystem
- the sediment ecosystem,
- STP,
- the terrestrial environment

from the local exposure and emissions of boric acid and sodium tetraborates; and

- address data gaps in effects data.

Issue	Section of RAR	Identified information data gaps	Comment
Local exposure assessment at producing / importing and using sites	Local Exposure	• Information on local exposure and emissions to the aquatic compartment (including sediment) for all producing/importing sites • Information on local exposure and emissions to the atmosphere for all producing/importing sites • Information on local exposure and emissions to the aquatic compartment (including sediment) for processing sites • Information on local exposure and emissions to the atmosphere for processing sites	No emission or exposure data is available from borates producing/importing and using sites, for the aquatic and air compartments. Exposure estimates are based on conservative default assumptions specified in the TGD (Tier 1). According to the RIP guidance; where risks are identified, the exposure assessment should be refined using relevant and good quality monitoring data
Regional exposure assessment	Regional Exposure	• Monitoring data of boron in soil across Europe in agricultural soils. GEMAS project ongoing to fill this data gap	Data set on **soil** monitoring data is extremely limited. Exposure estimates are questionable and based on default assumptions specified in the TGD (Tier 1).
		• Monitoring data of boron in sediments across Europe	There are no monitoring data available on boron contents in **sediments** in Europe. Exposure estimates are questionable and based on default assumptions specified in the TGD (Tier 1).
		• Recent monitoring data of boron in freshwaters in certain EU countries (countries to be specified)	Considering the trend in consumer use of borates (e.g. decrease in their use in detergents) the data set on **freshwater** monitoring data is considered outdated in certain countries.
		• Monitoring data of boron in some relevant estuarine environments in the EU	There are no monitoring data available on boron contents in **estuarine water** in Europe. Exposure estimates are questionable and based on default assumptions specified in the TGD (Tier 1).
		• Monitoring data of boron in some relevant coastal environments in the EU	There are no monitoring data available on boron contents in **coastal water** in Europe. Exposure estimates are questionable and based on default assumptions specified in the TGD (Tier 1).
		• Monitoring data of boron in some relevant marine & estuarine sediment environments in the EU	There are no monitoring data available on boron contents in **estuarine and marine sediments** in Europe. Exposure estimates are questionable and based on default assumptions specified in the TGD (Tier 1).
STP Influent concentrations		• Recent monitoring data of boron in STP influents in certain EU countries (countries to be specified)	Considering the trend in consumer use of borates (e.g. detergents) the data set on boron concentrations in STP influents is considered outdated in certain countries

Issue	Section of RAR	Identified information data gaps	Comment
Fate borates in soil	Degradation	• Adsorption model – such as the constant capacitance model (CCM) - by Goldberg, needs to be validated for European soil types • Use model to improve the bioavailability & toxicity estimation of borates	Relevancy of available data is questionable. Kd values used for soil exposure assessment. Improved exposure estimations might be obtained from use of advanced soil models such as by Goldberg.
Fate borates in sediments	Degradation	• Adsorption model –CCM- by Goldberg, might be validated for European sediment types	Relevancy of available data is questionable. Kd value used for sediment exposure assessment. Improved exposure estimations might be obtained from use of advanced soil models such as by Goldberg.
End of life	Waste stream analysis	• Recent monitoring data of borates to quantify emissions from end of life to the environment	Considering the different legislative background (new EU-Member States) and recent trends the data set needs to be actualized
Effects-STP	Environmental Effects – STP	• Current boron concentrations of well functioning STPs • Good quality STP respiration test • Good quality STP nitrification test	PNEC-STP is uncertain due to the limitations of the available ecotoxicity data. A precautionary value was therefore proposed. To reduce the uncertainty and improve the accuracy of the PNEC-STP, good quality data are desirable, e.g. current boron concentrations of well functioning STPs and laboratory ecotoxicity data. PNEC-STP is added and shall be difficult to implement under REACH (i.e. compliance checking of exposure scenarios by companies). A total PNEC-STP is needed for practical compliance checking.
Effects sediment	Environmental Effects – sediment	• Good quality sediment ecotox tests; sufficient to build an SSD • The rapporteur agrees that more good quality sediment data are preferable, but does not consider this issue a data gap	PNEC-sediment is added and shall be difficult to implement under REACH (i.e. compliance checking of exposure scenarios by companies). A total PNEC sediment is needed for practical compliance checking.
Effects freshwater	Environmental Effects – freshwater	• Good quality freshwater ecotox tests to current testing methodologies	Depending on data used to derive PNEC-aquatic, some poor quality studies may be repeated. This could replace existing data of poorer quality, or be used as mean value. The current database is seen as having inadequate chronic studies to derive a SSD. Inclusion of an insect species seems especially appropriate. Study designs might be modified to evaluate hormetic effects (related to boron deficiencies). Information

Issue	Section of RAR	Identified information data gaps	Comment
			relevant to determining an AF might also be appropriate. Supplemental information may be obtained regarding existing studies which were considered to have inadequate documentation to be useful in PNEC derivation. If original study reports can be obtained to remedy these deficiencies, then the tests may not need to be repeated to meet current quality guidelines.
Effects soil	Environmental Effects – soil	• Good quality & relevant soil ecotox tests; sufficient to build an SSD • Good data to assess bioavailability & toxicity of borates in soil to be able to derive soil type specific PNEC values. (ex validated CCM model)	Available plant data included a large number of studies where exposure was via a sand-water or water-only method and these were excluded from use as not relevant. Micro-organism data was limited. Further data is needed on micro-organisms and invertebrates, including –if possible- insects. As a consequence of not using an SSD approach, the current PNECsoil-add could cause deficiency for some plants (especially crops). PNEC-soil is added and shall be difficult to implement under REACH (i.e. compliance checking of exposure scenarios by companies). A total PNEC soil is needed for practical compliance checking.
Effects estuarine	Environmental Effects – estuarine	• Good quality estuarine ecotox tests and speciation data	Current estuarine water ecotox data set is very limited. Central issue is whether estuarine organisms are more or less sensitive than freshwater or marine species. Fuller ecotox data set could improve derivations of PNEC-estuary.
Effects marine	Environmental Effects – marine	• Good quality ecotoxicity information applicable to marine species. • Rapporteur: Further ecotoxicity tests might not be necessary once more information on exposure is available	Limited quality data available for marine species. Although marine species are expected to be less sensitive to boron than freshwater species because of naturally high boron levels in marine ecosystems, relevant data could improve derivation of a PNEC-marine.

ANNEXES HUMAN HEALTH (HH) SECTION

Annex HH I: Respiratory irritation:

Drawbacks of the Garabrant et al. (1984) studies

- There is no indication of the temporal relationship between when a symptom was experienced and when the questionnaire was administered. It could have been days, weeks or months. Recall reliability can be in doubt.
- There is no assurance that the time when air samples were taken was relevant to the time symptoms were experienced. In the information on boric acid, the eight air samples upon which irritant effects were assessed had been collected in a plant that was no longer in existence at the time the symptom study was done.
- And even though the air samples were obtained for the purpose of representing exposure of a group of workers, there were too few (probably less than 6) to provide statistical power.
- The air samples used in the study may represent dust, but give no information about borate exposure.
- The respiratory irritation and complaints of dryness of nose, mouth and eye irritation are hardly surprising from a group involved in physical exertion in the high desert environment of the Mojave Desert.

Confounding Issues of the Wegman et al. (1991) study

- Subjects were instructed to press the event marker whenever a symptom occurred then asked at each hourly survey to report whether the event marker had been pressed in the past hour. The event marker was not that often pressed as symptoms were reported. Wegman stated that workers forgot due to job demands to press the event marker. It seems likely that workers were more attracted to press the event marker at higher dust/boron concentrations than at lower concentrations. The confirmed presses are taking the survey and the event marker presses into account, might under-represent the symptoms at lower concentration.
- Wegman et al. (1991), acknowledged that the severity scale had not been used on other irritant-exposure environments. Thus, although it has been shown to provide consistent data within the study reported, there is little information on how to interpret the absolute level of irritation.
- This study could not allocate the irritancy to a specific borate, but up to now there exists no method to specifically address that issue.
- The described effects can only be assigned to exposure ranges. For any symptom ≥ 3 the exposure ranges varied between 0,003 mg/m^3 to 1,187 mg/m^3, with an extreme of 29,442 mg/m^3 for the last exposure range. The number of 15-minute intervals allocated to the single exposure ranges was different among the different exposure ranges and varied between 1001 and 120.

Drawbacks of the Cain et al. 2004, 2007 studies:

- The mass median aerodynamic diameter (MMAD) within these studies might not be relevant and representative for workers being exposed to boric acid and the borates. MMAD is approx. half of the MMAD measured within the Wegman study at the borax facility (1991). The experimental design and the MMAD of both Cain studies (2004 and 2007) might not be representative for the true occupational exposure of workers.
- Respirable dust was measured by the MINIRAM, but larger particles are more likely to deposit in the nose and upper airways. As it is stated in Wegman, 1991, the irritation in the borax facilities might be caused by the “non-respirable” size range.
- Helsinki declaration for human experiments is not indicated within the study; only a subject committee from the University of California approved the protocol; this is neither a nationally nor an internationally approved ethic organisation. The following was indicated within the studies:
    - Cain 2004: At that time they gave written informed consent to participate. The Human Subjects Committee of the University of California, San Diego approved the protocol for the investigation.
    - Cain, 2007: The subjects gave written informed consent. The Human Subjects Research Protections Program at UCSD approved the protocol.

- As indicated in the study, carbon dioxide was used as a reference to scale the irritating effect. The reference gas CO_2 might alter normal lung function even if the exposure is as short as in the experiment (approx. 2 sec). This is problematic as the test substance had to be judged right after the exposure to CO_2. Acute effects of CO_2 start at 4-6 vol. % and can be derived from common toxicological textbooks (e.g. Marquardt & Schäfer, 2004): headache, tinnitus, heart palpitation, increase of blood pressure, excitement. At a concentration of 10% CO_2 cramps, unconsciousness, and apnoea are observed. Higher concentrations of CO_2 can lead to rapid unconsciousness and death. CO_2 concentrations up to 30% were administered in the current experiment, and, though only for 1-2 seconds, effects on the subjects cannot be excluded.
- In both studies, the volunteers have been trained and got familiarized with procedure and the different concentrations. There might be also a study bias, thus the subjects knew that they have been exposed. In addition, the scale of feel (comparison via carbon dioxide) might be rather subjective as well.
- The method has not been applied more than two times, according to a literature search of the http://www.ncbi.nlm.nih.gov/pubmed/ data base back to the year 2000. The following key-words, or combinations thereof have been used: chemesthesis, dosmetric model, sensory irritation, nasal secretion, plastic dome, mineral dust. Therefore, it can be concluded that the reliability of the methodology is not sufficiently evaluated.
- Cain, 2004: smokers were identified by telephone interview; allergies and bronchitis were not checked.

The effects did not increase with increasing exposure concentration. The dose of 0.88 mg/m^3 was lower than the effect at 0.44 mg/m^3 independent of time (12.5, 22.5, 27.5 minutes).

Annex HH II: Reproductive toxicity:

ANNEX HH II A

Quality Assessment of the 90-Day Dog Studies of Boric Acid and Borax (Paynter, 1963a,b)

- The test system is unsuitable because the age of the dogs is not identified in these studies. Age is a critical factor in a study that purports to evaluate male reproductive toxicity. Because the investigators did not know the ages of the dogs and because the dogs appear to be of varying ages, the test system is highly inappropriate for assessing male reproductive toxicity. The development of the testes is age-dependent. If a dog is either too young or too old, testicular endpoints may be affected by age. This deficiency alone should render these studies as unsuitable for quantitative risk assessment for endpoints of male reproductive toxicity.
- For unexplained reasons, the weight of the dogs varied significantly at the start of the experiment. The weight range of the male and female dogs at the start of the study was 6.0-10.4 and 4.2-11.5 kg, respectively. It is a generally accepted scientific principle that the animals used on a study should have similar body weights. The large difference in body weight at the beginning of the study calls into further question the age (and suitability) of the test system (animals).
- The test system is unsuitable because the source of the dogs is unknown. Although the authors state that purebred beagles were used, the source of the beagles is not stated in the 90-day studies (or in any of the Weir and Fisher studies). It was common practice in the 1960s to obtain dogs for research from dog pounds. In fact, some of the control dogs for other studies in the Weir and Fisher series were described by the authors as “mongrels”.
- The test system is unsuitable because the dogs may not have been housed properly. The report states that the dogs in the 90-day studies were housed individually in metal cages. Yet, a female dog became pregnant during the course of another Weir and Fisher dog study, in which the authors stated that the dogs were housed individually in metal cages. This finding strongly suggests irregularities in the housing of the dogs. If two dogs housed individually can cohabitate, it also raises questions about the possibility of “individually-housed” dogs gaining access to the wrong diets.
- The test system is unsuitable because confounding factors, including previous exposure to reproductive toxicants, were not identified. The dogs used for this study may have been exposed to

other chemicals, including chemicals that cause male reproductive toxicity, prior to placement on this study. Since the source of the dogs is unknown, there are no records on exposures to chemicals, drugs, and pesticides prior to the being placed on this study. Also, it was common practice in the 1960s to use the same dogs for more than one set of experiments. According to the FDA Redbook (FDA, 2000), "Healthy animals that have not been subjected to previous experimental procedures should be used" for toxicity studies.

- The test system is unsuitable because at least one of the dogs (female control dog #4996) was missing a left kidney. It is not clear whether the missing kidney was due to a congenital defect or to previous surgery. At any rate, it is highly unusual to select a dog with only one kidney for a controlled experiment.
- The test system is unsuitable because the study report says the dogs were treated with a vermifuge "as needed" during the course of the study. Vermifuge is a type of anti-helminthic agent, which has been placed on California's Proposition 65 list of chemicals "known to the state" to cause reproductive toxicity based on studies of developmental toxicity. Based on a literature search, there is no publically available evidence that vermifuge has ever been tested for effects on male reproduction. According to the US FDA Redbook (US FDA, 2000), "Generally, it is not possible to treat animals for infection during the course of a study without the risk of interaction between the treatment drug and the test substance." In addition, the dogs were "vaccinated against canine distemper, infectious canine hepatitis, and rabies.
- The dogs on the study were administered "Wayne Dog Feed" *ad libitum* throughout the study. In addition, the dogs were also given a 100 gram ration of canned meat (Hill Packing Company) 5 days per week. This ration was apparently given because the Wayne dog food with boric acid and borax was not well tolerated. First, it is not clear what role, if any, the canned meat ration had on overall food consumption, because the consumption of the canned meat was not recorded. Second, the canned meat was not analysed for chemical impurities that might affect male reproduction.
- The reporting of the methods and results is insufficient because the statistical test methods are not described. The level of statistical significance (i.e., the *p* value) is not reported.
- The reporting of the results of the histopathology is insufficient, because no individual data are reported. It is not possible to determine which specific dogs exhibited histopathological findings. The authors simply reported the results for the entire group. The absence of detailed pathology reports on each individual dog, and the absence of any report on the findings in the controls, is a very severe limitation in the interpretation of these studies.
- The histological description of the testes in the 90-day dog studies is incomplete and inadequate by today's standards. The standards described in the FDA Redbook (FDA, 2000) were not met. According to the FDA Redbook (FDA, 2000): "A thorough histological evaluation of the testis should include an examination of the interstitial compartment and the seminiferous tubule compartment. A histopathological evaluation of the intertubular cell compartment of the testis should include a general assessment of the Leydig cells, the blood vessels, and the cell types other than the Leydig cells typically found in the intratubular space. The general appearance of the seminiferous tubules should be noted. This should be followed by an examination of the seminiferous tubule compartment to detect any disruption in the normal sequence of the events that occurs during the normal process of spermatogenesis. The seminiferous epithelium should then be carefully observed to detect any of the following: presence of multinucleated cells, missing germ cell layers, increased germ-cell degeneration, abnormal development in germ cells, sperm release delay or failure, presence of germ cells in the seminiferous tubule lumen, and any changes in the Sertoli cells (vacuolization, sloughing, or nuclear changes). The general condition of the boundary layer should be noted."
- Another abnormality in the test results is that many test results always ended in the numbers 0 or 5. For example, food consumption was always reported as a value that ended with either 0 or 5. Similarly, the BUN results all end in either 0 or 5. One possible explanation is that the instruments for measuring food consumption and BUN only measured whole numbers and half numbers. Interestingly, the testes weights of 15/15 boric acid-exposed dogs always ended in either 0 or 5. In contrast, only 2/5 of the control dogs ended in either a 0 or 5. This suggests that the method of weighing the testes of the control dogs may have been different from that used to weigh the testes of exposed dogs.

- The test system is unsuitable because the dog is not an appropriate model for evaluating male reproductive effects. No regulatory agency recommends using the dog as a species for evaluating male reproductive toxicity.
- The reporting of the method of preparing the test diets is inadequate: "The test material was added to the diet on a weight/weight basis and thoroughly mixed in a large volume blender. The report does not state whether the blending was performed wet or dry. The report describes no analysis to ensure that the actual concentration of test material was consistent with the nominal concentration. The report does not describe any effort to determine whether the concentration of the test material in the diet was homogenous. This is a major flaw in the test system, since there is no verification of exposure to the test material. If the diets were not homogenous, the concentration of the test material in the diet given to the dogs may have varied from day to day. Dog diets are normally in chunks or pellets and, therefore, not easy to mix. Unlike rats, dogs cannot be satisfactorily fed a powdered diet.
- The results of the 90-day dog studies are called into question by the results of the 2-year dog studies conducted by Weir and Fisher. The effects seen at the mid-dose in the 90-day studies were not observed in the 2-year dog studies.
- The reporting of the results is insufficient because the average boron equivalent intake doses given at the bottom of Table 1 (Paynter, 1963a;b) does not match the average of the individual data provided. The average dose should be the average of the calculated dose for each of the 13 weeks of the study. But, the average dose reported is consistently lower than the average of the calculated dose for each of the 13 weeks of the study. For example, for male dog #4925, the reported average boron intake dose in Table 1 is 3.3 mg B/kg-d, but the average of the 13 weekly doses for this same dog is 5.2 mg B/kg-d. Likewise in the Borax study, dog #4984 reported average boron intake dose in Table 1 is 3.2 mg B/kg-d but the average of the 13 weekly doses for this same dog is 5.0 mg B/kg-d. This raises the serious possibility that the dose levels were incorrectly calculated in this study.
- The reporting of the results is inadequate because the body weight of individual dogs at week 13 (the end of the study) in Table 1 (Paynter, 1963a;b) do not match the same dog's body weight at autopsy (Table 5). Not only are the results of the body weights different between the two tables, but there is an inconsistent pattern to the difference in body weights. All of the control male dogs weighed less in Table 5 compared to Table 1. In contrast, only one of the mid- and high-dose male dogs weighed less in Table 5 compared to Table 1. If the body weights in Table 1 had been used instead of the body weights in Table 5 to calculate the relative weight of the testes, the relative testicular weight of the control group would have been less than originally reported, and the relative testicular weight of the mid- and high-dose groups would have been higher than originally reported. This observation calls into question the significance of the reported decrease in testicular weight, particularly at the mid-dose. These findings suggest that different dose groups of animals were weighed by different persons or on different scales. An alternative explanation is that different groups were autopsied on different days. Since the boric acid and borax studies were conducted simultaneously and incorporated a common control group, a large number of dogs would have been autopsied on a single day if all the dogs had been autopsied on the same day of the study. In fact, in the 90-day study, 70 male and female dogs would have been required to be autopsied on the same day. It is doubtful whether the same person could have conducted 70 autopsies of dogs on the same day.

Conclusions

The Weir and Fisher 90-day dog studies should be classified as Category 4 under the REACH Guidelines because the studies have an "unsuitable test system or conditions" and "insufficient reporting of methods and/or results data." Studies in rats and other species demonstrate that Boron can cause testicular toxicity and this is not in dispute. The 90-day dog studies, while adequate qualitatively to support this conclusion, are wholly inadequate to serve as the critical studies in quantitative risk assessment.

2-year studies - Weir, 1966a,b **a) Boric acid; b) borax** (predates OECD guideline and GLP)	(Hazelton Laboratories)	Sprague-Dawley rats, boric acid & borax, 35/35 males & females per group (Effects of boric acid and borax can be compared on the basis of boron (B) - equivalents; observations were similar for both substances)
low (5,9mg B/kg bw/day)	**mid (17,5mg B/kg bw/day)**	**high (58,8mg B/kg bw/day)**
- no significant effect on testis	- no significant effect on testis	- testicular atrophy and seminiferous tubule degeneration, atrophied seminiferous epithelium and decreased tubular size
- no significant effect on ovaries	- no significant effect on ovaries	- no significant effect on ovaries

Necropsies: weights of - brain, liver, spleen, kidneys & testis was recorded and body weight ratios were calculated

* After 6 & 12 months => 5 rats / sex / dose group

* After 24 months => all surviving rats

* All animals which died during the study or were sacrificed in moribund conditions were necropsied

Microscopic examination: gonads, brain, thyroid, heart, lung, liver, kidney, adrenal, pancreas, stomach, small- and large intestine, & unusual lesions

* After 6 & 12 months => 5 rats / sex / dose group

* After 24 months => 10 rats / sex /group

* selected tissues of rats which died during the study with unusual lesions

Results:

* Survival was compareable among the groups after 6, 12 and 24 months.

* Haematology - at each time of determination cell volume & heamoglobin values of males & females of the high dose group were below the normal range for rats or within the low normal range, and lower as in the corresponding controls

* Gross pathology: all males form the high dose group - underdeveloped, small & soft testis; significantly reduced absolute and relative testis weight at all time points; females from high dose and males & females from all other groups showed no consistent gross changes

* microscopic pathology: - at 6 months high dose males - degenerative changes reflected by complete atrophy of the seminif.epithel., decrease in tubular size, corresponding increase of interstitial tissue, no changes at low or mid dose

- at 6 months ovaries - comparabel among all dosed groups and controls

- at 12 months high dose males - distruction of seminif. epithel. in the high dose males was slightly more severe compared to the 6 months time point
- at 12 months - no effect on ovaries

- at 24 months - effects on male rats of the high dose were comparable to the effects at 12 months, some degree of degeneration was also seen in low- & mid-dose males but was not judged as compound related
- at 24 months - ovaries of control 6 dosed females were mostly in some stage of involution

Endpoints not investigated (because this was no reprotox - study):

oestrus cycle
adjusted litter weight reduced by 9%
average dam weight PND 0 reduced
average gestational period approx. 1 day longer

3-Generation Study - Weir, 1966c,d

a) Boric acid; b) borax
(predates OECD guideline and GLP)

(Hazelton Laboratories)

Sprague-Dawley rats, boric acid & borax, 35/35 males & females per group
(Effects of boric acid and borax can be compared on the basis of boron (B) - equivalents; observations were similar for both substances)

	low (5,9mg B/kg bw/day)	**mid (17,5mg B/kg bw/day)**	**high (58,8mg B/kg bw/day)**
P1:	Females: no consistent cross changes [a]	Females: no consistent cross changes [a]	Females: The incidence of non-funcitional ovaries or with decreased function was higher than normally observed in rats of this age (11,5 months), [b] Decreased ovulation in the majority of ovaries => was mentioned, however, not to be sufficient to explain the observed infertility [c]; inconsistant changes in the uterine appearance - not compound related; Only ovaries & uteri of the high dose group were examined
	Males: no consistent cross changes [a]	Males: no consistent cross changes [a]	Males: lack of viable sperms; small, soft, blue testis
F1A+ F1B	litters & pups - comparable to control with regard to: # of conceptions, # & size of litters, # of deaths, weight of pups at 24h & at weaning, cross signs of abnormalities of pups		no for treated males X treated females - therefore: - Co males X treated females (2 litters out of 16 matings, one abortion) [d] - Treated males X Co females (no litter) (During cross over mating no food was available in the cages)
P2:	Females: no consistent cross changes [a] Males: no consistent cross changes	Females: no consistent cross changes [a] Males: no consistent cross changes	- -
F2A+ F2B	litters & pups - comparable to control with regard to: # of conceptions, # & size of litters, # of deaths, weight of pups at 24h & at weaning, cross signs of abnormalities of pups		
P3:	Females: no consistent cross changes [a] Males: no consistent cross changes	Females: no consistent cross changes [a] Males: no consistent cross changes	- -
F3A+ F3B	litters & pups - comparable to control with regard to: # of conceptions, # & size of litters, # of deaths, weight of pups at 24h & at weaning, cross signs of abnormalities of pups		

[a] gonads were crossly un-remarkable, but were neither weighed nor microscopically examined in that group

[b] These findings were not confirmed in the concurrently conducted 2-year repeated dose study

[c] A deleterious effect on the ovum, on implantation, or on gestation after implantation was discussed as possible reason for infertility

[d] one female delivered 3 living & 2 stillborn pups, all living pups showedareas of skin irritationon the paws & died within 3 days;
birth of another litter was observed, but no traces of any pups in the breeding cage 24hours later

Study design:

- **duration: 2** years (until weaning of the second litter (F3B) of the P3 animals)

(conducted concurrently with a 2-year rat study (Weir 1966a,b) at the same doses in the same laboratory)

P1 => F1A (discarded) + F1B
F1B = P2 => F2A (discarded) + F2B
F2B = P3 => F3A + F3B (sacrificed after weaning)

- Animals were maintained in individual cages until maturity (14 weeks)
- 1 male with 2 females per breeding cage
- males remained with females for 21 days (then the animals were returned to their individual cages)
- 24 hours after birth litters were reduced to a max. of 8 pups: The first litter (FA) was discarded when 21 days old, the second litter (FB)was used for the next generation (they served as P animals)

- record on:

# of conceptions, # & size of litters, # of deaths, weight of pups at 24hours & at weaning, cross signs of abnormalities of pups:

=> no differences compared to controls were seen in low and mid dose; high dose - no litter

fertility index (# pregnancies/# matings), gestation index (# litters/# pregnancies), live birth index (# pups born alive/# pups),
lactation index (# pups weaned/# pups left to be nursed):

=> differences were observed, but no trend could be seen (test groups sometimes higher - sometimes lower than controls)

- necrospies:

all P1 animals; weight & microscopic analysis of main organs & testis from all dose groups, for ovaries & uterus only from the high dose

Study deficiencies:
too few animals (however, comparable results were obtained for boric acid and disodium tetraborate decahydrate), many unusual findings also in the control animals (e.g. small sickly pups with dry, wrinkled skin or blue markings on the body; high mortality during nursing - particularly high in controls), not all dose groups equally investigated
Endpoints not investigated:
oestrus cycle adjusted litter weight reduced by 9% average dam weight PND 0 reduced average gestational period approx. 1 day longer

RACB - Fail et al., 1991 Swiss CD-1 mice, boric acid (0; 1000; 4500; 9000ppm in feed), 20 males and 20 females per group

	low (26,6mg B/kg bw/day)	**mid (111,3mg B/kg bw/day)**	**high (220,9mg B/kg bw/day)**
FO:	* Sperm motility reduced by 12 %	* absolute testis weight 51% reduced * absolute epididym. weight 18% reduced * sperm number reduced by 72% * sperm motility reduced by 32% * increase of abnormal sperms: 53%	* absolute testis weight 86% reduced * absolute epididym. weight 23% reduced * sperm number reduced **to** 0,5% (=> no other sperm parameters could be evaluated)
continuous breeding:	* fertile * 4 normal litters (100%) for the fifth litter a reduced number of females (16/19) produced litter (84%)	* reduced fertility * 5 mating rounds - number of females producing litters decreased in subsequent matings: 95% / 85% / 30% / 5% / 5% * Number of live pups / litter was reduced * Life pup weight & adjusted life pup weight were reduced	* sterile * no litters
last of the 5 litters - reared until weaning: FO/F1	* no difference to control (in terms of bodyweight or viability)	* all born pups died prior to weaning	* no litters
Cross over mating:		* Co females X Co males: 74% fertility index, 79% according mating index * mid-dose males X Co females: 5% fertility index, 30% according mating index * mid-dose females X Co males: 65% fertility index, 70% according mating index => 1) adjusted litter weight reduced by 9% 2) average dam weight PND 0 reduced 3) average gestational period approx. 1 day longer	

F 1:	
second generation:	last litter from continuous breeding (No mid-dose litter was available) * numbers & viability of F2 pups: unultered * adjusted bodyweight of F2 pups: reduced by 3% * F1 adults: no change in organ weigths histology or sperm parameters, * oestrus cycle length was reduced by 10% (from 4,7 => 4,2 days) & time spent in di-oestrus was longer * 25% reduction in sperm concentration

Annex HH III: Worker-DNEL$_{\text{long-term, inhalation, systemic}}$

As it is not known whether the value of 10m^3 for light work covers all working conditions to be expected, DNELs for moderate and heavy work are presented below.

The according respiratory volumes are derived from Snipes et al., (1997) cited by US EPA (1997) and by ECB (2003).

Moderate work: 11,9 m^3 / day (8h)

$$\text{corrected inhalatory NOAEC} = \text{oral NOAEL} \quad x \quad \frac{1}{\text{sRV}_{\text{rat}}} \quad x \quad \frac{\text{ABS}_{\text{oral-rat}}}{\text{ABS}_{\text{inh-rat}}} \quad x \quad \frac{\text{sRV}_{\text{human}}}{\text{wRV}}$$

$$\text{corrected inhalatory NOAEC} = 17{,}5 \text{ mg B/kg bw/day } x \frac{1}{0{,}38} \quad x \quad \frac{100\%}{100\%} \quad x \quad \frac{6{,}7}{10}$$

$$\text{corrected inhalatory NOAEC} = 25{,}9 \text{ mg B/m}^3$$

sRV: standard Respiratory Volume, ABS: Absorption, wRV: worker Respiratory Volume
sRV$_{\text{rat}}$ = 0,38 m^3/day
sRV$_{\text{human}}$ = 6,7 m^3/day (8h); sRV$_{\text{human, moderate work}}$ = 11,9 m^3/day (8h)
ABS$_{\text{oral-rat}}$ = ABS$_{\text{inh-human}}$ = 100%

$$\text{Worker-DNEL}_{\text{long-term, inhalation, systemic}} = \frac{25{,}9 \text{ mg B/m}^3}{2{,}5 \text{ x } 5 \text{ x } 2} = 1{,}036 \text{ mg B/m}^3$$

Heavy work: 13,8 m^3 / day (8h)

$$\text{corrected inhalatory NOAEC} = \text{oral NOAEL} \quad x \quad \frac{1}{\text{sRV}_{\text{rat}}} \quad x \quad \frac{\text{ABS}_{\text{oral-rat}}}{\text{ABS}_{\text{inh-rat}}} \quad x \quad \frac{\text{sRV}_{\text{human}}}{\text{wRV}}$$

$$\text{corrected inhalatory NOAEC} = 17{,}5 \text{ mg B/kg bw/day } x \frac{1}{0{,}38} \quad x \quad \frac{100\%}{100\%} \quad x \quad \frac{6{,}7}{10}$$

$$\text{corrected inhalatory NOAEC} = 22{,}57 \text{ mg B/m}^3$$

sRV: standard Respiratory Volume, ABS: Absorption, wRV: worker Respiratory Volume
sRV$_{\text{rat}}$ = 0,38 m^3/day
sRV$_{\text{human}}$ = 6,7 m^3/day (8h); sRV$_{\text{human, moderate work}}$ = 10 m^3/day (8h)
ABS$_{\text{oral-rat}}$ = ABS$_{\text{inh-human}}$ = 100%

$$\text{Worker-DNEL}_{\text{long-term, inhalation, systemic}} = \frac{22{,}57 \text{ mg B/m}^3}{2{,}5 \text{ x } 5 \text{ x } 2} = 0{,}9 \text{ mg B/m}^3$$

The applied assessment factors are described in the section on DNEL-derivation.

ANNEXES ENVIRONMENTAL SECTION

ANNEXES TERRESTRIAL COMPARTMENT (TC)

- Annex TC I. Overview of ecotoxicity data for soil invertebrates. Values selected for the effects assessment are marked in bold.

- Annex TC II. Overview of the ecotoxicity data for higher plants. Values selected for the effects assessment are marked in bold.

- Annex TC III. Overview of the ecotoxicity data for soil microbial processes. Data useful for PNEC derivation are marked in bold

- Annex TC IV - Toxicity data not relevant for PNECsoil derivation

- Annex TC V: Soil characteristics of EU soils

Annex TC I. Overview of ecotoxicity data for soil invertebrates. Values selected for the effects assessment are marked in bold.

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/L(E)Cx (with x > 10)*	L(E)C50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Eisenia andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Mortality	**315**		630	589.2	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Juvenile production	**39.4**		78.8	77.4	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Growth (juvenile dry weight)	**78.8**		157.3	95.5	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Hatching Success	**78.8**		157.3	120.2	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Hatching Failure	**19.8**		39.4		Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (synchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Mortality	**315**		629.3	620	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (synchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Juvenile production	**78.8**		157.3	99.4	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (synchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Growth (juvenile dry weight)	**78.8**		157.3	165.8	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (synchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Hatching Success	**78.8**		157.3	86.3	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (synchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	63	Hatching Failure	≥ 78.8			172.1	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Mortality	≥174.8				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/L(E)C x (with x > 10)*	L(E)C50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Eisenia Andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Juvenile production	**52.5**		98 / 58 (20%)	77.9	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Growth (juvenile dry weight)	**5.2**		8.7 / 4.0 (20%)	25.7	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Hatching Success	**52.5**		98 / 66.7 (20%)	98	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Hatching Failure	**52.5**		98		Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Cocoon production	**98**		175 / 100.1 (20%)	136.2	Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Mortality	≥ 174.8				Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Juvenile production	**52.5**		98 / 57 (20%)	75.7	Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Growth (juvenile dry weight)	**52.5**		98 / 45.5 (20%)	59.4	Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Hatching Success	**52.5**		98 / 69.2 (20%)	90.4	Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Hatching Failure	**52.5**		98		Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	56	Cocoon production	**98**		174.8 / 73.4 (20%)	107.6	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei*	Artificial	6.09	9	14.9	3.5	1	7	Mortality				860.2	Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/L(E)Cx (with x > 10)*	L(E)C50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		(earthworm)	soil												background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	7	Mortality				649.9	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	14	Mortality				696.1	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	14	Mortality				581.1	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Clay-loam reference soil	6.05	12.8	30.1	1.0	1	7	Mortality				772.7	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Clay-loam reference soil	6.05	12.8	30.1	1.0	1	7	Mortality				673.5	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Clay-loam reference soil	6.05	12.8	30.1	1.0	1	14	Mortality				689.1	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia andrei* (earthworm)	Clay-loam reference soil	6.05	12.8	30.1	1.0	1	14	Mortality				567.9	Nominal added dosis; background concentration reported
2	H_3BO_3	*Lumbricus terrestris* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	7	Mortality				786.2	Nominal added dosis; background concentration reported
2	H_3BO_3	*Lumbricus terrestris* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	14	Mortality				501.4	Nominal added dosis; background concentration reported
2	H_3BO_3	*Lumbricus terrestris* (earthworm)	Clay-loam reference soil	6.05	12.8	30.1	1.0	1	7	Mortality				651.4	Nominal added dosis; background concentration reported
2	H_3BO_3	*Lumbricus terrestris*	Clay-loam reference	6.05	12.8	30.1	1.0	1	14	Mortality				447.6	Nominal added dosis; background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/L(E)Cx (with x > 10)*	L(E)C50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		(earthworm)	soil												reported
2	H_3BO_3	*Eisenia Andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	7	Mortality				777.1	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia Andrei* (synchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	7	Mortality				576.6	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia Andrei* (clittelated) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	7	Mortality				693	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia Andrei* (non-clittelated) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	7	Mortality				610.8	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia Andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	7	Mortality				563.5	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia Andrei* (asynchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	14	Mortality				617	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia Andrei* (synchronous) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	14	Mortality				594.5	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia Andrei* (clittelated) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	14	Mortality				613	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia Andrei* (non-clittelated) (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	14	Mortality				533.3	Nominal added dosis; background concentration reported
2	H_3BO_3	*Eisenia Andrei* (earthworm)	Artificial soil	6.09	9	14.9	3.5	1	14	Mortality				795.2	Nominal added dosis; background concentration reported
															Stantec Consulting & Aquaterra Environmental Consulting, 2003

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/L(E)Cx (with x > 10)*	L(E)C50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Artificial soil	6.09	9	14.9	3.5	1	35	Juvenile production	**43.75**		87.5 / 72.0 (20%)	88	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Artificial soil	6.09	9	14.9	3.5	1	35	Mortality	**175**		262.5 / 181.6 (20%)	258.3	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Artificial soil	6.09	9	14.9	3.5	1	35	Reproduction	**87.5**		113.8 / 87.5 (20%)	94.8	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Clay loam soil	6.05	12.8	30.1	1.0	1	35	Juvenile production	**21.9**		43.8 / 8.1 (20%)	19.7	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Clay loam soil	6.05	12.8	30.1	1.0	1	35	Mortality	**113.8**		148.8 / 140.3 (20%)	174.6	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Clay loam soil	6.05	12.8	30.1	1.0	1	35	Reproduction	**21.9**		43.8 / 29.0 (20%)	32.4	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Artificial soil	6.09	9	14.9	3.5	1	7	Mortality				652.6	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Clay loam soil	6.05	12.8	30.1	1.0	1	7	Mortality				316.2	Nominal added dosis; background concentration reported
2	H_3BO_3	*Onychiurus folsomi* (springtail)	Clay loam soil	6.05	12.8	30.1	1.0	1	14	Mortality				248.48	Nominal added dosis; background concentration reported
															ESG International & Aquaterra Environmental Consulting, 2003
1	H_3BO_3	*Eisenia fetida* (earthworm)	Artificial soil	6.1	10	20	3.5	0	14	Growth	≥175 (1%)				Nominal added dosis; background concentration reported
1	H_3BO_3	*Eisenia fetida*	Artificial	6.1	10	20	3.5	0	14	Mortality	≥ 175 (0%)			>175	Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/L(E)Cx (with x > 10)*	L(E)C50	Comment
					%	%	mg B/kg_{dw}	d	d		mg B/kg_{dw}				
		(earthworm)	soil												background concentration reported
															Henzen 2000
1	H_3BO_3	*Folsomia candida* (springtail)	Artificial soil	6.09	9.0	14.9	9.9	1	28	Mortality		**68.1**		>70	Nominal added dosis; background concentration reported
1	H_3BO_3	*Folsomia candida* (springtail)	Artificial soil	6.09	9.0	14.9	9.9	1	28	Juvenile production		**13.8**		26.1	Nominal added dosis; background concentration reported
1	H_3BO_3	*Folsomia candida* (springtail)	Artificial soil	6.09	9.0	14.9	9.9	1	7	Mortality		205.4		314.2	Nominal added dosis; background concentration reported
1	H_3BO_3	*Folsomia candida* (springtail)	Artificial soil	6.09	9.0	14.9	9.9	1	14	Mortality		80.4		166.0	Nominal added dosis; background concentration reported
1	H_3BO_3	*Folsomia candida* (springtail)	Clay loam soil	6.05	12.8	30.1	<0.9	1	28	Mortality		**66.2**		>70	Nominal added dosis; background concentration reported
1	H_3BO_3	*Folsomia candida* (springtail)	Clay loam soil	6.05	12.8	30.1	<0.9	1	28	Juvenile production		**17.2**		30.5	Nominal added dosis; background concentration reported
1	H_3BO_3	*Folsomia candida* (springtail)	Clay loam soil	6.05	12.8	30.1	<0.9	1	7	Mortality		224.8		344.1	Nominal added dosis; background concentration reported
1	H_3BO_3	*Folsomia candida* (springtail)	Clay loam soil	6.05	12.8	30.1	<0.9	1	14	Mortality		51.4		131.8	Nominal added dosis; background concentration reported
															EPFL, 2003

EP: equilibration period

*: % effect (inhibition) between brackets. The % inhibition was calculated as: (A-B)/A * 100 where A is the response of the control soil and B is the response of the treated soil.

[1] Stantec Consulting & Aquaterra Environmental Consulting, 2003

Test species: *Eisenia andrei* (earthworm, synchronous and asynchronous cultures) and *Lumbricus terrestris* (earthworm).

Test protocol: Environment Canada (2002) or OECD (2000) test protocol.

Test soil: Both the acute and chronic toxicity tests were performed with an artificial and a clay loam reference soil. The ingredients of artificial soil were 70% silica sand, 20% kaolinite clay, 10% sphagnum peat and 1-3 g calcium carbonate per kg soil. The clay loam reference soil is a field collected soil from Alberta (Canada) and classified as a Delacour Orthic Black Chernozem.

Physico-chemical characteristics:

-artificial soil: pH water (1:2) 6.09, eCEC 18.5 cmol_c/kg, clay 14.9%, sand 77.3%, organic matter 9%, total carbon: 4.46%

-clay loam reference soil: pH water (1:2) 6.05, eCEC 34.5 cmol_c/kg, clay 30.1%, sand 26.6%, organic matter 12.8%, total carbon: 6.83%.

All tests were performed at 20°C with a photoperiod of 16 h light, 8 h dark.

Soil preparation: Test compound added in solution to soil. Soil moisture was 35% (based on wet weight)

Test concentrations:

- Chronic tests: 0-7-14-28-56-113-225-450-900-1800-3600 (comparison synchronous and asynchronous cultures) or 0-10-16-30-50-100-300-560-1000 mg boric acid/kg dw (comparison OECD and Environment Canada protocols) for the chronic tests in both soils; 10 replicates were used for the chronic tests, except for the OECD protocol where 4 replicates were used (8 in control).
- Acute tests: 0-2000-4000-5000-6000-8000-10000 mg boric acid/kg dw for *Eisenia Andrei* assays; 0-500-1000-2000-4000-6000-8000 mg boric acid/kg dw for *Lumbricus terrestris* assays. 4 replicates were used for all acute tests.

Equilibration period: 1 day.

Test duration: 7-14 days for acute tests; 56 (OECD protocol) or 56 to 63 (Environment Canada protocol) days for the chronic tests.

Endpoints: mortality, juvenile production, growth (juvenile dry weight), hatching success (mean number or percentage of hatched cocoons), hatching failure (mean number of unhatched cocoons) and cocoon production.

Analytics: boric acid was analysed in the test soils using ICAP/MS. Nominal concentrations were used for the derivation of toxicity thresholds.

Statistics: 7- and 14-day LCx values were generated using the Probit, Moving Average and the Trimmed Spearman-Karber methds. ECx values and their associated 95% confidence limits for the chronic tests were analysed by using either a linear or four nonlinear regression models (i.e., logistic, Gompertz, exponential and logistic with hormoesis). If data showed heteroscedasticity among treatments, data were weighed with the inverse of the variance of each treatment. NOEC values were estimated using ANOVA, Dunnett's and Fischer's protected LSD (Least Significant Difference) pairwise comparison tests.

Toxicity data: 56 to 63 days chronic NOEC data (added) varied between 5.2 and 314.6 mg B/kg dw.

Reliability: standard test and selection criteria fulfilled for Klimisch 1 (accepted standard guideline followed (OECD), well performed and well documented study) or 2 (no accepted standard guideline followed (Environment Canada), well performed and well documented study)

[2] ESG International & Aquaterra Environmental Consulting, 2003

Test species: *Onychiurus folsomi* (springtail) adults

Test protocol: Environment Canada (2002).

Test soil: Both the acute and the chronic toxicity tests were performed with an artificial and a clay loam reference soil. The ingredients of artificial soil were 70% silica sand, 20% kaolinite clay, 10% sphagnum peat and 0.25% calcium carbonate. The clay loam reference soil is a field collected soil from Alberta (Canada) and classified as a Delacour Orthic Black Chernozem.

Physico-chemical characteristics:

-artificial soil: pH water (1:2) 6.09, eCEC 18.5 $cmol_c$/kg, clay 14.9%, sand 77.3%, organic matter 9%, total carbon: 4.46%. The pH of treated soil varies from 7.41 to 7.66 and from 6.77 to 7.36 at start and end of test, respectively.

-Clay loam reference soil: pH water (1:2) 6.05, eCEC 34.5 $cmol_c$/kg, clay 30.1%, sand 26.6%, organic matter 12.8%, total carbon: 6.83%. The pH of treated soil varies from 5.60 to 5.73 and from 5.57 to 5.69 at start and end of test, respectively. All tests were performed at 20°C with a photoperiod of 16 h light, 6 h dark.

Soil preparation: Test compound (H_3BO_3) added in solution to soil and the soil/water mixture was mixed for about three minutes. Soil moisture was 35% (based on wet weight)

Test concentrations: chronic tests: 0-50-75-125-250-500-650-850-1000-1500 mg boric acid/kg dw, 10 replicates were used for the chronic tests; acute tests: 0-2000-4000-5000-6000-8000-10000 mg boric acid/kg dw and 0-125-250-500-1000-1500-2000 mg boric acid/kg dw in the artificial and clay loam reference soil respectively, 4 replicates were used for all chronic tests.

Equilibration period: 1 day.

Test duration: 7-14 days for acute tests; 35 days

Endpoints: mortality and juvenile production (mean number of juveniles produced) and reproduction (adult fecundity, i.e. mean number of juveniles produced per adult).

Analytics: total boric acid concentration was determined by analyzing for total boron by ICAP/AES using the protocol decribed by the Ontario Ministry of Environment and Energy (OMEE, 1996). The recovery of the nominal dose after 35 days ranged between 87 and 90% in the artificial soil, and between 47 and 53% in the clay loam reference soil. Nominal concentrations were used for the derivation of toxicity thresholds.

Statistics: 7- and 14-day LCx values were generated using the Probit, Moving Average and the Trimmed Spearman-Karber methds. ECx values and their associated 95% confidence limits for the chronic tests were analysed by using either a linear or four nonlinear regression models (i.e., logistic, Gompertz, exponential and logistic with hormoesis). If data showed heteroscedasticity among treatments, data were weighed with the inverse of the variance of each treatment. NOEC values were estimated using ANOVA, Dunnett's and Fischer's protected LSD (Least Significant Difference) pairwise comparison tests.

Toxicity data: 35 days chronic NOEC data (added) varied between 21.9 and 174.8 mg B/kg dw.

Reliability: standard test and selection criteria fulfilled for Klimisch 2 (no accepted standard guideline followed, well performed study, raw data not available).

[3] Henzen, 2000

Test species: *Eisenia fetida* (earthworm)

Test protocol: OECD n° 207 test protocol according to GLP

Test soil: the chronic toxicity tests were performed with an artificial soil. The ingredients of artificial soil were 70% silica sand, 20% kaolinite clay, 10% sphagnum peat.

Physico-chemical characteristics: artificial soil: pH 6.0-6.2. All tests were performed at 20°C ± 2°C under continuous low intensity illumination.

Soil preparation: Test compound added in solution to soil and soil/water mixtures were mixed mechanically for about two minutes. Soil moisture was 55% (based on dry weight)

Test concentrations: 0-1.1-3.3-10-32-100-320-1000 mg boric acid/kg dw.

Equilibration period: 0 days.

Test duration: 14 days

Endpoints: mortality, growth (wet weight).

Analytics: No analysis of total B concentrations in soil.

Statistics: NOEC values for survival, survival rates were compared pair –wise with those in the control using a binominal test (sig. level of 95%). To determine NOEC values for weight, a multiple comparison was made using a two-tailed Dunnett test (significance levels of 95% and 99%).

Toxicity data: 14 days chronic NOEC data (added) were all unbounded, i.e. ≥174.8 mg B/kg.

Reliability: standard test and selection criteria fulfilled for Klimisch 1 (standard guideline followed, well performed and well documented study).

[4] EPFL, 2003

Test species: *Folsomia candida* (springtail)

Test protocol: ISO 11267 (1999).

Test soil: the chronic toxicity tests were performed with an artificial and a clay loam reference soil. The ingredients of artificial soil were 70% quartz sand, 20% kaolinite clay, 10% sphagnum peat and $CaCO_3$ was added to reach a pH of 6 ± 0.5 (0.37 to 0.42 % $CaCO_3$ was required). The clay loam reference soil is a field collected soil from Alberta (Canada) and classified as a Delacour Orthic Black Chernozem.

Physico-chemical characteristics:

-artificial soil: pH water (1:2) 6.09, pH KCl (1:5) 6.3-6.4 at start and end of test, eCEC 18.5 $cmol_c$/kg, clay 14.9%, sand 77.3%, organic matter 9%, total carbon 4.46%, C_b 9.9 mg B/kg dw, WHC 71.6% (dry weight);

-clay loam reference soil: pH water (1:2) 6.05, pH KCl (1:5) 5.5 at start and end of test, eCEC 34.5 $cmol_c$/kg, clay 30.1%, sand 26.6%, organic matter 12.8%, total carbon 6.83%, C_b below detection limit (0.9 mg B/kg dw), WHC 85.5% (dry weight). All tests were performed at 20°C ± 2°C with a photoperiod of 16 h light, 8 h dark.

Soil preparation: Test compound added in solution to soil and mixed. Soil moisture was 50-60% of WHC.

Test concentrations: 0-20-35-50-80-120-180-270-400 mg boric acid/kg dw for the chronic tests in both soils; 0-270-370-520-730-1020-1430-2000-2800 mg boric acid/kg dw for 7-day acute toxicity in the artificial soil; 0-190-270-370-520-730-1020-1430-2000 mg boric acid/kg dw for 14-day acute toxicity in the artificial soil; 0-200-300-440-670-1000-1500-2250-3380 mg boric acid/kg dw for 7-day acute toxicity in the clay loam reference soil; 0-90-130-200-300-440-670-1000-1500 mg boric acid/kg dw for 14-day acute toxicity in the clay loam reference soil. 3 replicates are used for all concentrations (5 replicates in control).

Equilibration period: 1 day.

Test duration: 28 days for the chronic tests, 7 and 14 days for acute toxicity.

Endpoints: mortality, juvenile production.

Analytics: confirmation of boric acid content was performed by an extraction with 2M HNO_3 (1:10 soil:solution ratio) and by analyzing elemental boron in the filtrates using ICP/AES (detection limit 5 mg/kg). Recovery varied between 72 and 114 for the artificial soil and between 70 and 132% for the clay loam soil. Dose-response curves are based on nominal concentrations.

Statistics: ECx were calculated based on a log-logistic dose-response curve fitted by minimising the unweighted squared residuals sum (maximum likelihood).

Toxicity data: 28 days chronic EC10 data (based on added concentrations) varied between 13.8 and 68.1 mg B/kg dw.

Reliability: standard test and selection criteria fulfilled for Klimisch 1 (standard guideline followed, well performed and well documented study).

Annex TC II. Overview of the ecotoxicity data for higher plants. Values selected for the effects assessment are marked in bold.

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Seedling emergence	**46.9****		93.8 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (root)	28.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion dasystachyum* (northern wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Agropyion dasystachyum* (northern	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (root)	28.0*****				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg_{dw}	d	d		mg B/kg_{dw}				
		wheatgrass)													
3	H_3BO_3	*Agropyion riparium* (Streambank wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Seedling emergence			14.4*** (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Agropyion riparium* (Streambank wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Seedling emergence			1.1*** (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Agropyion riparium* (Streambank wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Shoot length	42.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Agropyion riparium* (Streambank wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Root length	56.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Agropyion riparium* (Streambank wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Shoot length	42.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Agropyion riparium* (Streambank wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Root length	28.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Agropyion riparium* (Streambank wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (shoot)	28.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion riparium* (Streambank wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Agropyion riparium* (Streambank	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (shoot)	28.0*****				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		wheatgrass)													
2	H_3BO_3	*Agropyion riparium* (Streambank wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion smithii* (Western wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Seedling emergence	**40.1****		80.2 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion smithii* (Western wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Shoot length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion smithii* (Western wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion smithii* (Western wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (shoot)	≥111.9				Nominal added dosis; background concentration reported
2	H_3BO_3	*Agropyion smithii* (Western wheatgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (root)	≥111.9				Nominal added dosis; background concentration reported
2		*Agropyion smithii* (Western wheatgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (shoot)	≥111.9				Nominal added dosis; background concentration reported
3	H_3BO_3	*Allium cepa* (Spanish onion)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Seedling emergence			10.7*** (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Allium cepa* (Spanish onion)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Shoot length	**56**				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
3	H_3BO_3	*Allium cepa* (Spanish onion)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Root length	42.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Allium cepa* (Spanish onion)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (total plant)	≥111.9				Nominal added dosis; background concentration reported
2	H_3BO_3	*Allium cepa* (Spanish onion)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (total plant)	≥111.9				Nominal added dosis; background concentration reported
3	H_3BO_3	*Avena sativa* (oat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Avena sativa* (oat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Avena sativa* (oat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Avena sativa* (oat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Avena sativa* (oat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	≥111.9				Nominal added dosis; background concentration reported
2	H_3BO_3	*Avena sativa* (oat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Avena sativa* (oat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	≥111.9				Nominal added dosis; background concentration reported
3	H_3BO_3	*Avena sativa* (oat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Beckmannia*	Artificial sandy	6.5	4.0	14.8	3.5	1	24	Seedling	**16.9****		33.8 (20%)		Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		syzigachne (American sloughgrass)	loam soil							emergence					background concentration reported
2	H_3BO_3	*Beckmannia syzigachne* (American sloughgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	24	Seedling emergence	**36.4****		72.8 (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Beckmannia syzigachne* (American sloughgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	24	Shoot length	42.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Beckmannia syzigachne* (American sloughgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	24	Root length	42.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Beckmannia syzigachne* (American sloughgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	24	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Beckmannia syzigachne* (American sloughgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	24	Root length	<28.0				Nominal added dosis; background concentration reported
3	H_3BO_3	*Beckmannia syzigachne* (American sloughgrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	24	Yield (whole plant)	42.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Beckmannia syzigachne* (American sloughgrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	24	Yield (whole plant)	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Bouteloua gracillus trachycaulum* (Grama grass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	8	Seedling emergence			6.1*** (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Bouteloua*	Clay loam field	6.2	11.9	30.6	1.0	1	8	Shoot length	42.0*****				Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg_{dw}	d	d		mg B/kg_{dw}				
		gracillus trachycaulum (Grama grass)	soil												background concentration reported
3	H_3BO_3	*Bouteloua gracillus trachycaulum* (Grama grass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	8	Root length	42.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bouteloua gracillus trachycaulum* (Grama grass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	8	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bouteloua gracillus trachycaulum* (Grama grass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	8	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bouteloua gracillus trachycaulum* (Grama grass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	8	Yield (whole plant)	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bouteloua gracillus trachycaulum* (Grama grass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	8	Yield (total plant)	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**45.1****		90.23(20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Brassica napus* (Canola)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence			>111.9**** (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**42.0**				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Brassica napus* (Canola)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**84**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**84**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica napus* (Canola))	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**23.7****		47.4 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**45.7****		91.5 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica*	Artificial sandy	6.5	4.0	14.8	3.5	1	5	Root length	**28.0**				Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg_{dw}	d	d		mg B/kg_{dw}				
		oleracea (cabbage)	loam soil												background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Brasica oleracea* (cabbage)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brasica oleracea* (cabbage)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica rapa* (Turnip)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence			16.6*** (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica rapa* (Turnip)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence			10.5*** (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Brassica rapa* (Turnip)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	56*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Brassica rapa* (Turnip)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	56*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Brassica rapa* (Turnip)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	84*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Brassica rapa* (Turnip)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	42.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica rapa* (Turnip)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	<28.0				Nominal added dosis; background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
															reported
2	H_3BO_3	*Brassica rapa* (Turnip)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Brassica rapa* (Turnip)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	<28.0				Nominal added dosis; background concentration reported
3	H_3BO_3	*Brassica rapa* (Turnip)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Seedling emergence	**26.4****		52.8 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Seedling emergence	**32.5****		64.9 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Artificial sandy loam soil	6.5	4.0	14.8	1.0	1	7	Shoot length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Shoot length	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Root length	42.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus*	Artificial sandy	6.5	4.0	14.8	3.5	1	7	Yield	**28.0**				Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		marginatus (Mountain bromegrass)	loam soil							(shoot)					background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (root)	**84**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (shoot)	**28.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Bromus marginatus* (Mountain bromegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (root)	56*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Calamagrostis canadensis* (Bluejoint marsh reed)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Seedling emergence			1.6*** (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Calamagrostis canadensis* (Bluejoint marsh reed)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Seedling emergence	**16.6****		33.3 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Calamagrostis canadensis* (Bluejoint marsh reed)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Calamagrostis canadensis* (Bluejoint marsh reed)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Calamagrostis canadensis* (Bluejoint marsh reed)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Shoot length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Calamagrostis*	Clay loam field	6.2	11.9	30.6	1.0	1	NR	Root length	**28.0**				Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		canadensis (Bluejoint marsh reed)	soil												background concentration reported
3	H_3BO_3	*Calamagrostis canadensis* (Bluejoint marsh reed)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Yield (total plant)	42.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Calamagrostis canadensis* (Bluejoint marsh reed)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Yield (total plant)	42.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Cucumis sativa* (Cucumber)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence			0.6*** (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**45.3****		90.7 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**28.0**				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Cucumis sativa* (Cucumber)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Daucus carota* (Carrot)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Seedling emergence	**22.0****		43.8 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Daucus carota* (Carrot)	Clay loam field soil	6.2	11.9	30.6	1.0	1	6	Seedling emergence	**27.9****		55.8 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Daucus carota* (Carrot)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Daucus carota* (Carrot)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Daucus carota* (Carrot)	Clay loam field soil	6.2	11.9	30.6	1.0	1	6	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Daucus carota* (Carrot)	Clay loam field soil	6.2	11.9	30.6	1.0	1	6	Root length	<28.0				Nominal added dosis; background concentration reported
3	H_3BO_3	*Daucus carota* (Carrot)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Yield (shoot)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Daucus carota* (Carrot)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Yield (root)	<28.0				Nominal added dosis; background concentration reported
3	H_3BO_3	*Daucus carota* (Carrot)	Clay loam field soil	6.2	11.9	30.6	1.0	1	6	Yield (shoot)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Daucus carota*	Clay loam field	6.2	11.9	30.6	1.0	1	6	Yield (root)	**42.0**				Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		(Carrot)	soil												background concentration reported
2	H_3BO_3	*Festuca rubra* (Red fescue)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Seedling emergence	**23.7****		47.4 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Festuca rubra* (Red fescue)	Clay loam field soil	6.2	11.9	30.6	1.0	1	6	Seedling emergence	**38.2****		76.5 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Festuca rubra* (Red fescue)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Festuca rubra* (Red fescue)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Festuca rubra* (Red fescue)	Clay loam field soil	6.2	11.9	30.6	1.0	1	6	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Festuca rubra* (Red fescue)	Clay loam field soil	6.2	11.9	30.6	1.0	1	6	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Festuca rubra* (Red fescue)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	6	Yield (total plant)	**56**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Festuca rubra* (Red fescue)	Clay loam field soil	6.2	11.9	30.6	1.0	1	6	Yield (total plant)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Glycine max* (Soybean)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Seedling emergence	**28.2****		56.4 (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Glycine max* (Soybean)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Seedling emergence			21.4*** (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Glycine max* (Soybean)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Shoot length	56*****				Nominal added dosis; background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
															reported
2	H_3BO_3	*Glycine max* (Soybean)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Root length	**28.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Glycine max* (Soybean)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Shoot length	42.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Glycine max* (Soybean)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Root length	28.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Glycine max* (Soybean)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (shoot)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Glycine max* (Soybean)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (root)	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Glycine max* (Soybean)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (shoot)	≥111.9				Nominal added dosis; background concentration reported
2	H_3BO_3	*Glycine max* (Soybean)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (root)	<28.0				Nominal added dosis; background concentration reported
3	H_3BO_3	*Hordeum vulgare* (Barley)	Clay loam field soil	6.2	11.9	30.6	1.0	1	4	Seedling emergence			>111.9 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Hordeum vulgare* (Barley)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	4	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Hordeum vulgare* (Barley)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	4	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Hordeum vulgare* (Barley)	Clay loam field soil	6.2	11.9	30.6	1.0	1	4	Shoot length	<28.0				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Hordeum vulgare* (Barley)	Clay loam field soil	6.2	11.9	30.6	1.0	1	4	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Hordeum vulgare* (Barley)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	4	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Hordeum vulgare* (Barley)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	4	Yield (root)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Hordeum vulgare* (Barley)	Clay loam field soil	6.2	11.9	30.6	1.0	1	4	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Hordeum vulgare* (Barley)	Clay loam field soil	6.2	11.9	30.6	1.0	1	4	Yield (root)	**56**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Koeleria macrantha* (june grass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	9	Seedling emergence			27*** (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Koeleria macrantha* (june grass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	9	Seedling emergence			17.0*** (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Koeleria macrantha* (june grass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	9	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Koeleria macrantha* (june grass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	9	Root length	<28.0				Nominal added dosis; background concentration reported
3	H_3BO_3	*Koeleria macrantha* (june grass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	9	Shoot length	84*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Koeleria macrantha* (june grass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	9	Root length	<28.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Koeleria*	Artificial sandy	6.5	4.0	14.8	3.5	1	9	Yield	≥111.9				Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		macrantha (june grass)	loam soil							(shoot)					background concentration reported
2	H_3BO_3	*Koeleria macrantha* (june grass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	9	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Koeleria macrantha* (june grass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	9	Yield (shoot)	≥111.9				Nominal added dosis; background concentration reported
2	H_3BO_3	*Koeleria macrantha* (june grass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	9	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Latuca sativa* (Lettuce)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**22.5****		45 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Latuca sativa* (Lettuce)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**37.0****		74 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Latuca sativa* (Lettuce)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	**42.0**				Nominal added dosis; background concentration reported
2	H3BO3	*Latuca sativa* (Lettuce)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	<28.0				Nominal added dosis; background concentration reported
3	H_3BO_3	*Latuca sativa* (Lettuce)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	<28*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Latuca sativa* (Lettuce)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	28.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Latuca sativa* (Lettuce)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Latuca sativa* (Lettuce)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**55.9**				Nominal added dosis; background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg_{dw}	d	d		mg B/kg_{dw}				
															reported
3	H_3BO_3	*Latuca sativa* (Lettuce)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**30.4****		60.9 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**49.0****		98 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Linum usitatissimum* (Flax)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	**28.0**				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**34.4****		68.7 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**30.5****		61.1 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	<28.0				Nominal added dosis; background concentration reported
3	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	56*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Lolium perenne* (Perennial ryegrass)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**27.7****		55.4 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Lycoperiscon*	Clay loam field	6.2	11.9	30.6	1.0	1	5	Seedling	**15.3****		30.6 (20%)		Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		esculentum (Tomato)	soil							emergence					background concentration reported
2	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	56*****				Nominal added dosis; background concentration reported
3	H3BO3	*Lycoperiscon esculentum* (Tomato)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	28.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	56*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Lycoperiscon esculentum* (Tomato)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Seedling emergence	**47.2****		94.5 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Seedling emergence	**34.6****		69.1 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Shoot length	<28.0				Nominal added dosis; background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
															reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Root length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Shoot length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Root length	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	NR	Yield (root)	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Medicago sativa* (Alfalfa)	Clay loam field soil	6.2	11.9	30.6	1.0	1	NR	Yield (root)	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Seedling emergence	**17.7****		35.2 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Seedling emergence	**38.3****		76.7 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Root length	<28.0				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Phleum pratense* (Timothy)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Shoot length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Root length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Phleum pratense* (Timothy)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	7	Yield (root)	42.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (shoot)	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Phleum pratense* (Timothy)	Clay loam field soil	6.2	11.9	30.6	1.0	1	7	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Raphanus sativus* (Radish)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**38.0****		76.1 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Raphanus sativus* (Radish)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**46.4****		92.9(20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Raphanus sativus* (Radish)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	42.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Raphanus sativus* (Radish)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	<28.0				Nominal added dosis; background concentration reported
3	H_3BO_3	*Raphanus sativus* (Radish)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	56*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Raphanus*	Clay loam field	6.2	11.9	30.6	1.0	1	5	Root length	28.0*****				Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		sativus (Radish)	soil												background concentration reported
2	H_3BO_3	*Raphanus sativus* (Radish)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Raphanus sativus* (Radish)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	28.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Raphanus sativus* (Radish)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	28.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Raphanus sativus* (Radish)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Schizachyrium scoparius* (Little bluestem)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	10	Seedling emergence	**46.0****		92.1 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Schizachyrium scoparius* (Little bluestem)	Clay loam field soil	6.2	11.9	30.6	1.0	1	10	Seedling emergence	**52.0****		104.1 (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Schizachyrium scoparius* (Little bluestem)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	10	Shoot length	84*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Schizachyrium scoparius* (Little bluestem)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	10	Root length	<28.0				Nominal added dosis; background concentration reported
3	H_3BO_3	*Schizachyrium scoparius* (Little bluestem)	Clay loam field soil	6.2	11.9	30.6	1.0	1	10	Shoot length	56*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Schizachyrium*	Clay loam field	6.2	11.9	30.6	1.0	1	10	Root length	56*****				Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg_{dw}	d	d		mg B/kg_{dw}				
		scoparius (Little bluestem)	soil												background concentration reported
2	H_3BO_3	*Schizachyrium scoparius* (Little bluestem)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	10	Yield (total plant)	≥111.9				Nominal added dosis; background concentration reported
2	H_3BO_3	*Schizachyrium scoparius* (Little bluestem)	Clay loam field soil	6.2	11.9	30.6	1.0	1	10	Yield (total plant)	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Trifolium pratense* (Red clover)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence	**17.1****		34.1 (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Trifolium pratense* (Red clover)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence			8.1*** (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Trifolium pratense* (Red clover)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	42.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Trifolium pratense* (Red clover)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Trifolium pratense* (Red clover)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	28.0*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Trifolium pratense* (Red clover)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**28.0**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Trifolium pratense* (Red clover)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Trifolium pratense* (Red clover)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Trifolium pratense* (Red clover)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	<28.0				Nominal added dosis; background concentration reported
3	H_3BO_3	*Trifolium pratense* (Red clover)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	28.0*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Triticum aestivum* (Wheat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence			>111.9**** (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Triticum aestivum* (Wheat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Seedling emergence	**55.8****		111.7 (20%)		Nominal added dosis; background concentration reported
2	H_3BO_3	*Triticum aestivum* (Wheat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Triticum aestivum* (Wheat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	**84**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Triticum aestivum* (Wheat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Triticum aestivum* (Wheat)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported
2	H_3BO_3	*Triticum aestivum* (Wheat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	**56**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Triticum aestivum* (Wheat)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	56*****				Nominal added dosis; background concentration reported
3	H_3BO_3	*Zea mays* (Corn)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Seedling emergence			7.7*** (20%)		Nominal added dosis; background concentration reported
3	H_3BO_3	*Zea mays*	Clay loam field	6.2	11.9	30.6	1.0	1	5	Seedling			>111.9****		Nominal added dosis;

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		(Corn)	soil							emergence			(20%)		background concentration reported
2	H_3BO_3	*Zea mays* (Corn)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Shoot length	<28.0				Nominal added dosis; background concentration reported
2	H_3BO_3	*Zea mays* (Corn)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Root length	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Zea mays* (Corn)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Shoot length	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Zea mays* (Corn)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Root length	**56**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Zea mays* (Corn)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (shoot)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Zea mays* (Corn)	Artificial sandy loam soil	6.5	4.0	14.8	3.5	1	5	Yield (root)	**42.0**				Nominal added dosis; background concentration reported
3	H_3BO_3	*Zea mays* (Corn)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (shoot)	56*****				Nominal added dosis; background concentration reported
2	H_3BO_3	*Zea mays* (Corn)	Clay loam field soil	6.2	11.9	30.6	1.0	1	5	Yield (root)	**56**				Nominal added dosis; background concentration reported
															Aquaterra, 1998
2	H_3BO_3	*Helianthus annus* L. cv. Hysun 31 (Sunflower)	Sandy loam	5.7	1.9	12	NR	7	14	Yield (shoot)	≥ 5.7 (15%)				Nominal added dosis; background concentration reported
															Aitken et al., 1988
4	$Na_2B_4O_7.10H_2O$	*Phaseolus vulgaris* L.	Fine sandy loam	6.0	NR	NR	NR	NR	NR	Yield (pods)	≥4 (-5%)				Nominal added dosis; no background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		(snap beans)													reported
4	$Na_2B_4O_7.10H_2O$	*Raphanus sativus* L. (radish)	Fine sandy loam	6.0	NR	NR	NR	NR	NR	Yield (roots)	≥4 (-50%)				Nominal added dosis; no background concentration reported
4	$Na_2B_4O_7.10H_2O$	*Phleum pratense* L. (timothy)	Fine sandy loam	6.0	NR	NR	NR	NR	NR	Yield (shoot)	2 (2%)		4 (31%)		Nominal added dosis; no background concentration reported
															Gupta, 1983
3	B	*Pisum sativum* L. Pig 16 (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (26%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. Pig 36 (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (31%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. CPI 65352 (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (25%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. SA 132 (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (25%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. SA 395 (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (35%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. SA 213 (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (46%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. SA 448 (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (31%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. SA 310 (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (24%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. SA 1512	Silty clay loam	NR	NR	NR	NR	NR	49	Yield	< 20		20 (41%)		Nominal added dosis; no background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		(pea)	texture							(shoot)					reported
3	B	*Pisum sativum* L. NGB 1574 (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (35%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. M93 (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	20 (7%)		40 (32%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. Alma (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (34%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. Early Dun (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (35%)		Nominal added dosis; no background concentration reported
3	B	*Pisum sativum* L. Pennant (pea)	Silty clay loam texture	NR	NR	NR	NR	NR	49	Yield (shoot)	< 20		20 (52%)		Nominal added dosis; no background concentration reported
															Bagheri et al., 1994
3	NR	*Phaseolus vulgaris* L. (field beans)	Natural soil (Ten Mill House)	5.8 - 6.5	NR	NR	NR	NR	105	Yield (seed)	3.14 (22%)		6.29 (42%)		Nominal added dosis;no background concentration reported
3	NR	*Phaseolus vulgaris* L (field beans).	Natural soil (Tea Hill)	5.8 - 6.5	NR	NR	NR	NR	105	Yield (seed)	3.14 (18%)		6.29 (61%)		Nominal added dosis; no background concentration reported
3	NR	*Phaseolus vulgaris* L. (field beans)	Natural soil (Roseberry)	5.8 - 6.5	NR	NR	NR	NR	105	Yield (seed)	1.57 (3%)		3.14 (26%)		Nominal added dosis; no background concentration reported
3	NR	*Phaseolus vulgaris* L. (field beans)	Natural soil (Bellevue)	5.8 - 6.5	NR	NR	NR	NR	105	Yield (seed)	1.57(-4%)		3.14 (26%)		Nominal added dosis no background concentration reported
3	NR	*Phaseolus vulgaris* L. (field beans)	Natural soil (Ten Mill House)	5.8 - 6.5	NR	NR	NR	365	105	Yield (seed)	≥6.29 (-21%)				Nominal added dosis; no background concentration reported
3	NR	*Phaseolus vulgaris* L (field	Natural soil (Tea	5.8 -	NR	NR	NR	365	105	Yield (seed)	≥6.29				Nominal added dosis; no background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg_{dw}	d	d		mg B/kg_{dw}				
		beans).	Hill)	6.5							(6%)				reported
3	NR	*Phaseolus vulgaris* L. (field beans)	Natural soil (Roseberry)	5.8 - 6.5	NR	NR	NR	365	105	Yield (seed)	≥6.29 (4%)				Nominal added dosis; no background concentration reported
3	NR	*Phaseolus vulgaris* L. (field beans)	Natural soil (Bellevue)	5.8 - 6.5	NR	NR	NR	365	105	Yield (seed)	≥6.29 (6%)				Nominal added dosis; no background concentration reported
3	NR	*Brassica oleracea* L. (cabbage)	Natural soil (Ten Mill House)	5.8 - 6.5	NR	NR	NR	NR	105	Yield (shoot)	≥6.29 (9%)				Nominal added dosis; no background concentration reported
3	NR	*Brassica oleracea* L. (cabbage)	Natural soil (Tea Hill)	5.8 - 6.5	NR	NR	NR	NR	105	Yield (shoot)	≥6.29 (-2%)				Nominal added dosis; no background concentration reported
3	NR	*Brassica oleracea* L. (cabbage)	Natural soil (Roseberry)	5.8 - 6.5	NR	NR	NR	NR	105	Yield (shoot)	≥6.29 (4%)				Nominal added dosis; no background concentration reported
3	NR	*Brassica oleracea* L. (cabbage)	Natural soil (Bellevue)	5.8 - 6.5	NR	NR	NR	NR	105	Yield (shoot)	≥6.29 (23%)				Nominal added dosis; no background concentration reported
3	NR	*Brassica oleracea* L. (cabbage)	Natural soil (Ten Mill House)	5.8 - 6.5	NR	NR	NR	365	105	Yield (shoot)	≥6.29 (-2%)				Nominal added dosis; no background concentration reported
3	NR	*Brassica oleracea* L. (cabbage)	Natural soil (Tea Hill)	5.8 - 6.5	NR	NR	NR	365	105	Yield (shoot)	≥6.29 (-9%)				Nominal added dosis; no background concentration reported
3	NR	*Brassica oleracea* L. (cabbage)	Natural soil (Roseberry)	5.8 - 6.5	NR	NR	NR	365	105	Yield (shoot)	≥6.29 (0%)				Nominal added dosis; no background concentration reported
3	NR	*Brassica oleracea* L. (cabbage)	Natural soil (Bellevue)	5.8 - 6.5	NR	NR	NR	365	105	Yield (shoot)	≥6.29 (-11%)				Nominal added dosis; no background concentration reported
															Gupta & Cutcliffe, 1984
3	H_3BO_3	*Hibiscus cannabinus* L.	Fine-loamy, mixed	6.7	NR	NR	33	> 7	151-170	Yield	4.75**		9.5 (16%)		Measured added dosis; background concentration

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comment
					%	%	mg B/kg_{dw}	d	d		mg B/kg_{dw}				
		(kenaf)	(calcareous) thermic Typic Torriorthent							(shoot)					reported
3	H_3BO_3	*Hibiscus cannabinus* L. (kenaf)	Fine-loamy, mixed (calcareous) thermic Typic Torriorthent	6.7	NR	NR	33	> 7	151-170	Yield (root)	<9.5		9.5 (21%)		Measured added dosis; background concentration reported
3	H_3BO_3	*Hibiscus cannabinus* L. (kenaf)	Fine-loamy, mixed (calcareous) thermic Typic Torriorthent	6.7	NR	NR	33	> 7	151-170	Yield (total plant)	4.75**		9.5 (17%)		Measured added dosis; background concentration reported
3	H_3BO_3	*Gossypium hirsutum* L. (cotton)	Fine-loamy, mixed (calcareous) thermic Typic Torriorthent	6.7	NR	NR	31.5	>7	151-170	Yield (shoot)	4.5**		9 (15%)		Measured added dosis; background concentration reported
3	H_3BO_3	*Gossypium hirsutum* L. (cotton)	Fine-loamy, mixed (calcareous) thermic Typic Torriorthent	6.7	NR	NR	31.5	>7	151-170	Yield (root)	≥9 (15%)				Measured added dosis; background concentration reported
3	H_3BO_3	*Gossypium hirsutum* L. (cotton)	Fine-loamy, mixed (calcareous) thermic Typic Torriorthent	6.7	NR	NR	31.5	>7	151-170	Yield (total plant)	4.5**		9 (15%)		Measured added dosis; background concentration reported
															Banuelos et al., 1996

EP: equilibration period

NR: not reported

*: % effect (inhibition) between brackets. The % inhibition was calculated as: (A-B)/A * 100 where A is the response of the control soil and B is the response of the treated soil.

**: calculated as ECx (x between 10 and 20%)/2

***: EC20 value lower than the lowest tested concentration

****: EC20 higher than the highest tested concentration

*****: no dose response curve

[1] Aquaterra, 1998

Test species: *Agropyion dasystachyum* (northern wheatgrass), *gropyion riparium* (Streambank wheatgrass), *Agropyion smithii* (Western wheatgrass), *Allium cepa* (Spanish onion), *Avena sativa* (oat), *Beckmannia syzigachne* (American sloughgrass), *Bouteloua gracillus trachycaulum* (Grama grass), *Brassica napus* (Canola), *Brasica oleracea* (cabbage), *Brassica rapa* (Turnip), *Bromus ciliatus* (Fringed bromegrass), *Bromus marginatus* (Mountain bromegrass), *Calamagrostis canadensis* (Bluejoint marsh reed), *Cucumis sativa* (Cucumber), *Daucus carota* (Carrot), *Festuca rubra* (Red fescue), *Glycine max* (Soybean), *Hordeum vulgare* (Barley), *Koeleria macrantha* (June grass), *Latuca sativa* (Lettuce), *Linum usitatissimum* (Flax), *Lolium perenne* (Perennial ryegrass), *Lycoperiscon esculentum* (Tomato), *Medicago sativa* (Alfalfa), *Phleum pratense* (Timothy), *Raphanus sativus* (Radish), *Schizachyrium scoparius* (Little bluestem), *Trifolium pratense* (Red clover), *Triticum aestivum* (Wheat), *Zea mays* (Corn).

Test protocol: no standard guideline was reported.

Test soil: the toxicity tests were performed with an artificial and a clay loam reference soil. The ingredients of artificial soil were 70% silica sand, 20% kaolinite clay, 10% sphagnum peat and maximum 0.3% calcium carbonate. The clay loam reference soil is a field collected soil from Alberta (Canada) and classified as a Delacour Orthic Black Chernozem. The soil beneath the sod was air-dried to about 10-20% moisture content, sieved (4 mm or 9 mm) and stored at 4°C until needed.

Physico-chemical characteristics:

-artificial soil: pH water (1:2) 6.4-6.6, eCEC 6-9 cmol$_c$/kg, clay 14.8%, sand 76.4%, organic matter 3-5%;

-clay loam reference soil: pH water (1:2) 6.1-6.3, eCEC 36 cmol$_c$/kg, clay 30.6%, sand 26.6%, organic matter 11.6-12.2%. All tests were performed ina growth chamber at 24°C± 2°C with a photoperiod of 16 h light:8 h dark, except for the first 48 h (dark).

Soil preparation: Test compound added in solution to soil and mixed until visible uniformity of colour and texture. Soil moisture was 30-40% (based on wet weight), corresponding to 70% of WHC.

Test concentrations: 0-160-240-320-480-640 mg boric acid/kg dw in both soils. 4 replicates were used (5 or 10 seeds per replicate).

Equilibration period: 1 day.

Test duration: 4 to 24 days, depending on the plant species

Endpoints: seedling emergence, shoot/root length, shoot/root wet/dry phytomass, or whole plant wet/dry phytomass.

Analytics: soils were digested with nitric acid and boron concentration in the filtrates was analysed using ICP. The recovery of the nominal doses was 70 and 68% in the clay loam reference soil and the artificial soil, respectively. NOEC and ECx values are based on nominal values. Boron concentrations in the unamended control soils were derived form graphs and estimated as 1.0 mg B/kg (5.7 mg boric acid/kg) for the clay loam reference soil and as 3.5 mg B/kg (20.25 mg boric acid/kg) in the artificial soil.

Statistics: EC50 and EC20 values were generated using the Probit method; NOEC values were estimated using ANOVA ($p<0.05$).

Toxicity data: 4 to 24 days NOEC data (added) varied between <28 and ≥ 111.9 mg B/kg dw.

The rejected data (Klimisch 3) are the result of a poor dose-response curve.

Reliability: no standard test, but selection criteria fulfilled for Klimisch 2

[2] Aitken, 1988

Test species: *Helianthus annus* L. cv. Hysun 31 (sunflower).

Test protocol: no standard guideline was reported.

Test soil: the toxicity tests were performed with six soils: two loamy sand soils, two sand soils, one sandy loam soil and one silty clay soil. Soils were air-dried and sieved (< 5 mm).

Physico-chemical characteristics:

Soil	Texture class	pH*	Extr B** mg B/kg	Org. Carbon %	Sand %	Silt %	Clay %
1	loamy sand	5.9	0.14	0.7	78	15	8
2	sand	5.7	0.14	0.5	93	6	2
3	sandy loam	5.7	0.16	1.1	78	10	12
4	sand	5.1	0.03	0.1	98	1	1
5	loamy sand	4.8	0.12	0.7	82	8	10
6	silty clay	4.8	0.65	1.7	18	32	49

* pH water (1:5)

** hot 0.01 M $CaCl_2$ extractable B

Soil preparation: Basal nutrients (N, K, S, Ca, Mg, Cu, Zn, Mn and Mo) were added in solution form and mixed throughout the soil. Soils 4, 5 and 6 were limed (with $CaCO_3$) to a pH of 6.5. Boron, as H_3BO_3 in solution, was applied at rates which covered the sufficiency and toxicity ranges. Soils were mixed and brought to field capacity (10kPa matric suction). Two plants were established in each container and grown for 14 days at field capacity (16h day at 30°C, 8h night at 25°C, 70% relative humidity).

Test concentrations: Seven rates of boron (0, 0.25, 0.5, 1, 2, 4 and 8 kg B ha^{-1}) were applied to each of soils 1-4. Nine rates of boron (0, 0.25, 0.5, 1, 2, 4, 6, 8 and 12 kg B ha^{-1}) were applied to soils 5 and 6. Rates in kg/ha were converted to mg/kg based on the following assumtions: depth: 10 cm and density: 1.4 kg/dm³. There were three replicates of each treatment.

Equilibration period: 7 days.

Test duration: 14 days

Endpoints: dry matter yield.

Analytics: No analysis of total soil B concentration. The boron concentration in soil solution extracts and hot $CaCl_2$ extracs was determined by ICP-AES.

Statistics: NOEC values are derived based on the reported Least Significant Difference (LSD, at significance level of $P < 0.05$) between treatments. No information was presented on how this LSD value was derived. The NOEC value is derived based on Table 2 of the original study, taking into account the LSD (least significant difference) to determine the NOEC and conversion of the value of 8 kg B/ha into 5.7 mg B/kg as explained in the discussion of this study. This calculation is indeed not mentioned in the original study but is a standard calculation:

1 ha = 100*100*0.1 m³ = 1000 m³

Average bulk density top soil = 1.4 kg/dm³ ➔ 1 ha = 1.4 * 10^6 kg dw

8 kg B / ha = 8 kg B / 10^6 kg dw = 5.7 mg B / kg DW

The assumption of a depth of 10 cm is based on the size of the containers used (11 cm high) and the density of 1.4 kg/dm^3 is an average for the top horizon of mineral soils (representative range 1.3 to 1.5 kg/dm^3). The choice of the density has only very limited effect on the final B concentration (max 10%)

The other 5 soils mentioned in the Aitken and McCallum study all had soil properties outside the relevant range and therefore these results are presented in the Annex IV

Toxicity data: 14 days NOEC data (added) varied between 1.4 and ≥8.6 mg B/kg dw. The NOEC for the only soil with properties within the relevant range for Europe was ≥ 5.7 mg B/kg dw.

Reliability: selection criteria fulfilled for Klimisch 2 (no standard test guideline followed, but well performed and well documented study)

[3] Gupta, 1983

Test species: snap beans (*Phaseolus vulgaris L. cv.* 'Eastern Butterwax'), radish (*Raphanus sativus L. cv.* 'Cherry Belle'), tomatoes (*Lycopersicon esculentum, Mill cv.* 'Better Boy'), timothy (*Phleum pratense L. cv.* 'Climax') and corn (*Zea mays L. cv.* 'North Star'). Toxicity data (NOEC values) could only be retrieved for snap beans, radish and timothy.

Test protocol: no standard guideline was reported.

Test soil: fine sandy loam

Physico-chemical characteristics: pH 6.0.

Soil preparation: Boron was added as sodium borate ($Na_2B_4O_7.10H_2O$) solution (no information on mixing). Sufficient quantities of N, P, K, S and Mo were added to prevent deficiencies. Fourteen plants of radish and 10 plants of the other four crops were grown in 4.5 L pails containing 3500 g (oven-dry basis) soil. Supplementary lighting was provided to give a daily 14 h photoperiod at an intensity of 1100 lx at the soil surface using both fluorescent and incandescent light sources. Day and night temperature regimes were about 22 and 16°C, respectively.

Test concentrations: 0-1-2-4 ppm B (assumed to be mg B/kg dw). Four replicates.

Equilibration period: not reported.

Test duration: not reported (at prebloom, five bean plants were harvested, leaving five plants to grow to maturity to the green pod stage. All 10 plants in each pail were harvested for tomatoes when plants were 15 cm high, and for corn when 25 cm high. Tomatoes and corn being rather large crops, they were not grown to maturity in the greenhouse and thus no final yields of corn or tomatoes could be obtained. Seven plants of radish were harvested when roots began to swell and the remaining seven plants at normal maturity of the roots. In the case of timothy, all the plants were harvested at the beginning of the heading stage and the dry weight of tops was recorded).

Endpoint: Effect of B on crop yields

Analytics: No measurement of soil B concentrations.

Statistics: NOEC values are derived based on the reported Least Significant Difference (LSD, at significance level of $P < 0.05$) between treatments. No information was presented on how this LSD value was derived.

Toxicity data: NOEC data (added) varied between 2 and ≥4 mg B/kg dw.

Reliability: 4 (no standard guideline followed, no soil properties reported, no equilibration or test duration reported, B doses reported as ppm)

[4] Bagheri et al (1994)

Test species: *Pisum sativum L.* (pea) genotypes Pig 16, Pig 36, CPI 65352, SA 132, SA 395, SA 213, SA 448, SA 310, SA 1512, NGB 1574, M93, Alma, Early Dun and Pennant

Test protocol: no standard guideline was reported.

Test soil: The soil was a bulk sample of silty clay loam texture from the surface (0-10 cm) of a red brown earth (Typic Haploxeralf) collected from the Glenthorne Research Farm, O'Halloran Hill, South Australia.

Physico-chemical characteristics: boiling $CaCl_2$ extractable B: 2.3 mg/kg

Soil preparation: four levels of applied boron. The exact test substance was not reported. No information on method of application or mixing.

Test concentrations: 0-20-40-60 mg B/kg dw. 3 replicates were used.

Equilibration period: NR

Test duration: 49 days

Endpoints: dry matter yield

Analytics: Extractable soil B concentrations were measured in a boiling $CaCl_2$ extract. No analysis of total soil B concentrations.

Statistics: Data for dry matter production and tissue boron concentrations were subjected to square root and logarithmic ($\log_e$) transformations, respectively. All data were analysed by factorial analysis and the significance of differences between means was calculated by the LSD test at significance level of 0.01. All NOEC/LOEC values are based on the data presented in Table 4 of the original study. The NOEC values are derived based on the LSD. The % inhibition is calculated as 100 – relative dry matter yield (as reported in columns 3, 4 and 5 of Table 4 in the original study)

Toxicity data: 49 days NOEC data (added) varied between <20 and 20 mg B/kg dw.

Reliability: 3 (no standard guideline followed, test substance not reported, no information on B application, no soil properties reported)

[5] Gupta U.C., Cutcliffe J.A., 1984

Test species: *Phaseolus vulgaris* L. (field beans) and *Brassica oleracea* L. var. *capitata* (cabbage).

Test protocol: field experiment, no standard guideline was reported.

Test soil: the toxicity tests were performed at four different locations in Canada: Ten Mill House (Culloden loamy sand soil), Roseberry (Culloden loamy sand soil), Tea Hill (Tignish fine sandy loam soil) and Bellevue (Alberry fine sandy loam soil). All 4 soils were classified as orthic humoferric podzols.

Physico-chemical characteristics: initial soil pH levels at all sites were within the range of 5.8 - 6.5. Hot water extractable B at the four locations ranged from 0.3 to 0.5 mg/kg soil.

Soil preparation: Boron in the form of Borate-65, containing 20% B, was added to a commercial grade N-P-K (8-16-8 at 550 kg/ha for beans and 15-20-10 at 1100 kg/ha for cabbage) fertilizer and the mixture was applied broadcast by hand and incorporated to a depth of about 10 cm prior to seeding or transplanting.

Test concentrations: 0 - 2.2 - 4.4 - 8.8 kg/ha B were applied to each soil. 4 replicates were used. Rates in kg/ha were converted to mg/kg based on the following assumtions: depth: 10 cm and density: 1.4 kg/dm³.

Equilibration period: field tests started either in the same year (exact equilibration period not reported) or one year after B application (equilibration period 365 days).

Test duration: The center row of each plot was harvested when the crops were fully developed or mature (about 3.5 months or 105 days for both crops). Each crop was grown successively for two seasons at each location.

Endpoints: marketable yields (pods and above ground biomass for beans and cabage, respectively)

Analytics: Soil samples were analyzed for hot water soluble B. Hot water soluble B concentrations decreased significantly with time. No analysis of total soil B concentrations.

Statistics: A separate analysis of variance was conducted at each site. A set of orthogonal comparisons were devised to test the significance of the first crop bean yield data. Least significant difference was determined at significance level P=0.05.

All NOEC/LOEC values are based on the data presented in Table 2 of the original study and the statistics reported in Table 3 of this study.

Boron application rates in kg/ha are converted into mg B/kg doses as described above for the Aitken and McCallum study and based on the same assumptions: depth 10 cm and density 1.4 kg/dm³ (as also reported in the discussion of this study). The assumption of a depth of 10 cm is based on the fact that all applications were incorporated to a depth of about 10 cm prior to seeding or transplanting.

The % inhibition is calculated as described above for the Gupta (1983) study.

Toxicity data: NOEC data (added) varied between 1.57 and ≥6.29 mg B/kg dw.

Reliability: 3 (no standard guideline followed, no soil properties reported, no information on leaching and actual soil B concentration during the test period)

[6] Banuelos, 1996

Test species: *Hibiscus cannabinus* L. (kenaf), *Gossypium hirsutum* L. (cotton)

Test protocol: no standard guideline was reported.

Test soil: Panoche soil (fine-loamy, mixed (calcareous), thermic Typic Torriorthent). The soil was collected from the upper 25 cm of the soil profile in a field on the west side of Central Valley in California (near Los Banos). Soil was air-dried and passed through a 2-mm sieve before use.

Physico-chemical characteristics: pH ~ 6.7, electrical conductivity (EC) was 7.8 dS/m, extractable B was <0.25 mg B/L in the soil saturation extract, and acid-soluble B concentration was ~ 33 mg B/kg soil.

Soil preparation: Boron uptake was evaluated for kenaf and cotton grown in B-amended (7.5 mg B/L) and in control soils (containing extractable B <1mg B L^{-1}) collected post-harvest from pots from an irrigation experiment with control and B amended water. Both types of soils, B-amended and control were removed from the pots used for the irrigation experiment, thoroughly mixed separately, air-dried, passed through a 2-mm mesh, and redeposited into pots

Test concentrations: Initial concentrations: 35 (control) and 47 (B-amended) mg B/kg dw for kenaf, 33 (control) and 44 (B-amended) mg B/kg dw for cotton. Soil B concentrations decrease significantly during the experiment: post-harvest concentrations 31 (control) and 38 (B-amended) mg B/kg dw for kenaf and 30 (control) and 37 (B-amended) mg B/kg dw for cotton. The average of pre-plant and post-harvest total soil B concentrations was used for derivation of toxicity thresholds (Kenaf: 33 and 42.5 mg B/kg for control and B-amended soil, respectively; Cotton: 31.5 and 40.5 mg B/kg for control and B-amended soil, respectively). 18 replicates were used.

Equilibration period: >7 days (time between irrigation experiment and start soil experiment). The current experiment consisted of two experiments conducted at two different times: i) October to March and ii) March to September

Test duration: 151 days (i) and 170 days (ii)

Endpoints: yield in dry matter (leaves, root and total plant)

Analytics:. Water-soluble B in soil was determined on a saturated soil paste. Acid-soluble B was extracted after digestion with nitric acid, sulfuric acid and HCl. B concentration in extracts was analysed using inductively coupled plasma (ICP) emission spectrometry with an Emission Spectrometer Plasma 2000.

Statistics: Separate analysis of variance (ANOVA) was performed for each plant organ and for whole plants. The response variable was dry matter. Log transformation of young stem, root, and whole plant data was necessary to normalize it for ANOVA. Separate ANOVA were performed on the B responses in the soil for the treatments (B-amended water and control water). Data from acid-soluble B were transformed by ranks to stabilize the variances between treatrments in B analyses that excluded extractable B for the B treatment. Pearsons correlation and Kendall's tau-rank correlation tests were conducted to compare plant tissue concentrations of B with dry weight. All data presented represent pooled mean values from all three greenhouses (blocks) with standard errors from replications for all treatments per species, respectively. Values represent the pooled mean from experiments (i) and (ii) with 18 replications in each, respectively, followed by the standard error in parentheses. Mean separation between control and B-amended soils for each plant species was performed by Tukey's range test.

Toxicity data: NOEC data (added) varied between 4.5 and ≥9 mg B/kg dw.

Reliability: 3 (no standard guideline followed, only control and one dose tested)

Annex TC III. Overview of the ecotoxicity data for soil microbial processes. Data useful for PNEC derivation are marked in bold

Klimisch	Test subst.	Process	Medium	pH	OM	clay	Cb	EP	Duration	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	mg/kg$_{dw}$	d	d	mg B/kg$_{dw}$				
1	H_3BO_3	N transformation	Humic sand soil	6.0	2.1* **	4.5	NR	0	102		**15.4**		>17.5	Nominal added dosis; no background concentration reported
1	H_3BO_3	N transformation	Sandy loam soil	8.3	0.9* **	12.6	NR	0	28	3.0				Nominal added dosis; no background concentration reported
														Hanstveit et al., 2001
3	$Na_2B_4O_7$	N mineralisation	Loam soil (Webster)	5.8	4.4	23	NR	NR	20	27.0**		54.1 (14%)		
3	$Na_2B_4O_7$	N mineralisation	Clay loam soil (Harps)	7.8	6.4	30	NR	NR	20	≥54.1 (7%)				
														Liang & Tabatabai, 1977
3	$Na_2B_4O_7$	Nitrification	Loam soil	5.8	4.4	23	NR	NR	10			54.1 (92%)		
3	$Na_2B_4O_7$	Nitrification	Clay loam soil	7.8	6.4	30	NR	NR	10			54.1 (74%)		
														Liang & Tabatabai, 1978

EP: equilibration period

NR: not reported

*: % effect (inhibition) between brackets. The % inhibition was calculated as: (A-B)/A * 100 where A is the response of the control soil and B is the response of the treated soil.

**: calculated as ECx (x between 10 and 20%)/2
***Organic Carbon content

[1] Hanstveit et al., 2001

Soil process: Nitrogen transformation

Test protocol: according to OECD Guideline 216, study carried out in compliance with OECD Principles of Good Laboratory Practice (GLP).

Nitrogen transformation was studied by adding powdered lucerne meal (C/N ratio 13/1) to the soil samples treated with either the test substance or left untreated (control), and incubating the soil at constant temperature. The nitrogen transformation activity was determined by measuring the formation rate of nitrate in soils.

Test soil:

- sandy loam, taken from grassland located at the Maasdijk (Heerewaarden, The Netherlands), sand 63.4%, silt 24.0%, clay 12.6%, Organic matter 1.6%, pH (1:5) in water 8.3, pH (1:5) in 0.01 M $CaCl_2$ 7.6, CEC (buffered at pH 8.1) 9.0 $cmol_c/kg$, total nitrogen 0.12%, microbial biomass: 128 mg C/kg dw
- humic sand taken at the 'Droevendaal' experimental station (Wageningen, The Netherlands), sand 85.3%, silt 10.2%, clay 4.5%, Organic matter 3.6%, pH (1:5) in water 6.0, pH (1:5) in 0.01 M $CaCl_2$ 5.4, CEC (buffered at pH 8.1) 12.9 $cmol_c/kg$, total nitrogen 0.11%, microbial biomass: 106 mg C/kg dw

Soil samples were stored at refrigerator temperature pending use. Before the start of the experiment, soil samples were partly air-dried until they could be sieved over 2 mm.

Soil preparation: Soil moisture during the test was adjusted to *ca* 50% of WHC (i.e. water content of 21.1% for the sandy loam and 17.8% for the humic acid soil). Soils were amended with powdered lucerne meal (C/N ratio 13/1) at a ratio of 5 g/kg dw and thoroughly mixed. Borc acid (Manufacturing Grade, >99.9% purity) was added as a solution to soil and mixed thoroughly. All tests were performed at 20°C.

Test concentrations: 0.3, 3, 10, 30 and 100 mg boric acid /kg dw; i.e. 0, 0.05, 0.52, 1.75, 5.25 and 17.5 mg B/kg dw.

Equilibration period: 0 days.

Test duration: up to 102 days.

Endpoints: nitrification rate (mg NO_3-N produced/kg/day)

Analytics: No analysis of total soil B concentrations. Nitrate concentrations were measured in a 0.1M KCl extract (1:5 soil:solution ratio) by ion chromatography (4 replicates per treatment).

Statistics: In the original study report, nitrification rates were calculated based on the soil nitrate concentration after x days without taking the nitrate conentration at day 0 into acount. Morover, a 25% effect level was used as threshold for significance. Therefore, data analysis was repeated, based on the raw data reported. The nitrification rate was calculated as:

$$R_{NO_3,x} = \frac{\left(C_{NO_3,x} - C_{NO_3,0}\right)}{x}$$

With $R_{NO3,x}$, the nitrification rate during x days, $C_{NO3,x}$, the nitrate concentration in the soil sample after x days and $C_{NO3,x}$, the nitrate concentration in the soil sampleat day 0. However, this way only an average response (nitrification rate) could be calculated per treatment and no NOEC values could be derived. EC10 values for nitrification rate were based on a log-logistic dose-response curve fitted by minimising unweighted squared residuals sum (maximum likelihood):

$$Y = \frac{C}{1 + \exp^{(-B(x-A))}}$$

With Y = average response per treatment, X = log10 of the dose and A, B and C function parameters

Toxicity data: 102 days EC10 values (added) varied between 15.4 and 17.2 mg B/kg dw, 28 days NOEC (added) 3 mg/kg dw

Reliability: Klimisch 1 (well documented study according to OECD guidelines).

Only the humic sand soil has properties within the 10th and 90th percentile of soil properties for Europe. As OECD guideline 216 suggests the use of "extreme" soils with maximum availability of the test compound, values for the sand loam soil are also listed here.

[2] Liang & Tabatabai, 1977

Soil process: Nitrogen mineralisation

Test protocol: no standard guideline was reported.

Test soil: the toxicity tests were performed with natural surface soils (0-15 cm). Soils were air-dried and passed througha 2 mm screen before use.

Physico-chemical characteristics:

-Webster soil: pH water (1:2.5) 5.8, clay 23%, sand 38%, organic carbon 2.58%;

-Harps soil: pH water (1:2.5) 7.8, clay 30%, sand 26%, organic carbon 3.74%;

-Okoboji soil: pH water (1:2.5) 7.4, clay 34%, sand 16%, organic carbon 5.45%;

-Judson soil: pH water (1:2.5) 6.6, clay 45%, sand 1%, organic carbon 2.95%..

All tests were performed at 30°C.

Soil preparation: Test compound added in solution to soil (added dropwise without mixing). Soil moisture was *ca* 60% of WHC.

Test concentrations: 0-54.1 mg B/kg d.w (50 µmol B/10 g soil) in all soils

Equilibration period: 0 days.

Test duration: 20 days.

Endpoints: nitrogen mineralization (production of ammonium and nitrate)

Analytics: No analysis of total soil B concentrations.

Statistics: No statistics were reported on difference in N mineralisation between control and B-amended treatments. Only the % inhibition compared to control treatment was calculated for single dose tested. The NOEC/LOEC values were derived based on a 10% inhibition threshold (<10% inhibition: no significant effect; >10% inhibition: significant effect).

Toxicity data: 20 days NOEC values (added) varied between 27.0 and ≥54.1 mg B/kg dw.

Reliability: Klimisch 3 (only 1 dose tested, no information on replicates of B treatments).

[3] Liang & Tabatabai, 1978

Soil process: Nitrification of added NH_4-N substrate.

Test protocol: no standard guideline was reported.

Test soil: the toxicity tests were performed with natural surface soils (0-15 cm). Soils were air-dried and passed througha 2 mm screen before use.

Physico-chemical characteristics:

-Webster soil: pH water (1:2.5) 5.8, clay 23%, sand 38%, organic carbon 2.58%;

-Harps soil: pH water (1:2.5) 7.8, clay 30%, sand 26%, organic carbon 3.74%;

-Okoboji soil: pH water (1:2.5) 7.4, clay 34%, sand 16%, organic carbon 5.45%.

All tests were performed at 30°C.

Soil preparation: Test compound added in solution to soil (added dropwise without mixing). Soil moisture was *ca* 60% of WHC.

Test concentrations: 0-54.1 mg B/kg d.w (50 µmol B/10 g soil) in all soils

Equilibration period: 0 days.

Test duration: 10 days.

Endpoints: production of nitrites and nitrates

Analytics: No analysis of total soil B concentrations.

Statistics: No statistics were reported on difference in nitrification between control and B-amended treatments. Only the % inhibition compared to control treatment was calculated for single dose tested. The NOEC/LOEC values were derived based on a 10% inhibition threshold (<10% inhibition: no significant effect; >10% inhibition: significant effect).

Toxicity data: all unbounded LOEC values (significant negative effect at 54.1 mg B/kg dw, i.e. lowest dose tested).

Reliability: Klimisch 3 (only 1 dose tested, no information on replicates of B treatments).

Annex IV - Toxicity data not relevant for $PNEC_{soil}$ derivation

This annex lists all toxicity data that are judged of lower relevance for derivation of an EU-PNEC for the terrestrial environment. The main reasons for excluding these data are:

i) hydroponics or soil solution data only allowing calculating solution based NOEC or EC10 values Using the equilibrium-partitioning method, these data could in principle be used to derive a terrestrial PNEC. However, the additional uncertainty related to the use of Kd-values will be high. Preference is therefore given to the use of real soil data. The according data is thus not listed, but references for studies with relevant information are given in Tables A.1 and A.2.

ii) data on enzymatic processes Enzymatic processes are considered less relevant where they involve measurement of extracellular enzymatic activities, or when tests are not equivalent to the Annex V or OECD testguidelines or where their reliability or reproducibility is questionable. The according data is thus not listed but references for studies with relevant information are given in Table A.3.

iii) pH, OM or clay of the soils tested do not fall within the 10th and 90th percentile of the soil properties in Europe **(Table A.4 and A.5)**. Such data can be used to derive PNEC values for specific but less common EU soil types, this is with soil properties beyond the 10-90th percentiles.

Table A.1. Overview of study references with hydroponic ecotoxicity data for higher plants

Reference	Test subst.	Medium
Glaubig & Bingham, 1985	Not reported	sandy loam (mixed mesic Typic Xerorthent
Nable, 1988	Not reported	Hydroponic
Francois, 1991	Not reported	Sand culture
Salinas et al., 1981	Not reported	hydroponic
Eaton, 1944	Not reported	Sand culture
Francois & Clark, 1979	Not reported	Sand culture
Paull et al., 1992	Not reported	Hydroponic
Banuelos et al., 1999	Not reported	Seeds on saturated filter paper
El-Sheikh et al., 1971	Not reported	Sand culture
Lauter et al., 1989	Not reported	Hydroponic
Hodgkiss et al., 1942	Not reported	Sand culture
Francois, 1986	Not reported	Sand culture
Francois, 1989	Not reported	Sand culture
Francois, 1988	Not reported	Sand culture
Francois, 1992	Not reported	Sand culture
Chapman et al., 1997	Not reported	Hydroponic
Bingham et al., 1985	Not reported	Sand culture
Davis et al., 1978	Not reported	Sand culture
Chatterjee C. et al, 2005	H_3BO_3	Refined sand
Lee et al., 1996	Not reported	Sphagnum peatmoss-perlite mix
Banuelos et al., 1996	Not reported	Fine-loamy, mixed (calcareous) thermic Typic Torriorthent
Ben-Gal et al, 2002	H_3BO_3	Arava sandy loam soil
Ben-Gal et al., 2007	Not reported	Medium grade (2-5 mm) perlite growth media
Bergmann et al., 1995	H_3BO_3	Gravel-Hydroculture

Table A.2. Overview of study references with water based ecotoxicity data for microbial/enzymatic processes

Reference	Test subst.	Medium
Bowen & Gauch, 1966	H_3BO_3	Culture solution

Table A.3. Overview of study references with ecotoxicity data for enzymatic processes in soil.

Reference	Test subst.	Process

Reference	Test subst.	Process
Rogers & Li, 1985	$Na_2B_4O_7$	Dehydrogenase activity
Al-Khafaji & Tabatabai, 1979	$Na_2B_4O_7$	Arylsulfatase activity
Juma & Tabatabai, 1977	$Na_2B_4O_7$	Phosphatase (alkaline) activity
Tabatabai, 1977	$Na_2B_4O_7$	Urease activity
Stott et al., 1985	$Na_2B_4O_7$	Pyrophosphatase activity
Frankenberger & Tabatabai, 1991a	$Na_2B_4O_7$	L-glutaminase activity
Frankenberger & Tabatabai, 1991b	$Na_2B_4O_7$	L-asparaginase activity
Fu & Tabatabai, 1989	$Na_2B_4O_7.10H_2O$	Nitrate reductase activity

Table TC IV. Overview of the ecotoxicity data for higher plants in soils with properties beyond the EU 10-90th percentile bounderies. The pH, organic matter or clay content values which fall outside of the representative range are underlined.

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	H_3BO_3	*Helianthus annus* L. cv. Hysun 31 (Sunflower)	Loamy sand	5.9	1.2	8	NR	7	14	Yield (shoot)	≥ 5.7 (2%)				
2	H_3BO_3	*Helianthus annus* L. cv. Hysun 31 (Sunflower)	Sand	5.7	0.9	2	NR	7	14	Yield (shoot)	1.4 (8%)		2.9 (24%)		
2	H_3BO_3	*Helianthus annus* L. cv. Hysun 31 (Sunflower)	Sand	6.5	0.2	1	NR	7	14	Yield (shoot)	1.4 (0%)		2.9 (24%)		
2	H_3BO_3	*Helianthus annus* L. cv. Hysun 31 (Sunflower)	Loamy sand	6.5	1.2	10	NR	7	14	Yield (shoot)	4.3 (4%)		5.7 (17%)		
2	H_3BO_3	*Helianthus annus* L. cv. Hysun 31 (Sunflower)	Silty clay	6.5	2.9	49	NR	7	14	Yield (shoot)	≥ 8.6 (16%)				
															Aitken et al., 1988
3	H_3BO_3	*Lens culinaris* (ILL2024)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity (>76)	Yield (total plant)	15 (1%)		25 (45%)		
3	H_3BO_3	*Lens culinaris* (Cassab)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity (>76)	Yield (total plant)	<15		15 (78%)		
3	H_3BO_3	*Lens culinaris* (ILL213A)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity (>76)	Yield (total plant)	<25		25 (23%)		
3	H_3BO_3	*Lens culinaris* (ILL5883)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity	Yield (total plant)	<25		25 (74%)		

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
									(>76)						
3	H_3BO_3	*Lens culinaris* (Laird)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity (>103)	Yield (total plant)	<25		25 (73%)		
3	H_3BO_3	*Lens culinaris* (Nugget)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity (>76)	Yield (total plant)	<25		25 (93%)		
3	H_3BO_3	*Lens culinaris* (ILL2024)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Plant height	15 (9%)		25 (18%)		
3	H_3BO_3	*Lens culinaris* (Cassab)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Plant height	<15		15 (48%)		
3	H_3BO_3	*Lens culinaris* (ILL213A)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Plant height	12.5**		25 (11%)		
3	H_3BO_3	*Lens culinaris* (ILL5883)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Plant height	<25		25 (21%)		
3	H_3BO_3	*Lens culinaris* (Laird)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Plant height	<25		25 (35%)		
3	H_3BO_3	*Lens culinaris* (Nugget)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Plant height	<25		25 (54%)		
3	H_3BO_3	*Lens culinaris* (ILL2024)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Yield (root)	15 (15%)		25 (51%)		
3	H_3BO_3	*Lens culinaris* (Cassab)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Yield (root)	<15		15 (92%)		
3	H_3BO_3	*Lens culinaris* (ILL213A)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Yield (root)	≥ 25 (38%)				
3	H_3BO_3	*Lens culinaris* (ILL5883)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Yield (root)	<25		25 (78%)		
3	H_3BO_3	*Lens culinaris* (Laird)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Yield (root)	<25		25 (89%)		
3	H_3BO_3	*Lens culinaris* (Nugget)	Loamy calcarosol	7.5	NR	NR	NR	7	76	Yield (root)	<25		25 (95%)		

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
3	H_3BO_3	*Lens culinaris* (ILL2024)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity (>76)	Yield (seed)	≥ 25 (47%)				
3	H_3BO_3	*Lens culinaris* (Cassab)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity (>76)	Yield (seed)	<15		15 (83%)		
3	H_3BO_3	*Lens culinaris* (ILL213A)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity (>76)	Yield (seed)	≥ 25 (19%)				
3	H_3BO_3	*Lens culinaris* (ILL5883)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity (>76)	Yield (seed)	<25		25 (75%)		
3	H_3BO_3	*Lens culinaris* (Laird)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity (>103)	Yield (seed)	<25		25 (91%)		
3	H_3BO_3	*Lens culinaris* (Nuget)	Loamy calcarosol	7.5	NR	NR	NR	7	until maturity (>76)	Yield (seed)	<25		25 (96%)		
															Hobson et al., 2006
3	H_3BO_3	*Brassica rapa* (WWY Sarson)	Calcarosol	8	NR	NR	NR	7	35	Yield (shoot)	≥ 50 (15%) ($CaCl_2$ extraction)				
3	H_3BO_3	*Brassica rapa* (Local)	Calcarosol	8	NR	NR	NR	7	35	Yield (shoot)	≥ 50 (4%) ($CaCl_2$ extraction)				
3	H_3BO_3	*Brassica rapa* (Shillong)	Calcarosol	8	NR	NR	NR	7	35	Yield (shoot)	<25 ($CaCl_2$ extraction)		25 (67%) ($CaCl_2$ extraction)		
3	H_3BO_3	*Brassica rapa* (Kaga)	Calcarosol	8	NR	NR	NR	7	35	Yield (shoot)	<25 ($CaCl_2$ extraction)		25 (43%) ($CaCl_2$ extraction)		
3	H_3BO_3	*Brassica rapa* (WWY Sarson)	Calcarosol	8	NR	NR	NR	7	38	Yield (total plant)	12.5** ($CaCl_2$		25 (14%) ($CaCl_2$		

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	$mg\ B/kg_{dw}$	d	d		$mg\ B/kg_{dw}$				
											extraction)		extraction)		
3	H_3BO_3	*Brassica rapa* (WWY Sarson)	Calcarosol	8	NR	NR	NR	7	71	Yield (total plant)	<25 ($CaCl_2$ extraction)		25 (8%) ($CaCl_2$ extraction)		
3	H_3BO_3	*Brassica rapa* (Local)	Calcarosol	8	NR	NR	NR	7	38	Yield (total plant)	≥25 (0%) ($CaCl_2$ extraction)				
3	H_3BO_3	*Brassica rapa* (Local)	Calcarosol	8	NR	NR	NR	7	71	Yield (total plant)	<25 ($CaCl_2$ extraction)		25 (3%) ($CaCl_2$ extraction)		
3	H_3BO_3	*Brassica rapa* (Shillong)	Calcarosol	8	NR	NR	NR	7	38	Yield (total plant)	<25 ($CaCl_2$ extraction)		25 (21%) ($CaCl_2$ extraction)		
3	H_3BO_3	*Brassica rapa* (Shillong)	Calcarosol	8	NR	NR	NR	7	71	Yield (total plant)	<25 ($CaCl_2$ extraction)		25(78%) ($CaCl_2$ extraction)		
3	H_3BO_3	*Brassica rapa* (WWY Sarson)	Calcarosol	8	NR	NR	NR	7	NR	Root length	<25 ($CaCl_2$ extraction)		25 (4) ($CaCl_2$ extraction)		
3	H_3BO_3	*Brassica rapa* (Local)	Calcarosol	8	NR	NR	NR	7	NR	Root length	≥ 29 (4%) $CaCl_2$ extraction)				
3	H_3BO_3	*Brassica rapa* (Shillong)	Calcarosol	8	NR	NR	NR	7	NR	Root length	<25 ($CaCl_2$ extraction)		25 (62) ($CaCl_2$ extraction)		
3	H_3BO_3	*Brassica rapa* (WWY Sarson)	Calcarosol	8	NR	NR	NR	7	71	Plant height	≥ 25 (0%) ($CaCl_2$ extraction)				
3	H_3BO_3	*Brassica rapa* (Local)	Calcarosol	8	NR	NR	NR	7	71	Plant height	≥ 25 (4%) ($CaCl_2$ extraction)				
3	H_3BO_3	*Brassica rapa* (Shillong)	Calcarosol	8	NR	NR	NR	7	71	Plant height	<25 ($CaCl_2$ extraction)		25 (60%) ($CaCl_2$ extraction)		

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
															Kaur et al., 2006
3	H_3BO_3	*Trifolium vesiculosum* (arrowleaf clover)	“Cambissolo álico” with medium texture	4.4	1.3	22	NR	NR	135	Yield (shoot)	≥ 0.7				
3	H_3BO_3	*Trifolium vesiculosum* (arrowleaf clover)	“Cambissolo álico” with medium texture	4.4	1.3	22	NR	NR	135	Yield (root)	≥ 0.7				
3	H_3BO_3	*Trifolium vesiculosum* (arrowleaf clover)	“Cambissolo álico” with medium texture	4.4	1.3	22	NR	NR	135	Root length	≥ 0.7				
															Favaretto et al., 2007
3	H_3BO_3	*X. Triticosecale* WITTMACK cultivar IAC 3 (triticale)	Medium-textured dystrophic Hapludox	4.0	1.43	NR	NR	NR	NR	Yield (grain)		>1.33			
3	H_3BO_3	*X. Triticosecale* WITTMACK cultivar BR 4 (triticale)	Medium-textured dystrophic Hapludox	4.0	1.43	NR	NR	NR	NR	Yield (grain)		>1.33			
3	H_3BO_3	*X. Triticosecale* WITTMACK cultivar BR 53 (triticale)	Medium-textured dystrophic Hapludox	4.0	1.43	NR	NR	NR	NR	Yield (grain)		0.21			
3	H_3BO_3	*Triticum aestivum* L. cultivar IAPAR 38 (wheat)	Medium-textured dystrophic Hapludox	4.0	1.43	NR	NR	NR	NR	Yield (grain)		>1.33			
3	H_3BO_3	*X. Triticosecale* WITTMACK cultivar IAC 3	Medium-textured dystrophic Hapludox	4.0	1.43	NR	NR	NR	NR	Yield (total plant)		>1.33			

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		(triticale)													
3	H_3BO_3	*X. Triticosecale* WITTMACK cultivar BR 4 (triticale)	Medium-textured dystrophic Hapludox	4.0	1.43	NR	NR	NR	NR	Yield (total plant)		>1.33			
3	H_3BO_3	*X. Triticosecale* WITTMACK cultivar BR 53 (triticale)	Medium-textured dystrophic Hapludox	4.0	1.43	NR	NR	NR	NR	Yield (total plant)		1.14			
3	H_3BO_3	*Triticum aestivum* L. cultivar IAPAR 38 (wheat)	Medium-textured dystrophic Hapludox	4.0	1.43	NR	NR	NR	NR	Yield (total plant)		>1.33			
															Corrêa et al. 2005
3	B	*Cucumis melo* L., variety Top Mark (melon)	Very-fine, smectitic, thermic Halic Haploxerert	NR	1.4	54.3		NR	95	Yield (leaves)	≥42.7 (16%)				
3	B	*Cucumis melo* L., variety Top Mark (melon)	Very-fine, smectitic, thermic Halic Haploxerert	NR	1.4	54.3		NR	95	Yield (stem)	≥42.7 (-59%)				
3	B	*Cucumis melo* L., variety Top Mark (melon)	Very-fine, smectitic, thermic Halic Haploxerert	NR	1.4	54.3		NR	95	Yield (fruit)		12.6		21.8	
3	B	*Cucumis melo* L., variety Top Mark (melon)	Very-fine, smectitic, thermic Halic Haploxerert	NR	1.4	54.3		NR	95	Yield (total plant)		39.4		43.3	
															Goldberg et al., 2003
3	H_3BO_3	*Hordeum vulgare* L. cv. Stirling (barley)	Sandy soil	5.6	1.2	3.5	NR	NR	NR (>85 d)	Yield (shoot)		1.4		>8	
3	H_3BO_3	*Hordeum vulgare* L. cv.	Sandy soil	5.6	1.2	3.5	NR	NR	NR (>85 d)	Yield (grain)		2.6		>8	

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		Stirling (barley)													
															Riley et al. 1994
2	H_3BO_3	*Zea mays* L. (corn)	Fine, mixed, mesic, Fluventic Haploxerepts	7.5	0.6	22	NR	NR	70	Plant height	10 (-7%)	15.9	20 (17%)	63.4	
2	H_3BO_3	*Zea mays* L. (corn)	Fine, mixed, mesic, Fluventic Haploxerepts	7.5	0.6	22	NR	NR	70	Yield (shoot)	5 (6%)	7.2	10 (26%)	33.6	
															Hosseini et al. 2007
4	H_3BO_3	*Triticum aestivum* var. Schombergk (wheat)	calcarosol	8.0	NR	NR	NR	NR	42	Yield (shoot)	6**		12 (11%)		
															Nelson et al., 2007
3	H_3BO_3	Winter barley (Plaisant)	Soil-sand mix	NR	NR	NR	NR	NR	49	Yield (shoot)	<25		25 (26%)		
3	H_3BO_3	Winter barley (Victoria)	Soil-sand mix	NR	NR	NR	NR	NR	49	Yield (shoot)	<25		25 (27%)		
3	H_3BO_3	Winter barley (Lignee 527)	Soil-sand mix	NR	NR	NR	NR	NR	49	Yield (shoot)	12.5**		25 (11%)		
3	H_3BO_3	Winter barley (Robur)	Soil-sand mix	NR	NR	NR	NR	NR	49	Yield (shoot)	≥25 (7%)				
3	H_3BO_3	Winter barley (Cyclone)	Soil-sand mix	NR	NR	NR	NR	NR	49	Yield (shoot)	<25		25 (23%)		
3	H_3BO_3	Winter barley (Alger/Ceres)	Soil-sand mix	NR	NR	NR	NR	NR	49	Yield (shoot)	≥25 (-8%)				
3	H_3BO_3	Winter barley (ICB-104041)	Soil-sand mix	NR	NR	NR	NR	NR	49	Yield (shoot)	≥25 (7%)				
3	H_3BO_3	Winter barley	Soil-sand mix	NR	NR	NR	NR	NR	49	Yield	≥25 (-12%)				

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
		(Baluchistan)								(shoot)					
3	H_3BO_3	Winter barley (Zarjou)	Soil-sand mix	NR	NR	NR	NR	NR	49	Yield (shoot)	≥25 (-13%)				
3	H_3BO_3	Winter barley (Tokak)	Soil-sand mix	NR	NR	NR	NR	NR	49	Yield (shoot)	≥25 (10%)				
3	H_3BO_3	Winter barley (Galleon)	Soil-sand mix	NR	NR	NR	NR	NR	49	Yield (shoot)	≥25 (-9%)				
															Yau et al., 2002
2	$Na_2B_4O_7.10H_2O$	*Medicago sativa* (alfalfa) cv. Ladak	Natural soil ('Keith')	8.4	2.1	26	NR	NR	45	Yield (shoot)	≥40 (-11%)				
2	$Na_2B_4O_7.10H_2O$	*Medicago sativa* (alfalfa) cv. Ladak	Natural soil ('Keith')	8.4	2.1	26	NR	NR	90	Yield (shoot)	≥40 (-48%)				
2	$Na_2B_4O_7.10H_2O$	*Medicago sativa* (alfalfa) cv. Ladak	Natural soil ('Ulysses')	7.3	1.4	21	NR	NR	45	Yield (shoot)	10 (20%)		20 (37%)		
2	$Na_2B_4O_7.10H_2O$	*Medicago sativa* (alfalfa) cv. Ladak	Natural soil ('Ulysses')	7.3	1.4	21	NR	NR	90	Yield (shoot)	20 (18%)		40 (68%)		
2	$Na_2B_4O_7.10H_2O$	*Medicago sativa* (alfalfa) cv. Ladak	Natural soil ('Ascalon')	7.4	1.1	14	NR	NR	45	Yield (shoot)	5**		10 (18%)		
2	$Na_2B_4O_7.10H_2O$	*Medicago sativa* (alfalfa) cv. Ladak	Natural soil ('Ascalon')	7.4	1.1	14	NR	NR	90	Yield (shoot)	10 (6%)		20 (47%)		
2	$Na_2B_4O_7.10H_2O$	*Medicago sativa* (alfalfa) cv. Rambler	Natural soil ('Keith')	8.4	2.1	26	NR	NR	45	Yield (shoot)	≥40 (4%)				
2	$Na_2B_4O_7.10H_2O$	*Medicago sativa* (alfalfa) cv. Rambler	Natural soil ('Keith')	8.4	2.1	26	NR	NR	90	Yield (shoot)	≥40 (-33%)				

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Rambler	Natural soil (‘Ulysses’)	7.3	1.4	21	NR	NR	45	Yield (shoot)	10 (3%)		20 (65%)		
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Rambler	Natural soil (‘Ulysses’)	7.3	1.4	21	NR	NR	90	Yield (shoot)	10 (18%)		20 (66%)		
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Rambler	Natural soil (‘Ascalon’)	7.4	1.1	14	NR	NR	45	Yield (shoot)	<10		10 (32%)		
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Rambler	Natural soil (‘Ascalon’)	7.4	1.1	14	NR	NR	90	Yield (shoot)	10 (13%)		20 (62%)		
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Riley	Natural soil (‘Keith’)	8.4	2.1	26	NR	NR	45	Yield (shoot)	≥40 (11%)				
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Riley	Natural soil (‘Keith’)	8.4	2.1	26	NR	NR	90	Yield (shoot)	≥40 (14%)				
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Riley	Natural soil (‘Ulysses’)	7.3	1.4	21	NR	NR	45	Yield (shoot)	10 (4%)		20 (43%)		
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Riley	Natural soil (‘Ulysses’)	7.3	1.4	21	NR	NR	90	Yield (shoot)	10 (4%)		20 (39%)		
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Riley	Natural soil (‘Ascalon’)	7.4	1.1	14	NR	NR	45	Yield (shoot)	10 (-13%)		20 (35%)		
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Riley	Natural soil (‘Ascalon’)	7.4	1.1	14	NR	NR	90	Yield (shoot)	10 (14%)		20 (41%)		
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Agate	Natural soil (‘Keith’)	8.4	2.1	26	NR	NR	45	Yield (shoot)	≥40 (1%)				
2	$Na_2B_4O_7$.	*Medicago*	Natural soil	8.4	2.1	26	NR	NR	90	Yield	≥40 (-28%)				

Klimisch	Test subst.	Organism	Medium	pH	OM	clay	Cb	EP	Duration	Endpoint	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	mg B/kg$_{dw}$	d	d		mg B/kg$_{dw}$				
	$10H_2O$	*sativa* (alfalfa) cv. Agate	('Keith')							(shoot)					
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Agate	Natural soil ('Ulysses')	7.3	1.4	21	NR	NR	45	Yield (shoot)	5**		10 (14%)		
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Agate	Natural soil ('Ulysses')	7.3	1.4	21	NR	NR	90	Yield (shoot)	10 (11%)		20 (34%)		
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Agate	Natural soil ('Ascalon')	7.4	1.1	14	NR	NR	45	Yield (shoot)	10 (-19%)		20 (26%)		
2	$Na_2B_4O_7$. $10H_2O$	*Medicago sativa* (alfalfa) cv. Agate	Natural soil ('Ascalon')	7.4	1.1	14	NR	NR	90	Yield (shoot)	10 (8%)		20 (44%)		
															Gestring & Soltanpour, 1987

EP: equilibration period

NR: not reported

*: % effect (inhibition) between brackets. The % inhibition was calculated as: (A-B)/A * 100 where A is the response of the control soil and B is the response of the treated soil.

**: calculated as ECx (x between 10 and 20%)/2

[1] Aitken, 1988

Test species: *Helianthus annus* L. cv. Hysun 31 (sunflower).

Test protocol: no standard guideline was reported.

Test soil: the toxicity tests were performed with six soils: two loamy sand soils, two sand soils, one sandy loam soil and one silty clay soil. Soils were air-dried and sieved (5 mm).

Physico-chemical characteristics:

Soil	Texture class	pH*	Extr B** mg B/kg	Org. Carbon %	Sand %	Silt %	Clay %
1	loamy sand	5.9	0.14	0.7	78	15	8
2	sand	5.7	0.14	0.5	93	6	2
3	sandy loam	5.7	0.16	1.1	78	10	12
4	sand	5.1	0.03	0.1	98	<1	1
5	loamy sand	4.8	0.12	0.7	82	8	10
6	silty clay	4.8	0.65	1.7	18	32	49

* pH water (1:5)

** hot 0.01 M $CaCl_2$ extractable B

Soil preparation: Basal nutrients (N, K, S, Ca, Mg, Cu, Zn, Mn and Mo) were added in solution form and mixed throughout the soil. Soils 4, 5 and 6 were limed (with $CaCO_3$) to a pH of 6.5. Boron, as H_3BO_3 in solution, was applied at rates which covered the sufficiency and toxicity ranges. Soils were mixed and brought to field capacity (10kPa matric suction). Two plants were established in each container and grown for 14 days at field capacity (16h day at 30°C, 8h night at 25°C, 70% relative humidity).

Test concentrations: Seven rates of boron (0, 0.25, 0.5, 1, 2, 4 and 8 kg B ha^{-1}) were applied to each of soils 1-4. Nine rates of boron (0, 0.25, 0.5, 1, 2, 4, 6, 8 and 12 kg B ha^{-1}) were applied to soils 5 and 6. Rates in kg/ha were converted to mg/kg based on the following assumtions: depth: 10 cm and density: 1.4 kg/dm^3. There were three replicates of each treatment.

Equilibration period: 7 days.

Test duration: 14 days

Endpoints: dry matter yield.

Analytics: No analysis of total soil B concentration. The boron concentration in soil solution extracts and hot $CaCl_2$ extracs was determined by ICP-AES.

Statistics: NOEC values are derived based on the reported Least Significant Difference (LSD, at significance level of $P < 0.05$) between treatments. No information was presented on how this LSD value was derived.

Toxicity data: 14 days NOEC data (added) varied between 1.4 and ≥8.6 mg B/kg dw.

Reliability: selection criteria fulfilled for Klimisch 2 (no standard test guideline followed, but well performed and well documented study)

[2] Hobson et al., 2006

Test species: *Lens culinaris* (lentil accessions ILL2024, ILL213A, ILL5883 and Laird (ILL4139) and two Australian lentil varieties Cassab (ILL7200) and Nugget (ILL7180).

Test protocol: no standard guideline was reported.

Test soil: the toxicity tests were performed with the topsoil (loamy calcarosol, 5-15 cm) collected from a paddock west of Birchip (35°98'S, 142°92'E) in the southern Mallee of Victoria (soil sieved over 5 mm).

Physico-chemical characteristics: pH ($CaCl_2$) 7.5, EC 0.19 dS/m, Total carbon 2.1 % w/w, Olsen P 29 mg/kg, Exchangeable calcium 27 meq/100 g, Exchangeable magnesium 3.2 meq/100 g, exchangeable sodium 0.1 meq/100 g, exchangeable potassium 2.0 meq/100 g, exchangeable sodium percentage 0.1, field capacity 13.5 % w/w, wilting point 7.5 % w/w, $CaCl_2$ extractable B 0.9 mg/kg.

Soil preparation: B (as H_3BO_3) was dissolved in warm water and applied in solution to soil in plastic bags at 0, 15 and 25 mg/kg. All tests were performed in a temperature controlled naturally lighted glasshouse where minimum and maximum temperatures ranged diurnally from 10 to 20°C. Soils were kept at 85% field capacity during the experiment.

Test concentrations: ILL2024, and Cassab, were studied at 3 rates of applied B; 0, 15 and 25 mg/kg. The remaining 4 accessions were subjected to 2 rates of applied B; 0 and 25 mg/kg. All soils received basal nutrient dressings of P, S, Zn and N. 4 replicates were used.

Equilibration period: 7 days.

Test duration: 28, 76 days and until maturity (number of days not reported) for ILL2024, Cassab, ILL213A, ILL5883 and Nugget; 28, 103 days and until maturity (number of days not reported) for Laird.

Endpoints: total dry matter yield at 28 and 76 days after emergence and at maturity, plant height at 76 days after emergence root dry matter yield at 28 and 76 days and seed yield at maturity.

Analytics: No analysis of total soil B concentrations.

Statistics: REML analysis was performed using GenStat 6. Data were subjected to $\log_e$ transformation when required. The Wald statistic was used to determine significant differences between treatments. Least significant of difference (LSD) of interaction at $p<0.001$ was determined and used for deriving NOEC and LOEC values.

Toxicity data: NOEC data (added) varied between <15 and ≥25 mg B/kg dw.

Reliability: 3 (no standard guideline followed, only control and 1 or 2 doses tested, LSD (least significant difference) calculated for genotype x B effect, not for B effect alone)

[3] Kaur et al., 2006

Test species: *Brassica rapa* (genotypes WWY Sarson, Local, Shillong and Kaga)

Test protocol: no standard guideline was reported.

Test soil: the toxicity tests were performed with a typical calcarosol site in the Birchip region, Victoria, Australia (35.80°S, 142.87°E).

Physico-chemical characteristics: pH 8, Hot $CaCl_2$ extractable B 4 mg/kg.

Soil preparation: Test compound added in solution to soil. All tests were performed at 22°C day/16°C night, 16 photoperiod. Soils were kept at 85% field capacity durin the experiment.

Test concentrations: 3 doses (4 (control)-29-54 mg B/kg d.w (hot $CaCl_2$ extractable B)) were used for the soil assay (shoot dry matter experiment). Only 2 treatments (4 (control) and 29 mg B/kg (hot $CaCl_2$ extractable B)) were tested in the growth and morphology experiment. All soils received basal nutrient dressings of P, S, Zn and N. 4 replicates per treatment.

Equilibration period: 7 days.

Test duration: 35 days for shoot dry matter, 38 and 71 days for total dry matter, 71 days for plant height, NR for root length.

Endpoints: shoot dry matter, total dry matter, root length and plant height

Analytics: Boron was extracted from the soil by hot $CaCl_2$.The boron concentration was analysed in the tissues using Inductive Coupled Plasma Spectrometery (ICP) analysis. Statistics: Two-way analyses of variance were performed on all data to determine the significance of genotype x boron treatment interactions. Where interactions were significant, least significant differences (LSD) were calculated at $p=0.05$. NOEC and LOEC values were derived based on the LSD.

Toxicity data: NOEC data (added, $CaCl_2$ extractable) varied between <25 and ≥25 mg B/kg dw.

Reliability: 3 (no standard guideline followed, only $CaCl_2$ extractable B concentrations reported, LSD (least significant difference) calculated for genotype x B effect, not for B effect alone. For the growth and morphology experiments (total plant yield, plant height and root length), the soil was added to 20 cm pots lined with plastic bags. Another 3 cm of untreated soil was added on top of the pots to ensure the proper establishment of plant roots before they grew into the B containing soil. No influence on the B uptake was reported)

[4] Favaretto et al. 2007

Test species: *Trifolium vesiculosum* (arrowleaf clover)

Test protocol: no standard guideline was reported.

Test soil: the toxicity tests were performed with soil removed (in three layers of each 20 cm)) from a grassland field in Ponta Grossa, Paraná (Brazil). The soil was a "Cambissolo álico" with medium texture, high Al content, and low pH, organic matter and nutrients.

Physico-chemical characteristics: pH $CaCl_2$ layer A (0-20 cm) 4.5, pH layer B $CaCl_2$ (20-40 cm) 4.4 and pH CaCl2 layer C (40-60 cm) 4.3; eCEC layer A 2.15 $cmol_c\ dm^{-3}$, eCEC layer B 2.08 $cmol_c\ dm^{-3}$, eCEC layer C 1.95 $cmol_c\ dm^{-3}$; OM layer A 22.9 g dm^{-3}, OM layer B 16.3 g dm^{-3}, OM layer C 14.1 g dm^{-3}; sand layer A 700 g/kg, sand layer B 660 g/kg, layer C 720 g/kg; silt layer A 80 g/kg, silt layer B 120 g/kg, silt layer C 80 g/kg; clay layer A 220 g/kg, clay layer B 220 g/kg, clay layer C 200 g/kg; bulk density layer A 1.35 kg/dm^3, bulk density layer B 1.35 kg/dm^3, bulk density layer C 1.45 kg/dm^3. Boron concentration ($CaCl_2$ extrctable): 0.17, 0.16 and 0.13 mg/kg dw for layers A, B and C, respectively.

Soil preparation: All three soil layers received B (boric acid) according to the respective treatments. Layer A was limed (up to pH $CaCl_2$ 5) and fertilized one month before and at the day of testing, respectively.

Test concentrations: 0-0.25-0.5-0.75-1-2 kg/ha. Rates in kg/ha were converted to mg/kg based on a depth of 20 cm and the bulk density of the layers. 6 replicates

Equilibration period: NR.

Test duration: 135 days (the experiment was conducted until flowering - 4.5 months

Endpoints: shoot dry weight, root dry weight, root length

Analytics: Total soil B concentrations were not measured.

Statistics: Analyses of variance and mean comparison were made using SAS software. Soil and root variables were analyzed using a split plot model where rate of boron correspond to the whole plot and layer to the subplot; other varianbles were analyzed as one factor in a complete randomized model. Preliminary statistical analyses indicated that some variable had to be transformed in order to achieve the requisites for an analysis of variance. A regression between the log (standard deviation) and log (mean) was performed for each variable to define which transformation should be used. When necessary, the data were transformed, but presented in their original form. Significant differences among treatments were calculated by Tukey's test at $P<0.05$.

Toxicity data: NOEC values (added) were all ≥0.7 mg B/kg dw.

Reliability: 3 (no standard guideline followed, only tested in B deficiency range)

[5] Corrêa et al, 2005

Test species: *X. Triticosecale* WITTMACK triticale cultivars IAC 3, BR 4 and BR 53, and wheat (*Triticum aestivum* L.) cultivar IAPAR 38

Test protocol: no standard guideline was reported.

Test soil: The soil was a medium-textured dystrophic Hapludox, collected from the arable layer, dried and sieved (2mm).

Physico-chemical characteristics: pH ($CaCl_2$) = 4.0; M.O. = 20 g dm^{-3} P_{resin} = 2 mg dm^{-3}; H+Al = 64 $mmol_c$ dm^{-3}; K = 0.2 $mmol_c$ dm^{-3}; Ca = 2 mmol $mmol_c$ dm^{-3}; Mg = 1 mmol $_c$ dm^{-3}; total exchangeable bases = 3 $mmol_c$ dm^{-3}; eCEC = 67 $mmol_c$ dm^{-3}; B = 0.08 mg dm^{-3}; and Zn = 0.4 mg dm^{-3}, determining low fertility soil.

A bulk density of 1.4 kg dm^{-3} was assumed for calculation of soil properties on a weight basis instead of a volume basis.

Soil preparation: Liming was done to increase base saturation to 60% using dolomite limestone; the soil was kept covered for 20 days. Final pH and eCEC were not reported.

After that, sowing fertilization was done using 150 mg dm^{-3} of K as KCl, 50 mg dm^{-3} of N as carbamide, 200 mg dm^{-3} of P as simple superphosphate, and 2 mg dm^{-3} of Zn as zinc sulphate. Fertilizers were all mixed in the soil of 10-L pots, with 12 plants each. The experiment was carried out in a 4x4 factorial scheme randomized blocks design (n=4).

Test concentrations: 0-0.62-1.24-1.86 mg/dm^{-3} in both soils. 4 replicates were used.

Equilibration period: NR

Test duration: NR (until yield stage)

Endpoints: No of grains, plant dry material yield

Analytics: Chemical analysis to determine B background concentration was done using Hot Water Method. No measurement of total B concentration in soil.

Statistics: Dose-response curves were fitted with linear regression analysis (2nd order linear regression). No information on variation among replicates. No NOEC values reported.

Toxicity data: EC10 added data varied between 0.21 and >1.33 mg B/kg dw (0.29 to >1.86 mg B/dm^3)

Reliability: 3 (no standard guideline followed, response values derived from graphs, weak fit of the dose-response curves, no information on variation among replicates)

[6] Goldberg, 2003

Test species: *Cucumis melo* L. (muskmelon variety Top Mark)

Test protocol: no standard guideline was reported.

Test soil: Approximately 2000 kg of soil were collected from Section 4 of the Broadview Water District in the San Joaquin Valley of California. Soil samples were taken from the 0-25-cm depth using a shovel. The soil is a silty clay belonging to the Lillis soil series classified as a very-fine, smectitic, thermic Halic Haploxerert. The soil was homogenized and crushed to pass a 0.635-cm screen.

Physico-chemical characteristics: Organic carbon content 0.80+/-0.026 %, inorganic carbon content 0.23+/-0.010%, Aluminum oxide content 0.0923+/-0.0031%, Iron oxide content 1.187+/-0.0097%, clay content 54.34%, silt content 40.10%, sand content 5.56%, bulk density 1.35 mg m^{-3}.

Soil preparation: Each subsample was pretreated by mixing 72L of a solution containing 0, 0.463, 0.981, 1.61, 2.22, 3.33 or 5.27 mmol B L^{-1}. The soils were dried, crushed, and 24 kg were packed into 20 L containers.

Test concentrations: Added B corresponded to 0, 3.8, 8.0, 13.1, 18.0, 27.0 and 42.7 mg B/kg dw. 4 replicates were used (20L containers with 24 kg soil and two plants). Soils were irrigated during the experiment.

Equilibration period: not reported

Test duration: 95 days (from 12 July 2001 until 15 October 2001)

Endpoints: leaf dry weight, stem dry weight, fruit dry weight and whole plant dry weight.

Analytics: boron was extracted by 3 different methods (1:1 soil:distilled water, 1 M ammonium acetate and STPA-sorbitol) and extractes were analysed by ICP-OES. The DTPA-sorbitol method extracted the largest fraction. No measurement of total B concentration in soil.

Statistics: NOEC for leave and stem yield based on average values and standard deviations reported. EC10 values for fruit and total plant yield were based on a log-logistic dose-response curve fitted by minimising unweighted squared residuals sum (maximum likelihood):

$$Y = \frac{C}{1 + \exp^{(-B(x-A))}}$$

With Y = response, X = log10 of the dose and A, B and C function parameters

Toxicity data: The unbounded NOEC values (added) were ≥ 42.7 mg B/kg dw. EC10 data (added) varied between 12.6 and 39.4 mg B/kg dw.

Reliability: 3 (no standard guideline followed, B substance not reported, no information on B concentration in irrigation water during the experiment and therefore no control of exposure concentration during the experiment)

[6] Riley et al. 1994

Test species: *Hordeum vilgare* L. cv. Stirling (barley)

Test protocol: no standard guideline was reported.

Test soil: a bulk sample was collected from the surface (0-10 cm) of a virgin sandy soil from Lancelin (Australia). Soil was air-dried, sieved through a 3.86 mm sieve and thoroughly mixed.

Physico-chemical characteristics: pH (1:5 soil:water): 5.6; clay content: 3.5%; organic carbon: 0.69%; B-extractable in 0.05 M mannitol/0.01 M $CaCl_2$: <0.5 mg/kg

Soil preparation: Soil aliquots of 3.5 kg were weighed into polythene bags in undrained plastic pots and given a basal nutrient dressing by surface application of solutions. Boron solutions were also applied to the surface. After drying, the nutrients were thoroughly mixed through the soils by shaking in a plastic bag.

Test concentrations: 0, 0.5, 1, 2, 4 and 8 mg B/kg soil, added as H_3BO_3. 3 replicates

Equilibration period: not reported

Test duration: until maturity of barley plants (>85 days)

Endpoints: shoot yield, grain yield

Analytics: analysis of mannitol extractable B (concentrations of <0.5, <0.5, <0.5, 1.0, 2.1 and 4.9 mg B/kg were determined for the various doses). No analysis of total B concentrations in soil.

Statistics: Data for shoot yield and grain yield at the various B doses were derived from graphs. ECx values were calculated based on a log-logistic dose-response curve fitted by minimising unweighted squared residuals sum (maximum likelihood).

Toxicity data: EC10 data (added) varied between 1.4 and 2.6 mg B/L.

Reliability: 3 (no standard guideline followed, response data derived from graphs)

[7] Hosseini et al., 2007

Test species: *Zea mays* L. (corn) cv. 704

Test protocol: no standard guideline was reported.

Test soil: the soil was collected from the Ap horizon of a fine, mixed, mesic, Fluventic Haploxerepts. It comes from an uncultivated field. The soil was air-dried and passed through a 2 mm sieve before use.

Physico-chemical characteristics: pH water (7.5), electrical conductivity (ECe) of 0.5 dS/m, calcium carbonate equivalent (CCE) of 35%, 0.6% organic matter, cation exchange capacity (CEC) of 11.5 $cmol_c$/kg, 22% clay, and 42% silt content, 0.4 mg/kg DTPA-extractable Zn, and hot water-soluble B of 0.22 mg/kg.

Soil preparation: Plastic pots (1.6 L) were filled with 2 kg of the soil and B treatment was added to the soil in powder form (as boric acid). Soils were thoroughly mixed and irrigated to field capacity. Treatments consisted of seven levels of B (0, 2.5, 5, 10, 20, 40, 80 $\mu g\ g^{-1}$ as boric acid). As this study was on Zn-B interactions, two sources of Zn were also tested, only results for soils without added Zn are presented here.

Test concentrations: 0-2.5-5-10-20-40 and 80 mg/kg dw. 3 replicates were used.

Equilibration period: not reported

Test duration: The experiment lasted for 10 weeks (70 days) in the greenhouse.

Endpoints: height and shoot dry weight

Analytics: No analysis of total B concentrations in soil.

Statistics: NOEC and LOEC values for dry matter yield and plant height were derived based on analysis of variance using MSTATC computer program. ECx values were calculated based on a log-logistic dose-response curve fitted by minimising unweighted squared residuals sum (maximum likelihood).

Toxicity data: NOEC data (added) varied between 5 and 10 mg B/kg dw.

Reliability: selection criteria fulfilled for Klimisch 2 (no standard test guideline followed, but well performed and well documented study)

[8] Nelson et al, 2007

Test species: *Triticum aestivum* var. schombergk (wheat)

Test protocol: no standard guideline was reported.

Test soil: The top 50 mm layer of a calcarosol with high clay content was collected from a fallow paddock in North-West Victoria, Australia (142°43’12’’E, 35°58’33’’s).

Physico-chemical characteristics: pH 8.0 and high clay content

Soil preparation: The soil was sieved (2mm), amended with B as boric acid, referred to as low, medium and high B. Method of application or mixing was not reported. Soil was packed into PVC pots (104 mm diameter and 300 mm depth) to a bulk density of 1.3 g/cm^3. The soil was moistened to 75% field capacity using a 1% nutrient solution and placed in a glasshouse maintained with a night/day temperature cycle of 10-22°C

Test concentrations: 0-12-24 mg/kg dw, 4 replicates were used.

Equilibration period:not reported

Test duration: 42 days

Endpoints: shoot dry weight

Analytics: No analysis of total B concentrations in soil.

Statistics: Least signicifant difference was determined at the 5% level

Toxicity data: the NOEC value (added) at 42 days was 6 mg B/kg dw.

Reliability: 4 (no standard test guideline followed, limited information on soil characteristics, no information on equilibration period, limited information on statistics)

[9] Yau, 2002

Test species: Winter barley (*Hordeum vulgare* L.): European varieties (Plaisant, Victoria, Lignee 527, robur and Cyclone), West Asian and North African varieties (Alger/Ceres, ICB-104041, Baluchistan, Zarjou and Tokak) and Australian variety (Galleon)

Test protocol: no standard guideline was reported.

Test soil: the toxicity tests were performed with a soil-mix that contained one parte of soil (fine clay, thermic, montmorillonitic, Calcixerollic Xerochrept) and two parts of sand by volume.

Physico-chemical characteristics: alkaline, non-saline, low organic matter (no values reported)

Soil preparation: soil-B levels were prepared by mixing boric acid into the soil. Also $(NH_4)_2SO_4$ and superphosphate fertilizers were mixed into the soil before potting.

Test concentrations: 0-25 mg/kg dw, 2 replicates were used.

Equilibration period: not reported.

Test duration: 49 days

Endpoints: dry weight

Analytics: No analysis of total B concentrations in soil.

Statistics: % inhibition compared to control treatment calculated for single dose tested

Toxicity data: NOEC values (added) varied between <25 and ≥25 mg B/kg (%inhibitiont at 25 mg B/kg ranged between -13 and 27%).

Reliability: 3 (no standard test guideline followed, only control and 1 dose level of B tested, no information on physico-chemical characteristics of the soil).

[10] Gestring and Soltanpour, 1987

Test species: Alfalfa (*Medicago sativa* L.) cultivars 'ladak', 'Rambler', 'Riley', and 'Agate'

Test protocol: no standard guideline was reported.

Test soil: three Colorado soils: Keith (Aridic Argiustoll), Ulysses (Aridic Haplustoll) and Ascalon (Aridic Argiustoll).

Physico-chemical characteristics: Keith: pH (saturated paste) 8.4, organic matter 2.1%, sand 16%, silt 58% and clay 26%; Ulysses: pH (saturated paste) 7.3, organic matter 1.4%, sand 49%, silt 30% and clay 21%; Ascalon: pH (saturated paste) 7.4, organic matter 1.1%, sand 84%, silt 2% and clay 14%. All soils were air-dried, ground and sieved throughe a 6 mm screen.

Soil preparation: Soil and fertilizer materials (KNO_3, $Ca(H_2PO_4)_2.H_2O$, KCl, FeEDDHA and $ZnSO_4$) were thoroughly mixed and put in 1.8 L pots. Boron was supplied as $Na_2B_4O_7.10H_2O$.

Test concentrations: 0-10-20-40 mg B/kg dw. Three replicates for each soil – alfalfa cultivar – boron concentration were used.

Equilibration period: not reported

Test duration: ±45 and 90 days (first and second harvest, respectively)

Endpoints: shoot dry weight at two harvests

Analytics: no total soil B concentration was measured. At the end of the study soils were dried and analyzed for B in four extracts: saturation, AB-STPA, hot water and mannitol-$CaCl_2$. B in all exctracts was analyzed by ICP-AES.

Statistics: NOEC and LOEC values were derived based on ANOVA (Duncan's multiple range test at 5% significance level The NOEC/LOEC values are based on the data reported in Table 3 of the original study. Values within a column for each cultivar followed by the same letter do not differ significantly at the 5% level (Duncan's multiple range test). Consequently, the NOEC is the highest B dose followed by the same letter as the control.

Toxicity data: the NOEC values (added) varied between 5 and ≥40 mg B/kg dw.

Reliability: selection criteria fulfilled for Klimisch 2 (no standard test guideline followed, but well performed and well documented study)

Table A.5. Overview of the ecotoxicity data for soil microbial processes in soils with properties beyond the EU 10-90th percentile bounderies. The pH, organic matter or clay content values which fall outside of the representative range are underlined.

Klimisch	Test subst.	Process	Medium	pH	OM	clay	Cb	EP	Duration	NOEC*	EC10	LOEC/ECx (with x > 10)*	EC50	Comments
					%	%	mg/kg$_{dw}$	d	d	mg B/kg$_{dw}$				
1	H_3BO_3	N transformation	Sandy loam soil	$\underline{7.6}$	$\underline{1.6}$	12.6	NR	0	102		17.2		>17.5	Nominal added dosis; no background concentration reported
														Hanstveit et al., 2001
3	$Na_2B_4O_7$	N mineralisation	Silty clay loam soil (Okoboji)	7.4	9.3	$\underline{34}$	NR	NR	20	27.0**		54.1 (14%)		
3	$Na_2B_4O_7$	N mineralisation	Judson soil	6.6	5.1	$\underline{45}$	NR	NR	20	54.1 (7%)				
														Liang & Tabatabai, 1977
3	$Na_2B_4O_7$	Nitrification	Silty clay loam	7.4	9.3	$\underline{34}$	NR	NR	10	<54.1		54.1 (74%)		
														Liang & Tabatabai, 1978

EP: equilibration period

NR: not reported

*: % effect (inhibition) between brackets. The % inhibition was calculated as: (A-B)/A * 100 where A is the response of the control soil and B is the response of the treated soil.

**: calculated as ECx (x between 10 and 20%)/2

[1] Hanstveit et al., 2001

Soil process: Nitrogen transformation

Test protocol: according to OECD Guideline 216, study carried out in compliance with OECD Principles of Good Laboratory Practice (GLP).

Nitrogen transformation was studied by adding powdered lucerne meal (C/N ratio 13/1) to the soil samples treated with either the test substance or left untreated (control), and incubating the soil at constant temperature. The nitrogen transformation activity was determined by measuring the formation rate of nitrate in soils.

Test soil:

- sandy loam, taken from grassland located at the Maasdijk (Heerewaarden, The Netherlands), sand 63.4%, silt 24.0%, clay 12.6%, Organic matter 1.6%, pH (1:5) in water 8.3, pH (1:5) in 0.01 M $CaCl_2$ 7.6, CEC (buffered at pH 8.1) 9.0 $cmol_c$/kg, total nitrogen 0.12%, microbial biomass: 128 mg C/kg dw
- humic sand taken at the ‘Droevendaal’ experimental station (Wageningen, The Netherlands), sand 85.3%, silt 10.2%, clay 4.5%, Organic matter 3.6%, pH (1:5) in water 6.0, pH (1:5) in 0.01 M $CaCl_2$ 5.4, CEC (buffered at pH 8.1) 12.9 $cmol_c$/kg, total nitrogen 0.11%, microbial biomass: 106 mg C/kg dw

Soil samples were stored at refrigerator temperature pending use. Before the start of the experiment, soil samples were partly air-dried until they could be sieved over 2 mm.

Soil preparation: Soil moisture during the test was adjusted to *ca* 50% of WHC (i.e. water content of 21.1% for the sandy loam and 17.8% for the humic acid soil). Soils were amended with powdered lucerne meal (C/N ratio 13/1) at a ratio of 5 g/kg dw and thoroughly mixed. Borc acid (Manufacturing Grade, >99.9% purity) was added as a solution to soil and mixed thoroughly. All tests were performed at 20°C.

Test concentrations: 0.3, 3, 10, 30 and 100 mg boric acid /kg dw; i.e. 0, 0.05, 0.52, 1.75, 5.25 and 17.5 mg B/kg dw.

Equilibration period: 0 days.

Test duration: up to 102 days.

Endpoints: nitrification rate (mg NO_3-N produced/kg/day)

Analytics: No analysis of total soil B concentrations. Nitrate concentrations were measured in a 0.1M KCl extract (1:5 soil:solution ratio) by ion chromatography (4 replicates per treatment).

Statistics: In the original study report, nitrification rates were calculated based on the soil nitrate concentration after x days, without taking the nitrate concentration at day 0 into acount. Morover, a 25% effect level was used as threshold for significance. Therefore, data analysis was repeated, based on the raw data reported. The nitrification rate was calculated as:

$$R_{NO_3,x} = \frac{\left(C_{NO_3,x} - C_{NO_3,0}\right)}{x}$$

With $R_{NO3,x}$, the nitrification rate during x days, $C_{NO3,x}$, the nitrate concentration in the soil sample after x days and $C_{NO3,x}$, the nitrate concentration in the soil sampleat day 0. However, this way only an average response (nitrification rate) could be calculated per treatment and no NOEC values could be derived. EC10 values for nitrification rate were based on a log-logistic dose-response curve fitted by minimising unweighted squared residuals sum (maximum likelihood):

$$Y = \frac{C}{1 + \exp^{(-B(x-A))}}$$

With Y = average response per treatment, X = log10 of the dose and A, B and C function parameters.

Toxicity data: 102 days EC10 values (added) varied between 15.4 and 17.2 mg B/kg dw.

Reliability: Klimisch 1 (well documented study according to OECD guidelines).

It should be noted that even though this soil falls outside the 10th to 90th percentile for European soils, this approach should be reconsidered here, as the OECD guideline clearly suggests the use of more "extreme" soils.

[2] Liang & Tabatabai, 1977

Soil process: Nitrogen mineralisation

Test protocol: no standard guideline was reported.

Test soil: the toxicity tests were performed with natural surface soils (0-15 cm). Soils were air-dried and passed througha 2 mm screen before use.

Physico-chemical characteristics: Webster soil: pH water (1:2.5) 5.8, clay 23%, sand 38%, organic carbon 2.58%; Harps soil: pH water (1:2.5) 7.8, clay 30%, sand 26%, organic carbon 3.74%; Okoboji soil: pH water (1:2.5) 7.4, clay 34%, sand 16%, organic carbon 5.45%; Judson soil: pH water (1:2.5) 6.6, clay 45%, sand 1%, organic carbon 2.95%.. All tests were performed at 30°C.

Soil preparation: Test compound added in solution to soil (added dropwise without mixing). Soil moisture was *ca* 60% of WHC.

Test concentrations: 0-54.1 mg/kg d.w in all soils

Equilibration period: 0 days.

Test duration: 20 days.

Endpoints: nitrogen mineralization (production of ammonium and nitrate)

Analytics: No analysis of total soil B concentrations.

Statistics: No statistics were reported on difference in N mineralisation between control and B-amended treatments. Only the % inhibition compared to control treatment was calculated for single dose tested. The NOEC/LOEC values were derived based on a 10% inhibition threshold (<10% inhibition: no significant effect; >10% inhibition: significant effect).

Toxicity data: 20 days NOEC values (added) varied between 27.0 and 54.1 mg B/kg dw.

Reliability: Klimisch 3 (only 1 dose tested, no information on replicates of B treatments).

[3] Liang & Tabatabai, 1978

Soil process: Nitrification of added NH_4-N substrate.

Test protocol: no standard guideline was reported.

Test soil: the toxicity tests were performed with natural surface soils (0-15 cm). Soils were air-dried and passed througha 2 mm screen before use.

Physico-chemical characteristics: Webster soil: pH water (1:2.5) 5.8, clay 23%, sand 38%, organic carbon 2.58%; Harps soil: pH water (1:2.5) 7.8, clay 30%, sand 26%, organic carbon 3.74%; Okoboji soil: pH water (1:2.5) 7.4, clay 34%, sand 16%, organic carbon 5.45%. All tests were performed at 30°C.

Soil preparation: Test compound added in solution to soil (added dropwise without mixing). Soil moisture was *ca* 60% of WHC.

Test concentrations: 0-54.1 mg/kg d.w in all soils

Equilibration period: 0 days.

Test duration: 10 days.

Endpoints: production of nitrites and nitrates

Analytics: No analysis of total soil B concentrations.

Statistics: No statistics were reported on difference in nitrification between control and B-amended treatments. Only the % inhibition compared to control treatment was calculated for single dose tested. The NOEC/LOEC values were derived based on a 10% inhibition threshold (<10% inhibition: no significant effect; >10% inhibition: significant effect).

Toxicity data: all unbounded LOEC values (NOEC (added) <54.1 mg B/kg dw).

Reliability: Klimisch 3 (only 1 dose tested, no information on replicates of B treatments).

Annex V: Soil characteristics of EU soils

The values of the soil parameters in the ecotoxicity tests were compared with ranges reported for European soils. The data on the EU soil characteristics were obtained for the following regions and sources:

- Scattered world soil properties data from the International Soil Reference and Information Center (ISRIC)
- World soil types and soil properties data from the Food and Agriculture Organization (FAO) of the United Nations
- European soil properties and (heavy) metal concentration data from: "*Agricultural Soils in Northern Europe: A Geochemical Atlas* " (Reimann et al 2003)
- European soil properties and heavy metal concentration data from Dick Brus of the Alterra Research Institute for the Green World, Soil Research Center
- ICP Forest database
- UK National Soil Inventory
- Italian Soil Survey Dataset

The estimation of the frequency distribution of soil physico-chemical parameters known to influence the bioavailability of metals (i.e. pH, OM %, and clay %) throughout the EU was performed using the point-based analysis. Conversion of pH $CaCl_2$ into pH H_2O was based on the following regression, derived for 86 soils from The Netherlands:

$$\text{pH } H_2O = 0.89 * \text{pH } CaCl_2 + 1.19 \qquad (n=86, R^2=0.88)$$