

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

STRATEGY FOR LIMITING RISK

Substance name: Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)

EC Number: 237-159-2

CAS Number: 13674-87-8

Submitted by: Ireland

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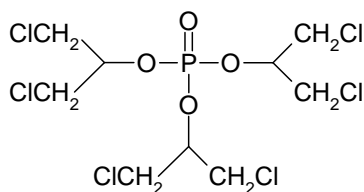
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PART A: PROPOSAL

A.1 PROPOSAL FOR STRATEGY FOR LIMITING RISK

A.1.1 Identity of the substance

CAS Number: 13674-87-8
 EINECS Number: 237-159-2
 IUPAC Name: Tris[2-chloro-1-(chloromethyl)ethyl] phosphate
 Molecular formula: C₉H₁₅Cl₆O₄P
 Structural formula:



Molecular weight: 430.91
 Synonyms¹:
 2-Propanol, 1,3-dichloro-, phosphate (3:1)
 Tris(1,3-dichloro-2-propyl) phosphate
 Tris(1-chloromethyl-2-chloroethyl) phosphate
 1,3-Dichloro-2-propanol phosphate (3:1)
 Phosphoric acid, tris(1,3-dichloro-2-propyl)ester
 TDCP: this common acronym is used throughout this report

Smiles notation O=P(OC(CCl)CCl)(OC(CCl)CCl)OC(CCl)CCl

A.2 SUMMARY OF THE JUSTIFICATION

A.2.1 Identified hazard and risk

An European Union Risk Assessment Report² (RAR) (HSA/EA, 2008) was carried out for tris[2-chloro-1-(chloromethyl)ethyl] phosphate (herein referred to as ‘TDCP’) in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances.

Article 10(3) of the Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances states that:

¹ For the sake of simplicity, company trade names are not listed here, since they may be subject to change.

² Work on the RAR began before enlargement of the EU to 27 Member States in 2006. Therefore the conclusions of the risk assessment are based on information regarding the former EU of 15 member states.

‘Following a rapporteur’s evaluation of the risk of that substance to man and the environment, it shall suggest a strategy for limiting these risks, including control measures and/or surveillance programmes, if appropriate’.

The RAR for TDCP concluded that there is a need for limiting the risk associated with reasonable worst case dermal exposure of workers to TDCP, during the following scenarios in relation to repeated dose toxicity and carcinogenicity:

- 1) Manufacture of TDCP
- 2) Manufacture of flexible PUR foam
 - a) Slabstock
 - b) Moulded

As a result of these conclusions, a strategy for limiting these risks is required.

It should be noted that in the case of the typical dermal exposure of workers during the manufacture of TDCP (scenario 1), manufacture of flexible PUR foam – slabstock (scenario 2a), and manufacture of flexible PUR foam – moulded (scenario 2b), the RAR concluded there was no need for risk reduction measures beyond those that are being applied already.

Regulation EC No. 793/93 on the evaluation and control of the risks of existing chemicals was repealed by the REACH Regulation (1907/2006) on 1st June 2008. Art 136(3) of the REACH Regulation lays down transitional measures regarding existing substances, stating that a Member State whose rapporteur has not forwarded by 1st June 2008 the risk evaluation and, where appropriate, the strategy for limiting the risks, in accordance with Article 10(3) of Regulation (EEC) No. 793/93 shall:

- a) *Document information on hazard and risk in accordance with Annex XV Part B of this Regulation*
- b) *Apply Article 69(4) of this Regulation on the basis of the information referred to in point (a) and*
- c) *Prepare a documentation of how it considers that any other risks identified would need to be addressed by action other than an amendment of Annex XVII of the Regulation.*

As the risk evaluation and strategy for limiting risks was not forwarded by 1st June 2008, this transitional Annex XV report has been compiled in accordance with Article 136(3). In a letter dated 10th July 2008, the European Chemicals Agency (ECHA) invited all REACH Competent Authorities preparing transitional dossiers under Art 136(3) of the REACH Regulation to use a revised draft format for Annex XV restriction reports “to the extent that is possible”. Hence the rapporteur has attempted to adhere to this request during the development of this transitional Annex XV report.

This transitional Annex XV report will outline the recommended strategy for limiting the risk associated with reasonable worst case dermal exposure during the manufacture of TDCP (worker scenario 1), manufacture of flexible PUR foam – slabstock (worker scenario 2a), and manufacture of flexible PUR foam – moulded (worker scenario 2b). This strategy has been developed through an interactive process with the industry consortium involved in the development of the RAR.

Throughout this transitional Annex XV report reference is made to particular sections of the RAR for TDCP; particularly in Sections B.4 (Environmental Fate Properties), B.5 (Human Health Hazard Assessment), B.6 (Human Health Hazard Assessment of Physico-chemical properties) and B.7

(Environmental Hazard Assessment). Section B.9 provides an assessment of the information relevant to dermal exposure of workers only, as this is where the risk needs to be further controlled, as identified in the RAR.

A.2.2 Justification that action is required at community-wide basis

The RAR for TDCP concluded that there is a need for limiting the risk associated with reasonable worst case dermal exposure of workers to TDCP, during the following scenarios in relation to repeated dose toxicity and carcinogenicity:

- 1) Manufacture of TDCP
- 2) Manufacture of flexible PUR foam
 - c) Slabstock
 - d) Moulded

As a result of these conclusions, action is required at community wide basis to ensure reduction of the exposure to a level that allows adequate control of identified risk.

A.2.3 Justification that a safe system of work is the most appropriate measure

Establishing a safe system of work is considered a proportionate measure to the risk to workers, identified for reasonable worst case dermal exposure. The RAR concluded that there is no concern for humans via the environment or consumers. There was also no concern for workers exposed to TDCP via the inhalation route. It is felt that a ‘safe system of work’ approach is a proportionate mechanism to address the identified risk to workers. This can be achieved through technical and/or organisational means, using the existing framework of occupational health and safety legislation as the basis.

Hence the rapporteur recommends that:

Existing Community legislation for workers’ protection is generally considered to give an adequate framework to limit the risks of the substance to the extent needed.

PART B: INFORMATION ON HAZARD AND RISKS

B.1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

B.1.1 Name and other identifiers of the substance

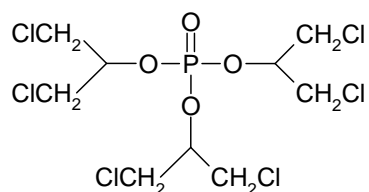
Chemical Name: Tris[2-chloro-1-(chloromethyl)ethyl] phosphate
EC Name: Tris[2-chloro-1-(chloromethyl)ethyl] phosphate
CAS Number: 13674-87-8
IUPAC Name: Tris[2-chloro-1-(chloromethyl)ethyl] phosphate

B.1.2 Composition of the substance

B.1.2.1 Impurities

The impurity profile of the commercial product TDCP is specific to individual manufacturers. Details are given in the confidential annex of the RAR report for TDCP (HSA/EA, 2008). The impurity profile does differ between suppliers but the impurity content is low. The structures of the impurities do not suggest that they would have had a strong influence on any of the test results.

Chemical Name: Tris[2-chloro-1-(chloromethyl)ethyl] phosphate
EC Number: 237-159-2
CAS Number: 13674-87-8
IUPAC Name: Tris[2-chloro-1-(chloromethyl)ethyl] phosphate
Molecular Formula: $C_9H_{15}Cl_6O_4P$
Structural Formula:



Molecular Weight: 430.91
Typical concentration (% w/w):
Concentration range (% w/w): 93-99.9%

B.1.3 Physico-chemical properties

The physico-chemical property values of TDCP that have been reported in the RAR for TDCP (HSA/EA, 2008) are summarised in **Table B.1**.

Table B.1 Summary of physico-chemical properties

REACH ref Annex, §	Property	IUCLID section	Value	Comments
VII, 7.1	Physical state	3.1	Liquid	
VII, 7.2	Melting point	3.2	27°C	Cited in a MITI report, origin unknown
			Melting point -58°C; freezing point -40°C	Melting point determination by DSC (compliant with OECD Guideline 102) Akzo-Nobel, Inc. 2001a and b, cited in USEPA, undated
			26.66°C	Akzo Nobel, 2003, cited in USEPA, undated
			<-20°C**	Cuthbert and Mullee, 2002a
VII, 7.3	Boiling point	3.3	>200°C	Cited in a MITI report. HSDB cites this value as peer-reviewed
			200°C (at 533 Pa)	Reduced pressure value Akzo Nobel, 2003, cited in USEPA, undated
			~326°C** (decomp.)	Boiled with decomposition. Cuthbert and Mullee, 2002a
VII, 7.4	Relative density	3.4 density	1.52	
			1.52	
			1.5022 at 20°C	Specific gravity. Budavari, 2001 (The Merck Index); Lewis, 2000 (Sax's Dangerous Properties of Industrial Materials), cited in USEPA, undated
			1.48 kg/l at 25°C	Bulk density. HSDB, 2003, cited in USEPA, undated
			1.513 at 20°C**	Cuthbert and Mullee, 2002a
VII, 7.5	Vapour pressure	3.6	12 Pa at 20°C	More information required.
			1.3 Pa at 30°C	Peer-reviewed reference, although value is much higher than might be expected for the main component.
			3.2 Pa at 20°C	Result certificate only

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REACH ref Annex, §	Property	IUCLID section	Value	Comments
			5.6 x 10 ⁻⁶ Pa at 25°C **	The result is consistent with the chemical structure of the main component and the other properties, in particular the boiling point. Tremain, 2002.
VII, 7.6	Surface tension	3.10		No study available, but not expected to exhibit surface activity
VII, 7.7	Water solubility	3.8	110 mg/l	Cited in a MITI report
			7 mg/l at 24°C	HSDB cites this value as peer-reviewed (source AQUASOL database). May originate in a paper by Hollifield (1979) ²
			100 mg/l at 30°C	May originate in a paper cited by Sasaki <i>et al.</i> .
			42 mg/l	Akzo-Nobel, Inc. 2001a and b, cited in USEPA, undated
			18.1 mg/l at 20°C**	Cuthbert and Mullee, 2002b.
VII, 7.8	Partition coefficient n-octanol/water (log value)	3.7 partition coefficient	3.6 – 3.7	Cited in a MITI report.
			3.65	HSDB cites this value as peer-reviewed.
			3.76	Sasaki et al, 1981. Does not comply with good practice.
			1.59 – 3.65	Estimates
			2.4	Akzo-Nobel, Inc. 2001a and b, cited in USEPA, undated
			3.8	WHO, 1998, cited in USEPA, undated
			3.65	Accepted calculation method (SRC KOWWIN v. 1.67)
			3.69 ± 0.36**	Cuthbert and Mullee, 2002b
VII, 7.9	Flash point	3.11		252°C is an open cup result.
			>107.22°C	Seta closed cup method Akzo Nobel, 2003, cited in USEPA, undated
	Autoflammability (autoignition temperature)	3.12	513°C	Akzo Nobel, 2000
VII, 7.10	Flammability	3.13		Not expected to be flammable. Derogation accepted by TC NES
VII, 7.11	Explosive properties	3.14		Not expected to be explosive. Derogation accepted by TC NES
VII, 7.13	Oxidizing properties	3.15		Not expected to be oxidising. Derogation accepted by TC NES

REACH ref Annex, §	Property	IUCLID section	Value	Comments
XI, 7.17	Viscosity	3.22	1,800 cP at 25°C 2,200 cP at 0°C 540 cP at 40°C	Akzo Nobel, 2003, cited in USEPA, undated
	Henry's law constant		1.24×10^{-04} Pa.m ³ /mol at 25°C	By calculation from VP and WS results

Studies marked ** were performed with a composite sample of purity 94.2%, derived from recent representative commercial products from the main manufacturers.

¹Klimisch code

²Hollifield (1979) sets out an approach to determine water solubility of various highly insoluble substances of environmental interest, based on plotting the turbidity of a series of solutions.

B.1.4 Justification for grouping

Not relevant for this proposal.

B.2 MANUFACTURE AND USES

B.2.1 Manufacture and import of the substance

There are two manufacturers of TDCP in Europe. Therefore, only limited information on the life cycle in the EU was included in the RAR on grounds of confidentiality. Further information on the life cycle is given in the confidential annex of the RAR for TDCP, which also describes how research into the life cycle was carried out.

Relationship between TCPP, TDCP and V6

In the RAR for TDCP, the substances TDCP, tris(2-chloro-1-methylethyl) phosphate (TCPP) and 2,2-bis(chloromethyl) trimethylene bis[bis(2-chloroethyl) phosphate (V6) were considered to be good candidates for a concurrent assessment in view of their similar use pattern and chemical similarity. All three substances are used predominantly in various types of polyurethane foam applications in the EU (>97.5% of TCPP; >85% of TDCP and >95% of V6). Chlorinated alkyl phosphate esters (particularly TCPP) were identified as possible substitutes for pentabromodiphenyl ether (pentaBDE) in the risk reduction strategy for that substance (EC 2001). However it has since become clear, from discussion with the industry, that in the EU these chemicals are not direct replacements for pentaBDE, and that changes in consumption are linked mostly with the decline in tris (2-chloroethyl) phosphate (TCEP) use and increase in the market for polyurethane (PUR) generally (communication, herein referred to as ‘comm.’, 1st March 2004). As discussed in **Section 2.1.2** of the RAR for TDCP, consumption levels appear to have stabilised in recent years; this risk assessment represents a realistic upper limit of EU production and consumption and significant increases are not anticipated in the near future.

B.2.1.1 Manufacturing process

The manufacturing process is carried out by reacting phosphorus oxychloride with an organic epoxide chemical in the presence of a catalyst. The crude product is washed and dehydrated to remove acidic impurities and residual traces of water and volatile chemicals. The product is then filtered, transferred to storage tanks for dispatch in road tankers or packed into drums (comm. 30th April 2001, Rhodia).

B.2.1.2 Manufacturing capacity

There are two manufacturers of TDCP in the EU: ICP-IL (formerly Supresta, whose TDCP business was owned earlier in the ESR process by Akzo Nobel) and Albemarle (whose TDCP business was owned earlier in the ESR process by Rhodia and previously by Albright and Wilson). References are made in accordance with the company that supplied information at the time. Total EU production in 2000 was less than 10,000 tonnes, with production taking place in Germany and the UK. Between 1998 and 2003, production has fluctuated slightly but the total EU sales tonnage has remained reasonably stable within approximately 10%. The EU consumption used in the RAR represents the upper limit of sales in the six year period for which data are available. In the RAR the rapporteur indicated that there was no reason to anticipate significant tonnage increases in the near future, based on industry information and general research.

B.2.1.3 Imports

Neither producer imported TDCP into the EU in the year 2000. Both are of the opinion that TDCP is not imported into the EU by any other party (comm. 26th February 2002, Akzo Nobel and comm. 6th March 2002, Rhodia).

In respect of automotive and furniture use, by far the most significant applications of TDCP, it is known that there is some import/export of finished articles, but overall the EU is a net exporter. There is no specific information regarding the movements of TDCP-containing furniture and vehicles. It is possible that finished goods containing TDCP in rebonded foam may be imported into the EU. This is not accounted for in the assessment as there is too little information, although it is not likely to be significant.

Both manufacturers exported TDCP from the EU in the year 2000. It is assumed that no handling (e.g. repackaging) takes place and that no losses of TDCP arise through export.

As a result of exports, consumption is somewhat less than production.

Table B.2 Production and consumption of TDCP in the year 2000

Life Cycle Stage	Tonnes in Year 2000
Production	< 10,000
Imports	None
Exports	Yes

Full details are given in the Confidential Annex of the RAR for TDCP (HSA/EA, 2008)

B.2.2 Uses

B.2.2.1 Introduction

TDCP is an additive flame retardant, i.e. it is physically combined with the material being treated rather than chemically combined. The amount of flame retardant used in any given application depends on a number of factors such as the flame retardancy required for a given product, the effectiveness of the flame retardant and synergist within a given polymer system, the physical characteristics of the end product (e.g. colour, density, stability, etc.) and the use to which the end product will be put.

Somewhat less than 10,000 tonnes of TDCP were consumed in the EU in the year 2000. Most TDCP is used in the production of flexible polyurethane (PUR) foam. TDCP is added directly at the point of production of flexible foams. Most foams containing TDCP are used in the automotive industry, with some use in furniture.

TDCP operates in the same marketplace as the flame retardant TCPP. Owing to the price differential between these products (TDCP is around twice the price of TCPP), TDCP is only used in those applications where a more efficient flame retardant is required to meet specific standards (comm. 19th March 2002, Rhodia).

Use of TDCP in products other than PUR tends to be associated with single users who have tried the product of their own accord and have decided to use it (comm. 19th March 2002, Rhodia). The low tonnage associated with these other uses confirms that TDCP is not widely used outside the polyurethane industry.

The use pattern and life cycle stages considered in this assessment are reported in **Table B.3** and shown in **Figure B.1**. Further information including information on the confidential life cycle stages is given in the Confidential Annex of the RAR report for TDCP (HSA/EA, 2008). Given that there are only two manufacturers and that both manufacturers have provided a detailed breakdown of tonnage, the life cycle is well defined.

Table B.3 Use pattern for TDCP

Ref. Env ¹	Ref. HH ²	Industry Category	Use category	Description	Percentage of total use
A	5	11	22	PUR foam for use in automotive applications	< 80%
B	2, 3	11	22	PUR foam for use in furniture	< 25%
C	-	Confidential	22	Confidential	<15%
D ³	-	Confidential	22	Confidential	
E	-	Confidential	22	Confidential	
F	-	Confidential	22	Confidential	
G	-	Confidential	47	Confidential	
H	-	Confidential	22	Confidential	
I	4	11	22	Rebonding of flexible foam	This is a form of recycling
J	-	11	22	Recycling as loose crumb	This is a form of recycling
Total					100%

Industry Category 11 = polymers industry Use category 22 = flame retardants and fire preventing agents Use category 47 = softeners

Notes:

1 – Reference letter used in the Environmental risk assessment

2 – Reference number used in the Human Health risk assessment

3 – Consultation suggests that supply has ceased; however it is not clear how long ago, and therefore it is assumed that the scenario could still be relevant. This is discussed in more detail in the Confidential Annex.

Product Register Data

Data from product registers have been provided by Denmark, Sweden and Switzerland. This information is summarised in **Table B.4**, together with data from the SPIN database (data about the use of substances in Norway, Sweden, Denmark and Finland). Data for Sweden in 1999 are for TDCP combined with TCPP and are therefore of limited use. In this regard, data for Sweden for the year 2000 indicate only limited products containing TDCP while data presented for TCPP for the year 2000 indicate that the diversity of usage reported in 1999 is owing to the inclusion of TCPP in the data (see HSA/EA, 2008a). Overall, the product register data do not provide new information concerning uses of TDCP.

It is notable that the industry’s view is that not all uses here are current or recommended uses. In particular, both manufacturers have indicated that uses in concrete and as a resin hardener do not apply to TDCP. Neither of these applications is included in the risk assessment as no further evidence of these applications has come to light in the research and consultation procedures.

Table B.4 Product register and SPIN data

Country	Year	Tonnage	Number of Products	Concentration*	Description
Denmark	-	226	4	10% to 100%	Industry group and product types are confidential
Sweden	1999	350**	45**	-	Plastics, concrete, textiles & insulation materials. 9/45 products available to consumers **
	2000	-	3	-	Use: raw material (fire prevention additive in plastics). Trade code: Industry for plastic products. No consumer products.
Switzerland	-	-	1	1%	Hardener in resin
<p>* Intervals used in the Danish Product Register are 0-1%, 1-5%, 5-10%, 10-20%, 20-50%, 50-80% and 80-100%. If limited data indicate confidential information, broader intervals are used.</p> <p>** Combined data with TCPP</p>					

A life cycle assessment study by SP, Sweden and IVL-Swedish Environmental Research Institute, Sweden (Simonson *et al*, undated) investigated emission of pollutants associated with different life cycle stages of sofas. Three sofas were tested. The purpose was to assess pollutant emissions at all stages of the sofas' life cycle, including in the event of fire. Emissions of the flame retardant (FR) itself were not investigated. The information and assumptions regarding the life cycle are useful for comparison with the assessment made in the current risk assessment. A schematic representation shows the life cycle stages of relevance for the flame retardant as:

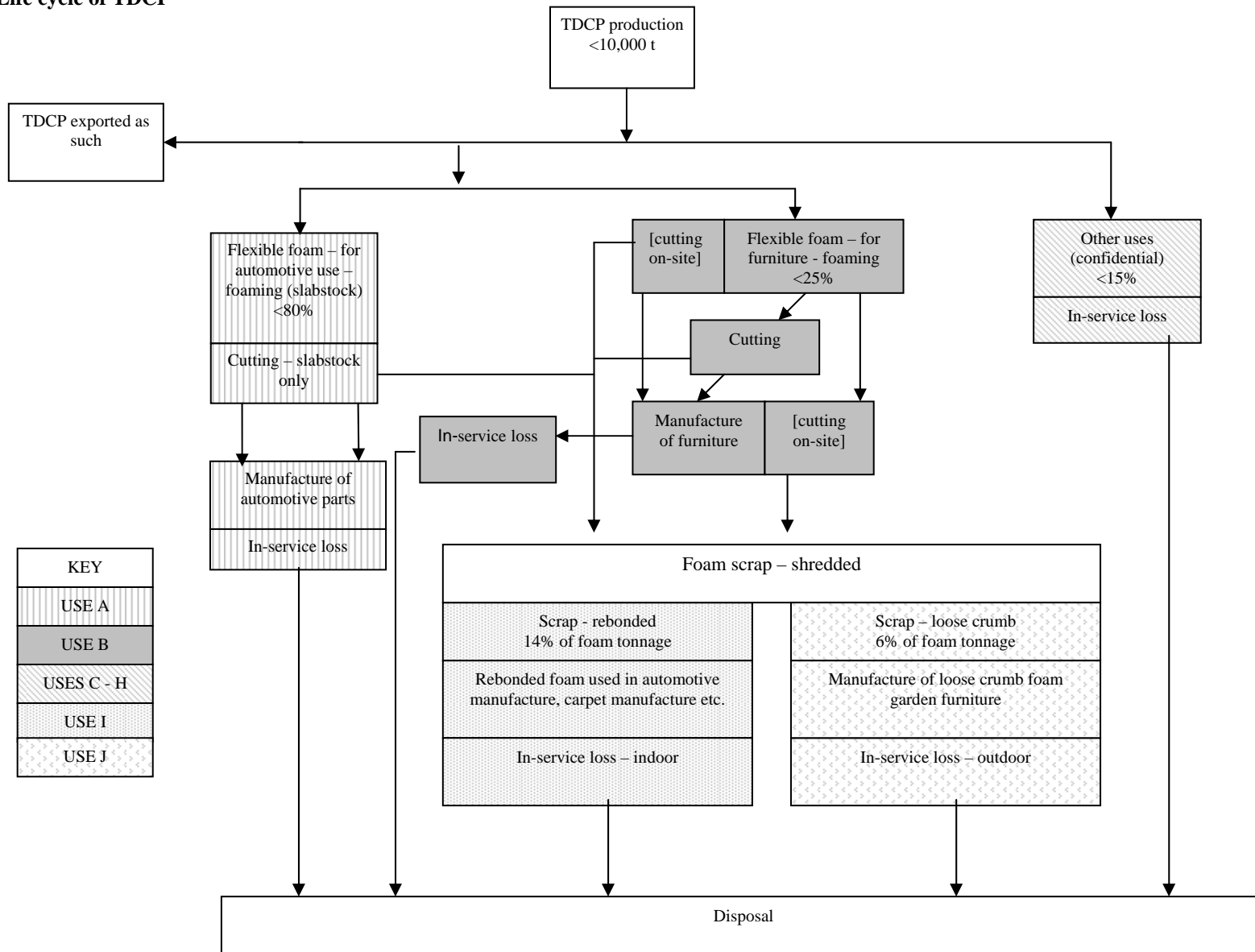
- flame retardant production; material (i.e. foam) production
- production of primary product (i.e. item of furniture)
- use of primary product (i.e. in-service)
- recycling processes (see below)
- incineration
- landfill/landfill fire
- fire of primary products.

Service lives of ten and fifteen years were used in the LCA, though this appears to have been used as a half-life in the assessment. The mode of recycling is of interest; the schematic indicates mechanical/feedstock recycling, but this is not believed by the rapporteur to be a valid route and is not assessed in the RAR for TDCP. Interestingly, elsewhere in the RAR, the only route of 'recycling' investigated for releases is for heat recovery (i.e. incineration).

B.2.3 Uses advised against

As of the date of this transitional Annex XV report, the two manufacturers of TDCP have not identified any uses they advise against (personal communication, herein referred to as 'pers. comm.' 10th September 2008, PEFRC).

Figure B.1 Life cycle of TDCP



B.3 CLASSIFICATION AND LABELLING

TDCP is not listed in Annex I of Directive 67/548/EEC.

B.3.1 Proposed classification for human health

An Annex XV proposing a harmonised classification and labelling for TDCP has been prepared by the rapporteur and submitted to ECHA, to be discussed by the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC) in due course. **Table B.5** contains the proposed harmonised classification and labelling.

Table B.5: Proposed harmonised classification and labelling for TDCP

Proposed classification for human health based on Directive 67/548/EEC criteria:	Carc. Cat 3; R40
Proposed labelling:	Xn; R40 S(2)-36/37
Proposed classification based on GHS criteria:	Carc. 2 with hazard statement H351

B.3.2 Classification for the environment

The Commission Working Group on the Classification and Labelling of Dangerous Substances Meeting on Environmental Effects of Existing Chemicals, Pesticides & New Chemicals agreed a classification for the environment (N; R51-53) on 28-30 September 2005.

B.3.3 Industry's self classification(s) and labelling

Both manufacturers of TDCP have self-classified TDCP as Xn; N; R40-51/53 (pers. comm. 10th September 2008, PEFRC).

B.4 ENVIRONMENTAL FATE PROPERTIES

Please refer to **Section 3.1.3** of the RAR for TDCP (HSA/EA, 2008).

B.4.1 Degradation

Please refer to **Section 3.1.3.1** of the RAR.

B.4.2 Environmental distribution

B.4.3 Bioaccumulation

Please refer to **Section 3.1.3.3** of the RAR.

B.4.3.1 Aquatic bioaccumulation

Please refer to **Section 3.1.3.3.1** of the RAR.

B.4.3.2 Terrestrial bioaccumulation

Please refer to **Section 3.1.3.3.2** of the RAR.

B.4.4 Secondary poisoning

Please refer to **Section 3.1.7** of the RAR.

B.5 HUMAN HEALTH HAZARD ASSESSMENT

B.5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

Please refer to **Section 4.1.2.1** of the RAR.

B.5.2 Acute toxicity

Please refer to **Section 4.1.2.2** of the RAR.

B.5.3 Irritation

Please refer to **Section 4.1.2.3** of the RAR.

B.5.3.1 Skin

Please refer to **Section 4.1.2.3.1** of the RAR.

B.5.3.2 Eye

Please refer to **Section 4.1.2.3.2** of the RAR.

B.5.3.3 Respiratory tract

Please refer to **Section 4.1.2.3.3** of the RAR.

B.5.3.4 Summary and discussion of irritation

Please refer to **Section 4.1.2.3.4** of the RAR.

B.5.4 Corrosivity

Please refer to **Section 4.1.2.4** of the RAR.

B.5.5 Sensitisation

Please refer to **Section 4.1.2.5** of the RAR.

B.5.6 Repeated dose toxicity

Please refer to **Section 4.1.2.6** of the RAR.

B.5.7 Mutagenicity

Please refer to **Section 4.1.2.7** of the RAR.

B.5.8 Carcinogenicity

Please refer to **Section 4.1.2.8** of the RAR.

B.5.9 Toxicity for reproduction

Please refer to **Section 4.1.2.9** of the RAR.

B.5.10 Other effects

Not relevant for this proposal.

B.5.11 Derivation of DNEL(s) or other quantitative or qualitative measure for dose response

B.6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

B.6.1 Explosivity

Please refer to **Section 4.2.2.1** of the RAR.

B.6.2 Flammability

Please refer to **Section 4.2.2.2** of the RAR.

B.6.3 Oxidising properties

Please refer to **Section 4.2.2.3** of the RAR.

B.7 ENVIRONMENTAL HAZARD ASSESSMENT

B.7.1 Aquatic compartment (including sediment)

Please refer to **Section 3.3.1** of the RAR.

B.7.2 Terrestrial compartment

Please refer to **Section 3.3.2** of the RAR.

B.7.3 Atmospheric compartment

Please refer to **Section 3.3.3** of the RAR.

B.7.4 Microbiological activity in sewage treatment systems

B.7.5 Non compartment specific effects relevant for the food chain (secondary poisoning)

B.8 PBT AND VPVB ASSESSMENT

B.8.1 Assessment of PBT/vPvB properties – Comparison with criteria of Annex XIII

Not relevant for this proposal.

B.2 Emission characterisation

B.9 EXPOSURE ASSESSMENT

B.9.1 General discussion on releases and exposure

TDCP is a liquid at room temperature with a low vapour pressure of 5.6×10^{-6} Pa at 25⁰C and a calculated saturated vapour pressure (SVC) of 1 µg/m³ at 21⁰C.

Occupational exposure to TDCP may occur during its manufacture and during the manufacture and cutting of polyurethane (PUR) foam. Inhalation of vapours and skin contact are the predominant routes of exposure. Oral exposure is not considered to be a significant route of exposure under normal working practices.

Descriptions of the processes and sources of occupational dermal exposure are discussed below along with a discussion of exposure levels. Most of this data was supplied by industry either directly or through trade organisations and forms part of the RAR for TDCP. In addition, personal dermal sampling data from flexible foam manufacturing plants using tris(2-chloro-1-methylethyl)phosphate (TCPP) and 2,2-bis(chloromethyl) trimethylene bis[bis(2-chloroethyl) phosphate] (V6) was used in order to ascertain dermal exposure levels for TDCP, as the processes are identical and the flame retardants are used in the same way. The data for TCPP and V6 was used in more than one scenario where it was felt appropriate by the rapporteur. The occupational exposure scenarios are:

- (1) Manufacture of TDCP
- (2) Manufacture of flexible PUR foam
 - (a) slabstock foams
 - (b) moulded foams
- (3) Cutting of flexible PUR foam*
- (4) Production of foam granules and rebonded PUR foam
- (5) Manufacture of automotive parts

* Scenario 3 covers the cutting of foam by furniture manufacturers, where it occurs.

B.9.1.1 Summary of the existing legal requirements

B.9.1.1.1 Directive 67/548/EEC on Classification Packaging and Labelling of Dangerous Substances

An Annex XV proposing harmonised classification for human health (HSA, 2008c) has been prepared for TDCP by the rapporteur and has been submitted to ECHA, to be reviewed by the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC) in due course. The proposed classification for human health is carc. cat. 3; R40 (see **Table B.6**). Both manufacturers of TDCP have indicated that they have self-classified this substance as Xn; N; R40-51/53 (pers. comm. 10th September 2008).

The Commission Working Group on the Classification and Labelling of Dangerous Substances Meeting on Environmental Effects of Existing Chemicals, Pesticides & New Chemicals agreed a classification for the environment (N; R51-53) on 28-30 September 2005.

As TDCP meets certain criteria for classification as dangerous, it should be packaged and labelled in accordance with Directive 67/548/EEC.

Table B.6 Proposed classification and labelling of TDCP

Classification	R-Phrase description	Accompanying S-Phrase
Carc. Cat. 3 R40	Carcinogen Category 3 - Substance which can cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment Limited evidence of carcinogenic effect	S2 – Keep out of reach of children S36 – Wear suitable protective clothing S37 – Wear suitable gloves
R51/53	Toxic to aquatic organisms, may cause long-term effects in the aquatic environment	S61 – Avoid release to the environment

B.9.1.1.2 Safety data sheets

Article 31 of Regulation (EC) No. 1907/2006 (herein called the REACH Regulation) states that any supplier of a substance or preparation shall provide the recipient of the substance or preparation with a safety data sheet (SDS) compiled in accordance with Annex II, where the substance or preparation meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC or 1999/45/EC. Such a recipient could be a downstream user of the substance e.g. manufacturer of flexible PUR foams.

As TDCP meets certain criteria for classification as dangerous in accordance with Directive 67/548/EEC, suppliers of TDCP would be required to supply a SDS to recipients.

Both manufacturers of TDCP provided an up-to-date SDS for TDCP (pers. comm. 11th September 2008, Albemarle and pers. comm.. 12th September 2008, ICL-IP) in which the classification Xn; N; R40-51/53 is communicated to recipients as well as information on hazards, composition, first-aid, fire fighting and accidental release measures, handling and storage, personal protection, physical and chemical properties, stability and reactivity, toxicology, ecotoxicology, disposal and transport.

In addition, article 35 of the REACH Regulation states that workers and their representatives must be granted access by their employer to hazard and exposure information for a substances and/or preparations he/she uses or may be exposed to in their course of work.

B.9.1.1.3 Occupational safety and health legislation

Regarding the production and use of TDCP, the following Directives are primarily applicable as general legislation governing occupational safety and health at European level.

B.9.1.1.3.1 Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work

Directive 89/391/EEC requires that employers take all measures necessary for the safety and health protection of workers. This should include measures for the prevention of occupational risks and the provision of information and training. In addition, employers should ensure the necessary organization and means are in place to ensure the safety and health protection of workers. The employer shall be alert to the need to adjust these measures to take account of changing circumstances, where necessary and should aim to always seek improvements to existing situations.

B.9.1.1.3.2 Directive 98/24/EC on the protection of workers from the risks related to exposure to chemical agents at work

Directive 98/24/EC lays down obligations on the employer regarding the determination and assessment of risk of hazardous chemical agents. It lists the general principles for preventing risks associated with hazardous chemical agents, which includes the following mechanisms which an employer should use to eliminate the risk or reduce it to a minimum:

- The design and organisation of systems of work at the workplace
- The provision of suitable equipment for work with chemical agents and maintenance procedures which ensure the health and safety of workers at work
- Reducing to a minimum the number of workers exposed or likely to be exposed
- Reducing to a minimum the duration and intensity of exposure
- Appropriate hygiene measures
- Reducing the quantity of chemical agents present at the workplace to the minimum required for the type of work concerned
- Suitable working procedures including arrangements for the safe handling, storage and transport within the workplace of hazardous chemical agents and waste containing such chemical agents

Where the nature of the activity does not permit risk to be eliminated by substitution, Directive 98/24/EC requires that the employer ensures that the risk is reduced to a minimum by application of protection and prevention measures in the following order of priority:

- Design of appropriate work processes and engineering controls and use of adequate equipment and materials, so as to avoid or minimise the release of hazardous chemical agents which may present a risk to workers' safety and health at the place of work
- Application of collective protection measures at the source of the risk, such as adequate ventilation and appropriate organisational measures
- Where exposure cannot be prevented by other means, application of individual protection measures including personal protective equipment

B.9.1.1.3.3 Directive 89/656/EEC on the use of Personal Protective Equipment

Directive 89/656/EEC requires that personal protective equipment shall be used when the risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organisation. Personal protective equipment must be appropriate for the risks involved and must correspond to the existing conditions of the workplace. The conditions of use of personal protective equipment in particular the period for which it is worn, shall be determined on the basis of the:

- Seriousness of the risk
- Frequency of exposure to the risk
- Characteristics of the workstation of each worker
- Performance of the personal protective equipment

B.9.1.1.4 Occupational Exposure Limit Values

An occupational exposure limit value (OELV) can be defined as an exposure standard for a chemical in workplace air, with reference to either an 8-hour reference period or a 15 minute reference period. OELVs provide a basis for ensuring that exposure to airborne contaminants in the workplace is controlled in such a way as to prevent adverse health effects. An OELV for a particular chemical represents the maximum exposure to the chemical in workplace air, which is considered consistent with this objective. In practice, exposure levels should be maintained well below the OELV and should always be as low as reasonably achievable (HSA, 2007).

There are currently no occupational exposure limit values for TDCP.

As described in **Section B.9.1**, TDCP is used during the production of flexible polyurethane foam. This process also involves the use of diisocyanate substances, such as toluene di-isocyanate (TDI and diphenylmethane diisocyanate) which are both classified as sensitisers and appear in Annex I of Directive 67/548/EEC. Companies using these substances must observe specific limit values of emission releases. **Table B.7** lists some representative OELVs applicable in several Member States for MDI and TDI. Companies using TDI and MDI must ensure that worker exposure is controlled to below the occupational exposure limit values and that appropriate risk assessment is carried out on the workplace and protective and preventative measures are put in place to ensure the health and safety of workers. An Industry representative involved in the production of flexible polyurethane foam has indicated that in order to achieve compliance with these strict requirements all processes include fume extraction techniques coupled with machine encapsulation. Factory emission techniques to atmosphere and attenuation are implemented where necessary (pers. comm. 28th July 2008, EUROPUR).

Table B.7 Occupational exposure limit values for TDI and MDI in several Member States

Member State	TDI Long-term (8 hrs) mg/m ³	MDI Long-term (8 hrs) mg/m ³
Ireland	0.02	0.02
United Kingdom	0.02	0.02
Germany	0.035	0.05
Denmark	0.035	0.05
Sweden	0.04	0.05

B.9.1.1.5 National legislation in Member States

The rapporteur consulted representatives from Member States, in order to ascertain whether any current or planned national regulations (or other measures) existed in other Member States, aimed at reducing the risks to workers from the manufacture of TDCP or the use of TDCP in the production of flexible PUR foam. Responses were received from Cyprus (pers. comm. 27th August 2008), United Kingdom (pers. comm. 8th September 2008, Health and Safety Executive), Denmark (pers. comm. 10th September 2008, Danish Ministry of the Environment) and Estonia (pers. comm. 12th September 2008, Ministry of Social Affairs of Estonia). All indicated that they do not have any current or planned national regulations or other measures to reduce the risks to workers from the manufacture of TDCP or its use in the production of flexible PUR foam. The same situation applies in Ireland.

B.9.1.2 Summary of the effectiveness of the implemented risk management measures

The information presented in the RAR suggests that it is possible that risk reduction measures were not being effectively implemented at the time when exposure monitoring was taken. Poor hygiene procedures observed during the monitoring of operators are thought to be the reason for the (reasonable worst case) dermal risk to workers involved in the manufacture of TDCP and in the use of TDCP during the manufacture of flexible PUR foam (slabstock and moulded). It is felt that the existing legal requirements should be sufficient to ensure reduction of the exposure to a level that allows adequate control of the identified risk, if implemented correctly.

B.9.2 MANUFACTURING

As indicated in **Section B.2**, TDCP is manufactured by two companies in the EU. In the year 2000, the total EU production was less than 10,000 tonnes, with production taking place in the UK and Germany. Between 1998 and 2003, production has fluctuated slightly but the total EU sales tonnage has remained reasonably stable within approximately 10 %.

In both production facilities, TDCP is produced in a closed system by reacting phosphorous oxychloride with an organic epoxide chemical in the presence of a catalyst. The crude product is washed and dehydrated to remove acidic impurities and residual traces of water and volatile chemicals. The product is then filtered, transferred to storage tanks for despatch in road tankers or packed into drums (comm. 30th April 2001, Rhodia).

B.9.2.1 Occupational Exposure

B.9.2.1.1 Measured dermal exposure data

Production plant 1

In a study conducted by industry (2002) hand exposures of 2 operators in one of the TDCP manufacturing plants were evaluated under actual working conditions. At this plant, TDCP is produced in a closed system. Filling stations for drumming are semi-automatic and equipped with local exhaust ventilation to remove vapours from the operator area. The plunger is also equipped to avoid drops falling down when the lance is transferred from one drum to another. Although the operator moves the lance from drum to drum, it is carried out using a boom so that the operator does not come into contact with the lance. The operator does secure lids and fits seals to the drums.

The entire reaction, washing, drying and storage tanks are closed and either purged with nitrogen or under vacuum. The processes are computer-controlled. The computers monitor and control reactors, reaction conditions such as temperature and pressure, chemical additions and process alarms. This limits the possibilities of operator contact with TDCP during the production steps. One operator per shift is assigned to the plant. The operators spend most of their time in the control room. Highest dermal exposures are likely to occur during drumming and activities such as material sampling and maintenance. Samples are taken from a sampling valve into a 250 g bottle. There is no local exhaust ventilation at the sampling point. The operator wears PVC gloves, safety spectacles, hard hat and work coveralls. Sampling takes less than 1 minute to complete. Analysis is carried out by a laboratory technician. Extraction ventilation and personal protective equipment are employed to reduce exposure.

Operators monitored were involved in production and drumming (one operation of drumming was monitored). In addition, a laboratory operator was monitored. For dermal exposure monitoring, 100 % cotton absorbent gloves were used as dosimeters. If protective gloves were used, the absorbent

gloves were worn beneath them. The protective gloves used were Vygen plus PVC gloves, cotton lined. The absorbent gloves were peeled off and replaced at times when the worker normally washed his hands and were placed in a plastic bag. They were extracted with toluene before chromatography.

The method for dermal monitoring has been developed and validated for TDCP. The limit of detection was evaluated to be 0.1 µg for TDCP on 3 µg on cotton gloves. **Table B.8** below gives a summary of these monitoring results.

Table B.8 Results of dermal monitoring carried out on operators involved in production of TDCP, drumming and laboratory work

Operator's Task	Length of time monitored (mins)	Dermal exposure TDCP (mg/kg bw)
Production	412	0.21
Drumming	151	0.07
Laboratory Operator	400	0.34

During the monitoring period, the production operator supervised the production of 3 batches, cleaned the funda filter and took a sample from the funda filter. He was located in the control room for most of the time. During these activities, he wore protective gloves (Vygen plus gloves). The operator carrying out the task of drumming TDCP drummed 25 drums (300 kg each), containing 90 % TDCP, for a period of 2.5 hours. He did not wear PPE when carrying out his tasks. The laboratory operator carried out TDCP crude testing (20 mins), TDCP stock tank testing (20 mins) and TDCP filtered testing (20 mins) during the monitoring period. Dermal exposure of 0.34 mg/kg bw was measured for a laboratory worker. He did not wear any PPE while carrying out his tasks.

Production plant 2

In a second TDCP production plant, TDCP is produced in a batch-wise manner. The system is a closed one, except for loading stations. All of the processes are computer controlled, with a specific operator permanently present in the control room. The filling stations are automatic and equipped with LEV.

The method used for measuring TDCP was the same as that described for plant 1 above. Monitoring was carried out on the chemical production and quality control line (1 operator monitored) and during drumming of the final product into steel drums and IBCs (1 operator monitored) for the duration of a typical working day. Both operators were monitored for the duration of their 8-hour shift.

B.9.2.1.2 Modelled dermal exposure data

EASE is a general purpose predictive model for workplace exposure assessments. For workers involved in the manufacture of TDCP, the appropriate EASE scenario would be a closed system (breached for sampling and maintenance) with no direct handling. For this, EASE predicted the dermal exposure to be very low.

For sampling of TDCP during the manufacturing process, default values were taken from the Technical Guidance Document (TGD) for the scenario quality control sampling of liquids. It is considered however, that the contact is intermittent, rather than incidental, with non-dispersive use and an exposure area of 210 cm². The exposure estimate for this was 0.1 to 1 mg/cm²/day. The exposure area of 210 cm² was selected as there is little opportunity for large-scale dermal exposure

during normal operations as most of the production takes place in closed systems with breaches for sampling and drumming.

For drumming of TDCP and TDCP blends, using the default values of reasonable worst-case dermal exposure for the scenario of drumming of liquids given in the TGD (non-dispersive use, with intermittent contact and an exposure area of 210 cm²), gave an estimate of 0.1 to 1 mg/cm²/day.

B.9.2.1.3 Summary of occupational exposure to TDCP during its manufacture

For the measured data, there were few data points from the monitoring carried out in the 2 production plants. However, the tasks carried out during the monitoring periods were typical of the normal work patterns and the results obtained appeared to be representative of the TDCP production industry. **Table B.9** below summarises the dermal exposure measurements taken in the two production plants.

Table B.9 Summary table of dermal exposure measurements taken in two production plants

Operator's Task	Length of time monitored (mins)	Dermal exposure TDCP (mg/kg bw)
Plant 1		
Production	412	0.21
Drumming	151	0.07
Laboratory Operator	400	0.34
Plant 2		
Operator 1 - production	480	-
Operator 2 - drumming	480	-

B.9.2.1.4 Values taken forward for risk characterisation

For dermal exposure the value taken forward for reasonable worst-case dermal exposure was 0.1 mg/cm²/day or 21 mg/day, which was equivalent to the highest value obtained during sampling (0.34 mg/kg bw, assuming a bodyweight of 70 kg and an exposure area of 210 cm²). Although this was the highest value obtained, there was another sample (0.21 mg/kg bw) of the same order of magnitude. The value taken forward for typical dermal exposure was 0.05 mg/cm²/day or 10.5 mg/day. This was equivalent to 0.15 mg/kg bw assuming an exposure area of 210 cm² and a bodyweight of 70 kg. It was within the range of the reported data from industry, although lower than the range of 0.1 to 1 mg/cm²/day predicted using EASE.

B.9.3 USES

B.9.3.1 Production of slabstock foam (scenario 2a)

Flexible polyurethane foams can be manufactured in continuous or batch manufacturing processes. This means that the mixed liquid chemicals are dispensed onto either a moving conveyor or into a static mould. Further information on the process can be found in **Appendix A** of the RAR report for TDCP. In a typical process, the initial ingredients (mainly water, isocyanate, polyether polyols and any other additive such as a flame retardant) are mixed together at a mixing head and then immediately applied to the bottom lining of a continuously moving trough formed by a horizontal bottom paper or foil and two vertical side papers or foils. After a few seconds, a cream is formed, the volume expands and the foam reaches its maximum height in 1-3 minutes. The blocks of foam

are cut off immediately after paper take-off, and then transferred through a transfer conveyer to the weigh scale and to the curing area. Some blocks can be randomly transferred to a specific area for temperature probing.

The amount of TDCP used depends on the foam grade required and is controlled by a meter. Continuous foaming machines can produce polyurethane foam at rates up to 500 kg/minute. The foaming section of the process is enclosed within a tunnel fitted with extraction for removal of diisocyanate vapours and blowing agent emissions (HMIP, 1995).

B.9.3.1.1 Occupational exposure

The main areas of potential dermal exposure can occur in the mixing head area where raw materials are mixed and contact with chemicals can occur. It can also occur during temperature supervision and cutting of the foam.

B.9.3.1.1.1 Measured exposure data

An industry consortium measured dermal exposure to TDCP at two polyurethane foam production and cutting facilities during February and May 2005. These plants were not identified in the RAR for TDCP, they are referred to throughout as Plant A and Plant B to distinguish them from the TDCP production plants which were referred to as production plants 1 and 2 in the RAR.

Twenty-eight dermal shift exposure samples were collected at Plant A as well as one short-term sample. At Plant B twelve dermal shift exposure samples were collected. The samples were collected by the operators wearing cotton gloves throughout their shift which were collected for analysis. The analysis technique used was the same as for analysis of the tubes, except the volume of desorbent used was greater. The LOD for the method used was 10 µg for the gloves.

The activities covered during the sampling exercise included operators working at the mixing head area, the paper take-off area, the cut-off area, the production area supervisors, the laboratory technician, and the operators in the foam conversion (loop slitting) area.

During the shifts monitored, TDCP-containing foam was manufactured for 1 hour (Plant B) and at Plant A, between approximately 5 hours (day 1) and almost 8 hours (day 2). The amount of TDCP in the runs varied between 3 % and 15 %. These were typical days at the plants where the sampling took place, and the 8-hour TWA results reflect this. That is, the sampling that took place was carried out over a whole shift regardless of how long the operatives were working with TDCP-containing foam, to determine typical shift-length exposures.

The dermal exposure results were presented by industry in a number of ways; total mg TDCP/pair of gloves; mg TDCP/hour; mg TDCP/kg bw and µg TDCP/cm²/day. In the RAR for TDCP total mg TDCP/pair of gloves has been used as representative of mg TDCP/day, as this is the preferred reporting method for risk assessment reports.

B.9.3.1.1.2 Dermal exposure

Tables B.10 and B.11 summarise the dermal result from Plants A and B, respectively.

Table B.10 Dermal exposure to TDCP measured at Plant A

Job title or work area	n	mg TDCP /pair of gloves (mg/day)
Supervisor/Ass. supervisor	4	1.0, 1.9, 2.0, 3.7

Mixing head area	6	3.4, 3.9, 11.5, 36.9, 41.6, 49.5
Paper take-off area	4	2.0, 3.0, 8.0, 12.6
Cut-off area	1	27.0
Lab technician	3	0.01, 0.02, 1.1
Truck unloading	1	0.71

Table B.11 Dermal exposure to TDCP measured at Plant B

Job title or work area	mg TDCP/ pair of gloves (mg/day)
Raw material/ Tank Form	0.22
Mixing head op. I	0.032
Mixing head op. II	0.052
Mixing head op. III	0.17
Supervisor	0.047
Side Paper take-off operator	0.029
Cut-off block operator	0.173
Cut-off Start/End operator	0.124
Bottom Paper operator	0.141
Lab technician	0.048

The dermal exposures for TDCP measured in the two plants ranged from 0.01 to 49.5 mg/day. The highest result was obtained by an operator in the mixing head area of Plant A. According to the industry report, the operator did not have much contact with foam, but may have had contact with the chemicals, although it was not clear when or how this had occurred. In addition, personal dermal sampling data from flexible foam manufacturing plants using V6 and TCPP have been used here (see supporting data in **Part H**), as the processes are identical and the flame retardants are used in the same way. The range of exposures taking all of the personal sampling results into account was 0.01 to 105 mg/day or 2.4×10^{-4} to 0.25 mg/cm²/day assuming an exposure area of 420 cm².

B.9.3.1.2 Values taken forward to risk characterisation

For the purposes of risk characterisation, the personal exposure data was used in the RAR for TDCP, including the data for V6 and TCPP (see supporting data in **Part H**). It was considered that these data best represent personal exposure, as the older data was from static monitoring.

For dermal exposure, the reasonable worst case (RWC) dermal exposure value taken forward to risk characterisation was 29.8 mg/day or 0.07 mg/cm²/day, assuming an exposure area of 420 cm². This is the 90th percentile of the measured values. For typical exposure, a value of 0.7 mg/day or 0.002 mg/cm²/day was taken forward. This was the median number from all the measured exposure values available.

B.9.3.2 Production of moulded foam (scenario 2b)

Moulded foams can be produced from TDI and also from a mixture of TDI and MDI. Predetermined quantities of mixed reactants are automatically or manually dispensed discontinuously into moulds, which may be stationary or continuously circulating on a track (HMIP, 1995 and BASF, undated).

The moulds are normally temperature conditioned prior to filling (HMIP, 1995) to around 40⁰C. After the reactants have been dispensed, the lid of the mould is closed and foaming takes place. Alternatively, the mixture is automatically injected into a closed mould with defined vents. With hot cure moulding, the moulds are heated to temperatures typically in the range 150⁰C to 230⁰C (HMIP, 1995). On completion of the curing cycle, the moulds are opened and the moulded shapes are removed for trimming and finishing. Some moulded items are subject to a crushing stage or vacuum treatment in order to break open the closed cells in the moulding. After removal of the moulded article the mould is cleaned by removal of residual foam material from the lid and from vents, etc. The mould is then treated with a mould release agent such as a wax, which may be an organic solvent or an aqueous dispersion (HMIP, 1995).

B.9.3.2.1 Occupational exposure

There was no exposure data for the production of moulded foam products. However in the RAR for TDCP, it was thought that the dispensing of the liquid foam into moulds would be similar to the dispensing of the foam mixture from the mixing head during PUR foam block manufacture (scenario 2a). Although not directly comparable, it was also felt that the results for work at the cutting of foam blocks (scenario 3) would give an indication of the likely range of exposures during cutting and trimming of moulded parts. Hence dermal exposure values from scenario 2a and 3 (see supporting data in **Part H**) were used for scenario 2b.

Industry carried out dermal exposure monitoring in 2005 at two flexible PUR foam manufacturing plants. Relevant results from this exercise have been used to illustrate the likely exposures during the manufacture of moulded products. These data were also used in Scenario 2a.

B.9.3.2.1.1 Measured dermal exposure data

Dermal exposure results from Plants A and B are presented in **Tables B.12** and **B.13**, respectively. Relevant dermal exposure data with V6 and TCPP are presented as supporting data in **Part H**.

Table B.12 Dermal exposure results for TDCP measured at Plant A

Job title or work area	n	mg TDCP / pair of gloves (mg/day)
Mixing head area ¹	6	3.4, 3.9, 11.5, 36.9, 41.6, 49.5
Paper take-off area ¹	4	2.0, 3.0, 8.0, 12.6
Cut-off area ¹	1	27.0
Block preparation ²	2	0.4, 1.8
Machine operator ²	7	0.06, 0.1, 0.2, 0.3, 0.6, 2.5, 3.0

¹Dermal exposure values taken from scenario 2a

²Dermal exposure values taken from scenario 3

Table B.13 Dermal exposure results for TDCP measured at Plant B

Job title or work area ¹	mg TDCP/ pair of gloves (mg/day)
Mixing head op. I ¹	0.032
Mixing head op. II ¹	0.052
Mixing head op. III ¹	0.17
Side Paper take-off operator ¹	0.029
Cut-off block operator ¹	0.173
Cut-off Start/End operator ¹	0.124
Bottom Paper operator ²	0.141
Loop slitter operator ²	0.41

¹Dermal exposure values taken from scenario 2a

²Dermal exposure values taken from scenario 3

The range of results for dermal exposure deemed to be relevant to this scenario was 0.029 to 105 mg/day.

B.9.3.2.2 Values taken forward to risk characterisation

The reasonable worst case dermal exposure value taken forward for risk characterisation was 7.5×10^{-2} mg/cm²/day or 31.5 mg/day. This is the 90th percentile of the data set used for this scenario, and assumed a bodyweight of 70 kg and an exposure area of 420 cm². The typical dermal exposure value taken forward for risk characterisation was 1.5×10^{-3} mg/cm²/day or 0.63 mg/day. This was the median value of the data set used for this scenario and was taken forward in line with TGD, and assumed the same bodyweight and exposure area as above.

B.9.3.3 Cutting of flexible foam (scenario 3)

The RAR for TDCP concluded there was no need for further risk reduction measures during the cutting of flexible foam. Hence the occupation exposure for this scenario will not be discussed further here. Please refer to **Section 4.1.1.1.4** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.4 Production of foam granules and rebounded PUR foam (scenario 4)

The RAR for TDCP concluded there was no need for further risk reduction measures during the production of foam granules and rebounded PUR foam. Hence the occupation exposure for this scenario will not be discussed further here. Please refer to **Section 4.1.1.1.5** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.5 Manufacture of automobile parts (scenario 5)

The RAR for TDCP concluded there was no need for further risk reduction measures during the manufacture of automobile parts. Hence the occupation exposure for this scenario will not be discussed further here. Please refer to **Section 4.1.1.1.6** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.6 Summary of occupational dermal exposure

A summary of the dermal exposures values taken forward to risk characterisation for scenarios 1, 2a and 2b are presented in **Table B.14**.

Table B.14 Summary of RWC and typical dermal exposure values for all scenarios taken forward for risk characterisation

Scenario	Dermal exposure (mg/cm ² /day)		Dermal exposure area (cm ²)
	RWC	Typical	
1.Occupational exposure during manufacture of TDCP	0.1	5 x 10 ⁻²	210
2a. Occupational exposure during manufacture of flexible PUR foam	7 x 10 ⁻²	2 x 10 ⁻³	420
2b. Occupational exposure during manufacture of moulded foam	7.5 x 10 ⁻²	1.5 x 10 ⁻³	420

B.9.4 Other sources (for example natural sources)

Not relevant for this proposal.

B.9.5 Summary of environmental exposure assessment

Not relevant for this proposal.

B.9.6 Combined human exposure assessment

Section 4.1.1.4 of the RAR for TDCP contains an assessment of the combined exposure to TDCP. That is the sum of all the specific sources (occupational exposure, consumer exposure and indirect exposure via the environment). Therefore, a worst case estimate for this combined exposure would be the sum of the RWC estimates, for inhalation and dermal exposures, for the three populations; i.e. workers, consumers and man exposed via the environment.

Occupational exposures were not included in the combined exposure calculation in the RAR for TDCP. The occupational exposure levels were found to be significantly higher than the estimated exposure to consumers or for indirect exposure via the environment. Therefore, the occupational exposure value would have dominated the combined exposure estimate, it was not considered necessary to include it in the combined exposure calculation of the RAR.

B.10 RISK CHARACTERISATION

B.10.1 Human health

This section of the transitional Annex XV report will focus on the risk characterisation associated with dermal exposure of workers to TDCP during the following scenarios, whereby the RAR concluded a strategy for limiting risks is required:

- 1) Manufacture of TDCP
- 2) Manufacture of flexible PUR foam
 - a) slabstock foams
 - b) moulded foams

For the purposes of risk characterisation, two types of worker exposure are considered. 'Typical' exposure covers the circumstances in which most workers are exposed and is based on normal industry working practice. 'Reasonable worst case' (RWC) exposures are intended to cover exposure situations where adequate control is lacking. RWC exposures are not considered as extreme incidents, but rather higher end exposures which are reasonably foreseeable.

B.10.1.1 Workers

To make a comparison between exposure data and data from the toxicological studies for each end-point, total body burdens have been calculated for workers for the worst-case and typical and dermal exposure scenarios. This section only includes the body burden dermal calculations for the worker scenarios whereby the RAR identified a risk. Please refer to **Section 4.1.3.2** of the RAR for information on the remaining exposure scenarios (3, 4 and 5).

Scenario 1: Manufacture of TDCP

With regard to TDCP production, the reasonable worst-case dermal exposure was found to be 0.1 mg/cm²/day. Using default values of a 70 kg worker with 210 cm² of exposed skin and assuming 15 % dermal absorption, the dermal body burden was calculated as 4.5 x 10⁻² mg/kg.

The typical dermal exposure was found to be 5 x 10⁻² mg/cm²/day, leading to a dermal body burden of 2.3 x 10⁻² mg/kg.

Scenario 2(a) Manufacture of flexible PUR foam: slabstock foams

Regarding the manufacture of flexible polyurethane foam (slabstock foam), the reasonable worst-case dermal exposure was found to be 7 x 10⁻² mg/cm²/day. Using default values of a 70 kg worker with 420 cm² of exposed skin and assuming 15 % dermal absorption, the dermal body burden was calculated as 6.3 x 10⁻² mg/kg.

The typical dermal exposure was found to be 2 x 10⁻³ mg/cm²/day, leading to a dermal body burden of 1.8 x 10⁻³ mg/kg.

Scenario 2(b): Manufacture of flexible PUR foam: moulded foams

Regarding the manufacture of flexible polyurethane foam (moulded foam), the reasonable worst-dermal exposure was found to be 7.5 x 10⁻² mg/cm²/day. Using default values of a 70 kg worker with 420 cm² of exposed skin and assuming 15 % dermal absorption, the dermal body burden was calculated as 6.8 x 10⁻² mg/kg.

The typical dermal exposure was found to be 1.5×10^{-3} mg/cm²/day, leading to a dermal body burden of 1.4×10^{-3} mg/kg.

Table B.15 below gives a summary of dermal body burden values for TDCP exposure scenarios 1, 2a and 2b.

Table B.15 Summary of dermal body burden values for TDCP for exposure scenarios

Scenario	Dermal body burden worst-case (mg/kg)	Dermal body burden typical case (mg/kg)
1	4.5×10^{-2}	2.3×10^{-2}
2 (a)	6.3×10^{-2}	1.8×10^{-3}
2 (b)	6.8×10^{-2}	1.4×10^{-3}

The exposure scenarios referred to by numbers in the above table are:

1. Manufacture of TDCP
2. Manufacture of flexible PUR foam
 - (a) slabstock foams
 - (b) moulded foams

B.10.1.1.1 Acute toxicity

In the RAR for TDCP, **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.2 Irritation and corrosivity

In the RAR for TDCP, **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.3 Sensitisation

B.10.1.1.3.1 Skin

In the RAR for TDCP, **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.3.2 Respiratory tract

In RAR for TDCP **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.4 Repeated dose toxicity

In relation to repeated dose toxicity, a LOAEL of 5 mg/kg/day was derived from a 2-year study in which rats were dosed with TDCP at concentrations of up to 80 mg/kg/day. This LOAEL was based on hyperplasia of the convoluted tubule epithelium observed in all male animals at 24 months in the kidney and the testicular effects observed at this dose. Assuming 100% absorption by the oral route, this leads to an internal body burden of 5 mg/kg/day.

The minimal margin of safety (MOS) for repeated dose toxicity is 150. This is established by taking into account an interspecies factor of 10 (4 for metabolic size differences * 2.5 for sensitivity differences), an intraspecies factor of 5, and a factor of 3 to take account of the use of a LOAEL rather than a NOAEL.

For TDCP production (scenario 1) with respect to dermal exposure, the body burden for reasonable worst-case exposure was found to be 4.5×10^{-2} mg/kg. This gave a MOS of 111. For dermal exposure, the typical body burden was found to be 2.3×10^{-2} mg/kg, leading to a MOS of 217.

When the MOSs were compared to the minimal MOS of 150, there was concern for this scenario for the reasonable worst case dermal exposure. Therefore, **conclusion (iii)** was drawn in the RAR. There was no concern for the typical dermal exposure.

For scenario 2a, the manufacture of flexible slabstock foam, with respect to the reasonable worst case dermal exposure, the body burden for reasonable worst-case exposure was found to be 6.3×10^{-2} mg/kg, leading to a MOS of 79. For this scenario, the typical dermal body burden was estimated to be 1.8×10^{-3} mg/kg, leading to a MOS of 2,778.

When the MOSs are compared to the minimal MOS of 150, there was some concern for this scenario in the case of dermal reasonable worst-case exposure. Therefore, **conclusion (iii)** was drawn. There was no concern for typical dermal exposure.

For scenario 2b, manufacture of moulded PUR foam, with respect dermal exposure, the body burden for reasonable worst-case exposure was found to be 6.8×10^{-2} mg/kg. This gave a MOS of 74. For this scenario the typical dermal body burden was estimated to be 1.4×10^{-3} mg/kg, leading to a MOS of 3,571.

When the MOSs are compared to the minimal MOS of 150, there was some concern for this scenario in the case of dermal reasonable worst-case exposure. Therefore, **conclusion (iii)** was drawn. There was no concern for typical dermal exposure.

In the RAR for TDCP, **conclusion (ii)** was drawn for this end-point for the remaining exposure scenarios 3, 4 and 5.

Tables B.16 below summarise the MOSs and conclusions for repeated dose toxicity for reasonable worst case and typical exposure during worker scenarios 1, 2a and 2b, respectively.

Table B.16 MOS values and conclusions for repeated dose toxicity of TDCP – Reasonable worst case and typical dermal exposure

Scenario	RWC Dermal			Typical Dermal		
	Body burden (mg/kg)	MOS	Concl	Body burden (mg/kg)	MOS	Concl
1.Manufacture of TDCP	4.5×10^{-2}	111	(iii)	2.3×10^{-2}	217	(ii)
2a.Manufacture of flexible PUR foam: Slabstock	6.3×10^{-2}	79	(iii)	1.8×10^{-3}	2,778	(ii)
2b.Manufacture of flexible PUR foam: Moulded	6.8×10^{-2}	74	(iii)	1.4×10^{-3}	3,571	(ii)

B.10.1.1.5 Mutagenicity

In RAR for TDCP **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.6 Carcinogenicity

In a 2-year carcinogenicity study, there was a significant increase in the incidence of renal cortical tumours and testicular interstitial cell tumours in animals dosed with 20 and 80 mg/kg/day. A

LOAEL of 5 mg/kg/day is taken from this study, based on the hyperplasia of the convoluted tubule epithelium observed in the kidneys of all male animals at 24 months. Hyperplasia is often considered as a pre-neoplastic lesion, which can lead to tumour formation. Based on the available data, it is not unreasonable to assume that the tumours observed in the 2-year carcinogenicity study developed through hyperplastic changes. Assuming 100% oral absorption, this gives an internal body burden of 5 mg/kg/day.

The minimal MOS for carcinogenicity is 150. This is established by taking into account an interspecies factor of 10 (4 for metabolic size differences * 2.5 for sensitivity differences), an intraspecies factor of 5, and a factor of 3 to take account of the use of a LOAEL rather than a NOAEL.

As the internal body burden here is the same as that for the repeated dose toxicity section above, the calculated MOSs will also be the same. Therefore, it is not proposed to repeat the calculations scenario-by-scenario here.

The MOS values calculated in **Section B.10.1.1.4** (Repeated dose toxicity) are presented in **Table B.17**, below. The conclusions for carcinogenicity when the MOSs are compared with the minimal MOS of 150 are also presented.

For scenarios 1 (manufacture of TDCP), 2a (manufacture of flexible slabstock PUR foam) and 2b (manufacture of flexible moulded PUR foam), when the MOSs are compared with the minimal MOS of 150, there is concern for the reasonable worst case dermal exposure. Therefore, **conclusion (iii)** is drawn for the reasonable worst case dermal exposure for all three scenarios. For all three scenarios, there is no concern for typical dermal exposure.

For scenarios 3 (cutting of flexible PUR foam), 4 (production of foam granules and rebonded foam) and 5 (manufacture of automotive parts), **conclusion (ii)** is drawn for the reasonable worst case and typical dermal exposures.

In RAR for TDCP, **conclusion (ii)** was drawn for this end-point for the remaining exposure scenarios 3, 4 and 5.

Tables B.17 below summarise the MOSs and conclusions for carcinogenicity for reasonable worst case and typical dermal exposures during worker scenarios 1, 2a and 2b, respectively.

Table B.17 MOS values and conclusions for carcinogenicity of TDCP – Reasonable worst case and typical dermal exposure

Scenario	RWC Dermal			Typical Dermal		
	Body burden (mg/kg)	MOS	Concl	Body burden (mg/kg)	MOS	Concl
1.Manufacture of TDCP	4.5 x 10 ⁻²	111	(iii)	2.3 x 10 ⁻²	217	(ii)
2a.Manufacture of flexible PUR foam: Slabstock	6.3 x 10 ⁻²	79	(iii)	1.8 x 10 ⁻³	2,778	(ii)
2b.Manufacture of flexible PUR foam: Moulded	6.8 x 10 ⁻²	74	(iii)	1.4 x 10 ⁻³	3,571	(ii)

B.10.1.1.7 Toxicity for reproduction

B.10.1.1.7.1 Effects on fertility

In the RAR for TDCP, **conclusion (ii)** is drawn for effects on male fertility for all exposure scenarios.

With respect to effects on female fertility, there was no data available. Therefore, it was considered in the RAR for TDCP that a data gap existed for female fertility. As discussed in **Section 4.1.3.1** of the RAR, it was considered that the endpoint for female fertility is likely to be already covered by the low LOAEL of 5 mg/kg derived from the chronic toxicity study with TDCP and any risk for female fertility will be addressed within the risk characterisation for repeated dose toxicity and carcinogenicity. Therefore, a **conclusion (i) “on hold”** is drawn for effects on female fertility for all exposure scenarios.

B.10.1.1.7.2 Developmental toxicity

In the RAR for TDCP, **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.8 Summary of risk characterisation for workers

With respect to worker scenarios 1 (manufacture of TDCP), 2a (manufacture of flexible PUR foam – slabstock) and 2b (manufacture of flexible PUR foam – moulded), the MOS for reasonable worst case dermal exposures for repeated dose toxicity and carcinogenicity are below the minimal MOS and therefore **conclusion (iii)** is drawn. There is no concern for the typical dermal exposure for these exposure scenarios. A **conclusion (ii)** is drawn for the remaining scenarios (worker scenarios 3, 4 and 5) for these endpoints.

A **conclusion (i) “on hold”** is drawn for effects on female fertility for all exposure scenarios.

A **conclusion (ii)** is drawn for all other endpoints for all worker exposure scenarios.

B.10.1.2 Consumers

Conclusion (ii) is drawn for consumers for all exposure scenarios for all endpoints except effects on female fertility, for which a **conclusion (i) “on hold”** is drawn.

B.10.1.3 Indirect exposure of humans via the environment

Conclusion (ii) is drawn for exposure of humans via the environment for all exposure scenarios for all endpoints except effects on female fertility, for which a **conclusion (i) “on hold”** is drawn.

B.10.2 Combined exposures

Section 4.1.3.5 of the RAR for TDCP contains a discussion on the risk characterisation of the combined exposure to TDCP. That is the sum of all the specific sources (occupational exposure, consumer exposure and indirect exposure via the environment). Therefore, a worst case estimate for this combined exposure would be the sum of the RWC estimates, for inhalation and dermal exposures, for the three populations; i.e. workers, consumers and man exposed via the environment.

Occupational exposures were not included in the combined exposure calculation in the RAR for TDCP. The body burdens for the reasonable worst case and typical occupational exposures were found to be significantly higher than those for consumers or for indirect exposure via the environment. Therefore, the occupational exposure value would have dominated the combined exposure estimate, resulting in conclusion (iii)'s being drawn, as per those for the worker risk characterisation. It was therefore considered more appropriate to exclude occupational exposure from the combined exposure risk characterisation of the RAR.

Conclusion (ii) is drawn for combined exposure for all exposure scenarios for all endpoints except effects on female fertility, for which a **conclusion (i) “on hold”** is drawn.

B.10.3 Environment

Not relevant for this proposal.

PART C: INFORMATION ON ALTERNATIVES

As the control measures recommended in this transitional Annex XV dossier do not include recommendations for restriction of TDCP, analysis of alternatives was not performed.

- C.1 INFORMATION ON THE RISKS TO HUMAN HEALTH AND THE ENVIRONMENT RELATED TO THE MANUFACTURE OF USE OF THE ALTERNATIVES**
- C.2 AVAILABILITY OF ALTERNATIVE, INCLUDING THE TIME SCALE**
- C.3 HUMAN HEALTH RISKS RELATED TO ALTERNATIVES**
- C.4 ENVIRONMENTAL RISKS RELATED TO ALTERNATIVES**
- C.5 TECHNICAL AND ECONOMICAL FEASIBILITY**
- C.6 OTHER INFORMATION ON ALTERNATIVES**

PART D: JUSTIFICATION FOR ACTION ON A COMMUNITY-WIDE BASIS

As this transitional Annex XV dossier does not include a recommendation for a Community-wide restriction of TDCP, Part D has not been completed.

D.1 CONSIDERATIONS RELATED TO HUMAN HEALTH AND ENVIRONMENTAL RISKS

D.2 CONSIDERATIONS RELATED TO INTERNAL MARKET

D.3 OTHER CONSIDERATIONS

D.4 SUMMARY

PART E: JUSTIFICATION WHY RECOMMENDING A SAFE SYSTEM OF WORK AS THE MOST APPROPRIATE RISK REDUCTION MEASURE

E.1 IDENTIFICATION AND DESCRIPTION OF RISK MANAGEMENT OPTIONS

E.1.1 Risk to be addressed – the baseline

The RAR for TDCP concluded that there is a need for limiting the risk associated with reasonable worst case dermal exposure of workers during the manufacture of TDCP (scenario 1), manufacture of flexible PUR foam – slabstock (scenario 2a), and manufacture of flexible PUR foam – moulded (scenario 2b) in relation to repeated dose toxicity and carcinogenicity. As a result of this RAR conclusion, a strategy for limiting these risks is required. It should be noted that in the case of the typical dermal exposure of workers during all scenarios, there was no need for risk reduction measures beyond those that are being applied already.

In order to adequately address the risks identified in the worker scenarios 1, 2a and 2b, the first step would be to establish the extent to which risk management measures were in place at the time when exposure measurements were taken.

E.1.1.1 Manufacture of TDCP (scenario 1)

In the case of scenario 1 (manufacture of TDCP), operators involved in drumming, laboratory testing and production (cleaning of a funda filter and sampling) at production plant 1 were monitored for dermal exposure to TDCP. The RAR reported that the operator who was being monitored during the drumming operation (which lasted 2.5 hours) and the laboratory operative who was being monitored during the testing (three 20 minute sessions) were both not wearing PPE when carrying out their tasks.

A representative from production plant 1 informed the rapporteur that at the time monitoring measurements were taken in 2002, operators were not wearing gloves due to the fact that contaminated gloves led to contaminated controls. Operators relied on washing their hands often. Now operators change their gloves when they become contaminated. This has reduced the contamination of the surfaces of the equipment and other surfaces which operators may touch. The industry representative indicated that this has improved the working conditions of the operators, which has motivated them to keep the equipment free from contamination. Employee discipline is necessary to maintain high standards in personal hygiene. Routine inspections in the plant verify their consistent use of gloves (per. comm. 10th September 2008, Albemarle).

The operator who was being monitored during production was wearing gloves (according to the hygiene report) but these gloves were said to have been contaminated (pers. comm. 10th September 2008, Albemarle).

From this information recorded in the RAR for TDCP, it appears that adequate hygiene procedures were not being implemented at the TDCP production plants where exposure monitoring was carried out. The manufacturers of TDCP have informed the rapporteur that, as a consequence of monitoring measurements taken for the RAR for TDCP improved hygiene procedures are now being implemented (pers. comm. 31st July 2008, PEFRC). In all operations, where skin contact is possible

suitable gloves must be used. During filter plate changing operations chemically impervious suits are used.

The revised hygiene procedures applied include the following procedures:

- Contaminated gloves must be discarded and replaced at the end of a working day or shift. Contaminated gloves must not be taken into control rooms, mess rooms or changing rooms such that they could contaminate work surfaces, other clothing or PPE. Grossly contaminated gloves should not be used for an extended period of time. Also gloves should be replaced if they have tears, punctures or splits.
- Office based personnel and visitors to site should wear a minimum of disposable gloves when they visit and intend to go inside the production plants and associated areas.
- Gloves and other PPE are to be disposed and stored at a dedicated place.

(Pers. comm. 31st July 2008, PEFRC)

Subsequent to the monitoring documented in the RAR, follow up hygiene surveys were performed in 2005 and 2006. These surveys confirmed that the hygiene procedures had improved (pers. comm. 19th September 2008, Albemarle). Dermal exposure measurements were repeated in 2005 by Albemarle with the analogous substance V6 and resulted in low exposures. PEFRC believe these results illustrate that the implemented hygiene procedures are sufficiently protective (pers. comm. 31st July 2008, PEFRC).

Subsequent to the monitoring documented in the RAR, in an attempt by one TDCP manufacturer to identify appropriate personal protective equipment, glove permeation studies were performed with two types of gloves (Ansell-Edmont Neoprene No. 29-500 and Vygen Plus PVC). The test method was ASTM F1383-99A. The break-through time was > 110 minutes for 4 consecutive days (pers. comm. 31st July 2008, PEFRC).

E.1.1.2 Use of TDCP in the manufacture of flexible PUR foam (scenarios 2a and 2b)

In the case of scenario 2a (manufacture of flexible PUR foam – slabstock) the highest dermal exposure value was obtained by an operator in the mixing head area of Plant A. The RAR indicates that according to an industry report, the operator did not have much contact with foam, but may have had contact with the chemicals although it is not clear when or how this had occurred.

An industry representative of PUR foam manufacturers informed the rapporteur that at the mixing head of a PUR foam process there is no contact with foam, this only occurs further down the production line. At the mixing head there is very little contact with chemicals during production. This industry representative indicated that exposure to chemicals may happen when the mixing head is being assembled or disassembled if that is deemed to be necessary for any reason. The industry representative indicated that it could be possible that the operator who was monitored at the mixing head may have also had duties in other areas of the plant (pers. comm. 9th September 2008, EUROPUR).

In the case of scenario 2b (manufacture of flexible PUR foam – moulded) there was no exposure data available. However, it was thought that the dispensing of the liquid foam into moulds would be similar to the dispensing of the foam mixture from the mixing head during PUR foam block manufacture. Although not directly comparable, it is also felt that the results for work at the cutting of foam blocks (see scenario 3) would give an indication of the likely range of exposures during

cutting and trimming of moulded parts. Therefore exposure data from Scenarios 2a and 3 (cutting of flexible PUR foam) were used. The highest exposure value was that obtained by the operator in the mixing head area of Plant A under scenario 2a. An industry representative informed the rapporteur that in a moulding operation there is automatic blending from a (typically) 20 tonne tank until the pouring head, which is a protected area, to which workers have no access (pers. comm.. 10th September 2008, Euro-Moulders).

E.1.2 Possible further risk reduction measures

E.1.2.1 Introduction

This section explores possible mechanisms to reduce the risks posed to workers as a result of dermal exposure to TDCP during the:

- 1) Manufacture of TDCP
- 2) Manufacture of flexible PUR foam
 - (a) slabstock foams
 - (b) moulded foams

The Technical Guidance Document (TGD) on Development of Risk Reduction Strategies (EC, 1998) outlines several possible risk reduction measures. Those related to packaging, distribution and storage are not relevant for the uses of concern in this case, nor are those for waste. **Table E.1** sets out the potential risk reduction measures relevant for manufacturing and professional use of TDCP.

Table E.1 Possible Risk Reduction Measures for Manufacture and Professional Use

- | |
|---|
| <ul style="list-style-type: none"> ▪ Control on manufacture ▪ Restrictions on the marketing and use of TDCP in flexible polyurethane foam ▪ Re-design the process itself, or change the substance or material used in it ▪ Safe system of works, such as specified standards of physical containment or extraction ventilation ▪ Application of good manufacturing practise, for example under ISO standards ▪ Classification and labelling ▪ Separation of personnel ▪ Monitoring and maintenance of equipment ▪ Dust suppression methods, such as the use of the substance in tablet or pellet form ▪ Occupational exposure limit and/or air monitoring in the workplace ▪ Accurate hazard information (e.g. safety data sheets) and/or better delivery of safety information or the provision of warning signs in the workplace ▪ Biological exposure indices and/or biological monitoring of workers ▪ Medical survey of workers ▪ Training ▪ Use of personal protection equipment ▪ Licensing of operator of certain operations ▪ End of pipe control to minimise, neutralise or render less harmful any emissions that cannot practicably be avoided otherwise ▪ Limit values for emission and effluent monitoring ▪ Environmental quality standards and/or environmental monitoring |
|---|

E.1.2.2 Possible further risk reduction measures for the manufacture of TDCP (scenario 1)

Several of the possible risk reduction measures listed in **Table E.1** can immediately be disregarded in the case of the identified risk associated with the manufacture of TDCP. The following measures can be disregarded as they are concerned with environmental exposure:

- End of pipe control to minimise, neutralise or render less harmful any emissions that cannot practicably be avoided otherwise
- Limit values for emission and effluent monitoring

- Environmental quality standards and/or environmental monitoring

Controls on the manufacture of TDCP are not viable as there are other uses of the substance for which there is no concern (e.g. scenarios 3, 4 and 5). This is thought to be the case as appropriate risk reduction measures are in place in scenarios 3, 4 and 5.

A Community-wide restriction on the marketing and use of TDCP would be disproportionate to the risk. The risk associated with the manufacture of TDCP has been identified in the case of reasonable worst case dermal exposure to workers in industrial settings only. It should be noted that in the case of the typical dermal exposure of workers during the manufacture of TDCP (scenario 1) there was no need for risk reduction measures beyond those that are being applied already.

It is therefore recommended that the risk to workers during the manufacture of TDCP can be reduced to an adequate level using technical and/or organisational means. As mentioned above, there are other uses of TDCP for which there is no concern (e.g. scenarios 3, 4 and 5) as appropriate risk reduction measures are in place.

Dust suppression methods (e.g. the use of the substance in tablet or pellet form) are not practical for the manufacture of TDCP (scenario 1). As regards using classification and labelling measures to reduce the risk, relevant industries are self-classifying TDCP as Xn; N; R40-51/53. An Annex XV dossier to propose harmonised human health classification and labelling for TDCP (Xn; R40) will also be submitted to the ECHA and will be discussed by the RAC and SEAC in due course.

With respect to establishing an occupational exposure limits and/or air monitoring in the workplace, this measure would not be relevant in addressing the identified risk i.e. worker dermal exposure. The biological monitoring of workers would also not be necessary in this instance.

Taking the above into consideration and in light of the fact that the RAR has identified a risk for reasonable worst case dermal exposure of workers, the following risk reduction measures are considered to be appropriate for the manufacture of TDCP:

- Re-design the process itself, or change the substance or material used in it
- Safe system of works, such as specified standards of physical containment or extraction ventilation
- Application of good manufacturing practice, for example under ISO standards
- Separation of personnel
- Monitoring and maintenance of equipment
- Accurate hazard information (e.g. safety data sheets) and/or better delivery of safety information or the provision of warning signs in the workplace
- Training
- Use of personal protection equipment
- Licensing of operator of certain operations

It is recommended that the culmination of some or all of the above controls on the workplace should be sufficient to reduce the risk to an acceptable level. As a minimum, controls such as safe systems of work, the monitoring and maintenance of equipment, accurate hazard information (e.g. safety data sheets), training and the use of personal protection equipment are recommended by the rapporteur to ensure an overall safe system of work.

Medical surveillance of workers may be appropriate, by providing more information about effects of the exposure but would not reduce the risk. The findings of such surveillance may provide assurance that the protective and preventative measures, adopted to control exposure are effective.

As mentioned in **Section E.1.1.1** it is documented in the RAR for TDCP that PPE was not used at the time of the dermal exposure monitoring, which was carried out during the scenarios where risk was identified. According to the Chemical Agents Directive (98/24/EC) where the nature of the activity does not permit risk to be eliminated by substitution, the employer must ensure that the risk is reduced to a minimum by application of protection and prevention measures. Directive 89/656/EEC requires that PPE shall be used when the risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organisation.

Where a risk assessment requires that PPE be used, consideration should be given to the appropriateness of the particular type of PPE during the selection process. Gloves with cotton backs should be avoided as chemical substances can be absorbed by the cotton and lead to continuous contact with the skin. Impervious suits and face masks should be worn where it is deemed necessary to protect against dermal exposure to TDCP.

Hazard information on TDCP should be contained in an up-to-date safety data sheet and should be made available to the operators who have the potential to be exposed to TDCP in the workplace, as required by the REACH Regulation. This obligation to provide information is considered sufficient in principle to provide the recipient with sufficient information for the selection of suitable occupational safety measures.

As there are other uses of TDCP for which there is no concern (e.g. scenarios 3, 4 and 5), it is felt that it should be possible for industries involved in the manufacture of TDCP to ensure that appropriate risk reduction measures are in place in order to ensure a safe system of work for workers.

E.1.2.3 Possible further risk reduction measures for the manufacture of flexible PUR foam (scenarios 2a and 2b)

It is recommended that the further risk reduction measures outlined in **Section E.1.2.2** should also be put in place to reduce the risk of dermal exposure of workers to TDCP during the manufacture of flexible PUR foam, both slabstock (scenario 2a) and moulded (2b).

E.2 COMPARISON OF INSTRUMENTS: RESTRICTION(S) VS. OTHER COMMUNITY-WIDE MANAGEMENT OPTIONS

The measures identified in **Section E.1.2.2**, recommended as possible measures for the management of risks from TDCP will now be assessed against the four criteria of effectiveness, practicality and monitorability. This will be compared to an assessment of a possible Community-wide restriction, carried out first under the same four criteria.

E.2.1 Restriction

A Community-wide restriction could be imposed for TDCP under Title VIII of the REACH Regulation.

E.2.1.1 Effectiveness

Placing a restriction on TDCP would have a high degree of effectiveness.

E.2.1.1.1 Risk reduction capacity

If a restriction were to be imposed and effectively implemented, it is assumed that all associated occupational risks would be eliminated.

E.2.1.1.2 Proportionality

Although a restriction on TDCP would have a high degree of effectiveness, such a measure would be disproportionate to the risk, which was identified in the RAR for TDCP in the case of reasonable worst case dermal exposure of workers. The RAR concluded that there is no concern for humans via the environment or for consumers. There was also no concern for workers exposed to TDCP via the inhalation route. It is felt that the risk to workers can be reduced using an approach that is more proportionate than a Community-wide restriction. This could be through technical and/or organisational means, as required by the existing framework of occupational health and safety legislation (see **Section B.9.1.1**). The effort needed for the appropriate industries to implement a restriction on the manufacture, marketing and/or use of TDCP would be disproportionate to the adverse effects identified in the RAR, that is for reasonable worst case dermal exposure of workers only.

E.2.1.2 Practicality

In the spirit of ‘Better Regulation’ a restriction should only be recommended where the risk associated with the use of the substance, cannot be reduced using other measures. In the case of the risk identified for reasonable worst case dermal exposure of workers to TDCP, it is felt that the risk can be reduced to an adequate level using technical and/or organisational measures, as required by the existing framework of occupational health and safety legislation.

E.2.1.2.1 Implementability

In order for a restriction to be implemented at Community level, an Annex XV dossier would have to be developed by the rapporteur, which would then have to be agreed by the RAC and SEAC. The timing of such agreement can only be estimated, but would potentially take a number of years before a restriction would be implemented at Community level.

E.2.1.2.2 Enforceability

A restriction could be enforced in the individual Member States, as part of national legislation for REACH enforcement.

E.2.1.2.3 Manageability

Once ECHA or a Member State has submitted an Annex XV dossier for restriction of TDCP, the RAC and SEAC would have overall responsibility to review and provide an opinion on whether or not a restriction is the most appropriate measure to limit the risk. The European Commission will make the final decision on any proposal to restrict TDCP, through the systems laid down in the REACH Regulation. It is felt that the level of ECHA or Member State resources that would be

required to develop and implement a Community-wide restriction would not be proportionate to the risk identified in the RAR. It is also felt that a restriction on the manufacture, marketing and/or use of TDCP would not be manageable for the relevant industries as it would put an end to production involving TDCP.

E.2.1.3 Monitorability

Means by which the European Commission can monitor restrictions using indicators such as concentration of substance in preparations or articles for example are already in place under the current legislative instrument (Marketing and Use Directive 76/769/EEC). Directive will be repealed by Title VIII and Annex XVII of the REACH Regulation on 1st June 2009. After this date, it is expected that the European Commission will continue to identify indicators in order to monitor restrictions listed in Annex XVII of the REACH Regulation.

E.2.1.4 Overall assessment against the three criteria

Although a restriction would be an effective risk reduction measure, it would be disproportionate to the risk identified in the RAR. From the information received from the industry consortium (given in **Section E.1** of this report), it is considered that there are technical and/or organisational measures (e.g. hygiene procedures) available to reduce the risk identified to an adequate level. From the rapporteur's assessment, a restriction on TDCP would not be practical in this case.

E.2.2 Safe system of work, in accordance with occupational health and safety legislation

The following risk reduction options for the manufacture of TDCP (scenario 1), the use of TDCP in the manufacturing of flexible PUR foam – slabstock (scenario 2a) and the manufacturing of flexible PUR foam – moulded (scenario 2b) are all related to changes in the workplace and safe system of work:

- Re-design the process itself, or change the substance or material used in it
- Safe system of works, such as specified standards of physical containment or extraction ventilation
- Application of good manufacturing practice, for example under ISO standards
- Separation of personnel
- Monitoring and maintenance of equipment
- Accurate hazard information (for example safety data sheets) and/or better delivery of safety information or the provision of warning signs in the workplace
- Training
- Medical surveys
- Use of personal protection equipment
- Licensing of operator of certain operations

As mentioned above, it is recommended that the culmination of some or all of the above controls on the workplace should be sufficient to reduce the risk to an acceptable level. As a minimum controls such as safe system of work, monitoring and maintenance of equipment, accurate hazard information (e.g. safety data sheets), training and the use of personal protection equipment are recommended by the rapporteur to ensure an overall safe system of work.

E.2.2.1 Effectiveness

Overall, it is felt that the measures listed in **Section E.2.2** above will be effective in reducing the risk of dermal exposure to worker to an adequate level. Preventative measures relating to the design and organisation of systems at the workplace, the provision of suitably (maintained) equipment, keeping worker exposure to a minimum, the provision of information and/or training and the use of appropriate hygiene measures are all required under the Chemical Agents Directive 98/24/EC (see **Section B.9.1.1.3.2**). From the information recorded in the RAR for TDCP, it appears that adequate hygiene measures were not being implemented at the relevant industries where exposure monitoring was carried out.

The use of PPE should also be used when the risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures; methods or procedures of work organisation as required by Directive 89/656/EEC (see **Section B.9.1.1.3.3**). From the information recorded in the RAR for TDCP, it appears that adequate PPE was not being used at the relevant industries where exposure monitoring was carried out.

Hazard information relating to TDCP should also be supplied to the recipient (e.g. worker or downstream user) of TDCP, in accordance with the REACH Regulation (see **Section B.9.1.1.2**).

Therefore the rapporteur believes the existing framework of occupational health and safety legislation should be used as a basis to ensure reduction of the exposure to a level that allows adequate control of the identified risk.

E.2.2.1.1 Risk reduction capacity

Establishing a safe system of work during the manufacture and use of TDCP would result in an adequate degree of effectiveness.

E.2.2.1.2 Proportionality

Establishing a safe system of work is considered a proportionate measure to address the risk faced from RWC dermal exposure of workers to TDCP. The RAR concluded that there is no concern for humans via the environment or to consumers. There was also no concern for workers exposed to TDCP via the inhalation route. It is felt that a 'safe system of work' approach is a proportionate mechanism to address the identified risk to workers. This can be achieved through technical and/or organisational means, using the existing framework of occupational health and safety legislation.

E.2.2.2 Practicality

The above measures to ensure a safe system of work are thought to be relatively easy to implement, except perhaps the re-design of the process itself. If this is not technically feasible, alternative technical and/or organisational measures must be implemented for example, physical containment, regular maintenance of equipment, use of appropriate PPE, etc. Separation of personnel may be practical in ensuring that a limited number of staff is exposed to TDCP. Adequate hygiene procedures should be implemented and strictly adhered to, in the case of employees that have a greater potential of being exposed to TDCP. Manufacturers of TDCP have already revised the hygiene procedures in place, as a consequence of the findings of the RAR for TDCP.

E.2.2.2.1 Implementability

These measures could be implemented very quickly (if they have not been implemented already) at plants engaging in the manufacture of TDCP (scenario 1) and in the use of TDCP in the manufacture of flexible PUR foam (slabstock and moulded).

E.2.2.2.2 Enforceability

Establishment of a safe system of work could be enforced in the individual Member States, as part of national legislation for the enforcement of occupational health and safety legislation e.g. the Framework Directive 89/391/EEC, Chemical Agents Directive 98/24/EC, PPE Directive 89/656/EEC and the REACH Regulation.

E.2.2.2.3 Manageability

Establishment of a safe system of work can be managed within the already existing health and safety management system at the industrial sites involved in the manufacture of TDCP and in the use of TDCP in the manufacture of flexible PUR foam (slabstock and moulded). The authorities can use existing health and safety legislation to ensure that a safe system of work is in place, as part of their enforcement programs.

E.2.2.3 Monitorability

Monitoring the implementation and effectiveness of the above recommended safe system of work can be carried out using existing monitoring arrangements, which already exist as part of the health and safety management system at the relevant industrial sites. Such industries can implement monitoring systems to ensure that established hygiene procedures are being adhered to. Such systems could range from local inspections, carried out by supervisor's onsite to ensure that hygiene procedures are being adhered to, to exposure monitoring, depending on the scale /resources of the particular site in question. Such monitoring systems should be sufficient to observe whether the risk reduction targets, set by the industry in question have been achieved.

E.2.2.4 Overall assessment against the three criteria

Establishment of a safe system of work through the implementation of a number of measures related to changes in the workplace is considered to be adequate to address the risk identified by the RAR in the case of reasonable worst case dermal exposure of workers to TDCP. It is thought that these measures are proportionate and will be sufficiently effective and practical for addressing the risk. It is also felt that these measures are relatively easy to implement, manage and monitor by the relevant industries and can be enforced by Member State Authorities using the existing framework of occupational health and safety legislation.

E.2.3 Risk Reduction recommendation

Based on the information given in **Section E.1** and **Section E.2** the rapporteur is of the opinion that the legislation for workers' protection currently in force at Community level is considered to give an adequate framework to limit the risks faced by workers from exposure to TDCP. A restriction would be disproportionate based on the results from the exposure assessments contained in the RAR.

E.3 COMPARISON OF RESTRICTION OPTIONS

Not relevant for this proposal.

E.3.1 Effectiveness

E.3.1.1 Risk reduction capacity

E.3.1.1.1 Effect on human health

E.3.1.1.2 Effect on the environment

E.3.1.1.3 Other effects

E.3.1.2 Proportionality

E.3.1.2.1 Economic feasibility

E.3.1.2.2 Technical feasibility

E.3.1.2.3 Other issues relating to proportionality

E.3.2 Practicality

E.3.2.1 Implementability

E.3.2.2 Enforceability

E.3.3 Monitorability

E.3.4 Overall assessment against the three criteria

E.4 Main assumptions used and decision made during analysis

E.5 The proposed restriction(s) and summary of the justifications

PART F: SOCIO ECONOMIC ASSESSMENT OF PROPOSED RESTRICTION(S)

As the control measures recommended in this transitional Annex XV dossier do not include recommendations for restrictions on the marketing and use of the substance in question, analysis of alternatives was not performed.

F.1 HUMAN HEALTH AND ENVIRONMENTAL IMPACTS

F.1.1 Human Health impacts

F.1.2 Environmental impacts

F.2 ECONOMIC IMPACTS

F.3 SOCIAL IMPACTS

F.4 WIDER ECONOMIC IMPACTS

F.5 DISTRIBUTIONAL IMPACTS

F.6 MAIN ASSUMPTIONS USED AND DECISIONS MADE DURING ANALYSIS

F.7 UNCERTAINTIES

F.8 SUMMARY OF THE BENEFITS AND COSTS

PART G: STAKEHOLDER CONSULTATION

G.1 LIST OF CONSULTEES

1. Albemarle Corporation
2. ICL-Industrial Products (formerly Supresta)
3. Phosphate Ester Flame Retardant Consortium (PEFRC)
4. European Association of Flexible Polyurethane Foam Blocks Manufacturers (EUROPUR)
5. European Association of Manufacturers of Moulded Automotive Polyurethane Parts (EURO-Moulders)
6. Danish Ministry of the Environment
7. Ministry of Social Affairs of Estonia
8. Permanent Representative for Cyprus
9. Health and Safety Executive, UK

PART H: SUPPORTING INFORMATION

H.1 DERMAL EXPOSURE FOR V6 AND TCPP

Dermal sampling data collected during the manufacture of flexible foam using V6 and TCPP are presented in **Table H.1** and **Table H.2**.

Table H.1 Dermal exposure to V6 during the manufacture of flexible PUR foam

Plant Identification	Operator	n	mg V6 /pair of gloves (mg/day)
Plant X	Mixing Head	2	0.06, 1.39
Plant X	Asst. Mixing Head	4	0.20, 0.31, 0.79, 1.47
Plant X	Side Paper Take Off	4	0.08, 0.12, 0.21, 0.48
Plant X	Bottom Paper	4	0.28, 0.39, 1.18, 7.99,
Plant X	Block Cutter	2	0.14, 0.28
Plant Y	Raw Mat'l/Tank Farm	1	5.2
Plant Y	Mixing Head	3	0.49, 0.54, 0.75
Plant Y	Supervisor	1	0.89
Plant Y	Side Paper Take Off	1	0.39
Plant Y	Cut Off Block	1	0.34
Plant Y	Cut Off Start/End	1	0.23
Plant Y	Bottom Paper	1	0.24

Table H.2 Dermal exposure to TCPP during manufacture of flexible PUR foam

Operator	Length of time monitored (mins)	Measured TCPP (mg/kg bw)	Mg/day
Production op. 1 (plant 1)	430	1.5	105
Production op. 2 (plant 1)	443	0.45	31.5
Production op. 3 (plant 1)	429	0.68	47.6
Production op. 4 (plant 1)	445	0.09	6.3
Production op. 5 (plant 2)	239	0.32	22.4
Production op. 6 (plant 2)	242	0.39	27.3
Production op. 7 (plant 2)	236	0.01	0.7
Sampling op. (plant 2)	313	0.003	0.21
Laboratory op. (plant 2)	417	0.003	0.21

H.2 DERMAL EXPOSURE TO TDCP (SCENARIO 3)

Dermal sampling data collected during the cutting of flexible PUR foam using TDCP are presented in **Table H.3** and **Table H.4**.

Table 9.24 Personal dermal exposure to TDCP measured at Plants A and B (scenario 3)

Plant identification	Job title or work area	n	mg TDCP /pair of gloves (mg/day)
Plant A	Block preparation	2	0.4, 1.8
Plant A	Machine operator	7	0.06, 0.1, 0.2, 0.3, 0.6, 2.5, 3.0
Plant B	Loop slitter operator	1	0.41

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