RAC WG/CLH/R/9/2023

27 April 2023

Report
of the 9th Meeting of the Committee for Risk Assessment Working Group on Harmonised Classification and Labelling (RAC-65 CLH WG)

ECHA Conference Centre (Telakkakatu 6, Helsinki) via Webex

Monday 24th April 2023 (10.00) to Thursday 27th April (14.30)

Summary Record of the Proceedings

1. Welcome and apologies

The Chair of RAC, Tim Bowmer, welcomed the participants to the 9th meeting of the RAC Working Group on CLH and reminded them that the Committee had agreed on the establishment of the group at RAC-56 in March 2021, with the first full working group meeting taking place in October 2021 ahead of RAC-59.

He informed that the meeting would be jointly chaired by the officers of the CLH team: Ari Karjalainen, Kirsi Myöhänen and Simon Uphill. Written consultations were organised on all dossiers prior to the working group meeting for RAC-65.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/CLH/A/9/2023), which was adopted with no modification and is attached to this Report as Annex I.

3. Declarations of conflicts of interests to the Agenda

The Chair informed that he had no potential conflicts with the agenda to declare and requested all participants to declare any potential conflicts of interest to any of the agenda items. Several participants of the meeting declared a potential conflict of interest on cases scheduled for the discussion as presented in Annex III to this Report; these all related to concurrent employment of the member by a Member State authority submitting a dossier for evaluation by RAC. The other co-Chairs all declared that they had no potential interests related to any of the agenda points for the meeting.

4. Harmonised classification and labelling (CLH)

4.1 Hazard classes to be proposed by the group for agreement (without plenary debate) by A-listing at RAC-65

The Working Group agreed to propose the following hazard classes to RAC-65 for A-listing (without discussing them in the WG) based on the written comments received from members during the consultation:

- 9-Octadecenoic acid (*Z*)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt: *mutagenicity, carcinogenicity, reproductive toxicity*
- 2,3-*epoxypropyl isopropyl ether: reproductive toxicity*
- *Tetrahy*drofurfuryl methacrylate: *STOT RE*
- Bixlozone (ISO): *acute toxicity via all routes, skin irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, hazards to the aquatic environment*
- Trimethyl phosphate: *acute toxicity via oral and dermal routes, mutagenicity, carcinogenicity, lactation*
- 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate: *acute inhalation toxicity, STOT SE, EUH071*
- Folpet (ISO); N-(trichloromethylthio)phthalimide: *acute oral and dermal toxicity, mutagenicity, STOT SE*
- 2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB]: *acute toxicity via all routes, skin corrosion/irritation, eye damage/irritation, respiratory sensitisation, mutagenicity, carcinogenicity, hazards to the aquatic environment*
- 1,1-dichloroethylene; vinylidene chloride: *hazards to the aquatic environment*

4.2 Hazard classes for discussion

4.2.1 Tetrahydrofurfuryl methacrylate (EC: 219-529-5; CAS: 2455-24-5)

The co-Chair welcomed the Dossier Submitter representatives and informed that **tetrahydrofurfuryl methacrylate** is used in formulation into mixtures, repacking (into coatings and inks), as monomer in polymerisation (wet process, dry process), end use in formulations, application of coatings/adhesives formulation, etc. The substance has no current Annex VI entry.

The DS (AT) proposes to classify the substance as Repr. 1B; H360FD and Skin Sens. 1A; H317.

Skin sensitisation, reproductive toxicity and STOT RE were the hazard classes open for comments

The deadline for the adoption of an opinion is 18 November 2023.

STOT RE The WG recommended no classification and A-listing at RAC-65. *Skin sensitisation* The WG recommended to classify the substance as Skin Sens. 1A; H317 and A-listing at RAC-65. *Reproductive toxicity* *Development* The WG recommended to classify the substance as Repr. 1B; H360D based on pre-birth death and total litter loss. *Fertility* The WG recommended to classify the substance as Repr. 2; H361f based on dose-dependent increase in uterus weight and gestational length. The WG recommended to A-list reproductive toxicity at RAC-65.	**Rapporteur** to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR. **SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for plenary discussion: none.**
4.2.2. Bixlozone (ISO); 2-(2,4-dichlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one (EC: -; CAS: 81777-95-9)	
The co-Chair welcomed the Dossier Submitter representative and an expert accompanying the CropLife Regular Stakeholder Observer. He informed that **bixlozone** is used as a herbicide, with representative uses in winter wheat, winter barley, winter oilseed rape and maize. The substance has no current Annex VI entry. The DS (NL) proposes to classify the substance as Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=10). All relevant hazard classes were open for comments. The deadline for the adoption of an opinion is 3 December 2023.	
<u>Physical hazards</u> The WG recommended no classification and A-listing at RAC-65. <u>Human Health</u> *Acute toxicity* The WG recommended no classification for acute toxicity via all routes and A-listing at RAC-65. *Skin corrosion/irritation* The WG recommended no classification and A-listing at RAC-65.	**Rapporteurs** to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR. **SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for plenary discussion: none.**

Skin sensitisation The WG recommended no classification and A-listing at RAC-65. *Mutagenicity* The WG recommended no classification and A-listing at RAC-65. *STOT SE* The WG recommended no classification and A-listing at RAC-65. *STOT RE* The WG recommended no classification and A-listing at RAC-65. *Serious eye damage/eye irritation* The WG recommended no classification and A-listing at RAC-65. *Carcinogenicity* The WG recommended no classification and A-listing at RAC-65. *Reproductive toxicity* The WG recommended no classification for fertility, development and lactation and A-listing at RAC-65. <u>Environment</u> The WG recommended to classify the substance as Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=10). The WG recommended to A-list aquatic toxicity at RAC-65.	
4.2.3. Trimethyl phosphate (EC: 208-144-8; CAS: 512-56-1)	
The co-Chair informed the Committee that **trimethyl phosphate** is used as a gasoline additive to prevent spark plug fouling and engine rumble. It is also used as a flame retardant for paints and polymers and it is a raw material for making insecticides. TMP is also used as methylating agent. The substance has no current Annex VI entry. The DS (AT) proposes to classify TMP as Carc. 1B; H350, Muta. 1B; H340, Repr. 1B; H360FD, Acute Tox. 4; H302 (ATE=1257 mg/kg bw) and STOT RE 2; H373 (nervous system). Acute toxicity via oral and dermal route, mutagenicity, carcinogenicity, reproductive toxicity and STOT RE were the hazard classes open for comments.	

The deadline for the adoption of an opinion is 22 November 2023.	
Acute toxicity The WG recommended to classify the substance as Acute Tox. 4; H302 (ATE=1300 mg/kg bw) and A-listing at RAC-65. The WG recommended no classification for acute dermal toxicity and A-listing at RAC-65. *Mutagenicity* The WG recommended to classify TMP as Muta. 1B; H340 and A-listing at RAC-65. *Carcinogenicity* The WG recommended to classify the substance as Carc. 1B; H350 and A-listing at RAC-65. *STOT RE* The WG recommended to classify the substance as STOT RE 2; H373 (nervous system), as dose dependent neurotoxic effects were observered in rats, rabbits and dogs. It was agreed to A-list this hazard class at RAC-65. The WG recommended no classification for STOT RE (kidney) or based on mortality data. *Reproductive toxicity* *Fertility* The WG recommended to classify TMP as Repr. 1B; H360F and A-listing at RAC-65. *Development* The WG recommended to classify TMP as Repr. 1B; H360D and A-listing at RAC-65. *Lactation* The WG recommended no classification for Lactation and A-listing at RAC-65.	**Rapporteur** to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR. **SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for plenary discussion: none.**
4.2.4. Barium chromate (EC: 233-660-5; CAS: 10294-40-3)	
The co-Chair welcomed the Dossier Submitter representatives. He informed that **barium chromate** is used in pyrotechnics, high-temperature batteries, safety matches, use as a corrosion inhibitor in metal-joining compounds, as a pigment in paints, in ceramics, in fuses, in metal primers, and in ignition control devices. It was also indicated that in Japan the use of barium chromate in explosive fuses has been reported (IARC, 1990). According	

to ECHA's disseminated database (ECHA Dissemination, 2021) the substance is used by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The substance is used at industrial sites in coating products, adhesives and sealants, pH regulators and water treatment products and laboratory chemicals. The substance has no current Annex VI entry. The DS (NL) proposes to classify barium chromate as Carc. 1B; H350. Mutagenicity, carcinogenicity and reproductive toxicity were the hazard classes open for comments. The deadline for the adoption of an opinion is 8 December 2023.	
RAC agreed with the read-across to zinc chromate and zinc tetrahydroxy chromate that have similar water solubility. *Mutagenicity* The WG recommended no classification based on inconclusive data due to a lack of *in vivo* tests, and A-listing at RAC-65. *Carcinogenicity* The WG recommended to classify the substance as Carc. 1B; H350 and A-listing at RAC-65. *Reproductive toxicity* The WG recommended no classification based on a lack of data, and A-listing at RAC-65.	**Rapporteur** to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR. **SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for plenary discussion: none.**
4.2.5. 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate (EC: 223-861-6; CAS: 4098-71-9)	
The co-Chair welcomed the Dossier Submitter representative and informed that **isophorone di-isocyanate** is used as raw material for the industrial manufacture of resins/hardeners for coating materials, adhesives, sealants, elastomers, polyurethanes. The substance has current Annex VI entry as Acute Tox. 3*; H331, STOT SE 3; H335, Skin Irrit. 2; H315, Eye Irrit. 2; H319, Resp. Sens. 1; H334, Skin Sens. 1; H317 and Aquatic Chronic 2; H411. The DS (DE) proposes <u>to modify</u> Acute Tox. 1; H330 (ATE=0.031 mg/L (dusts/mists)), Skin Corr. 1; H314, Eye Dam. 1; H318, Skin Sens. 1A; H317 and <u>to remove</u> STOT SE 3; H335. Acute inhalation toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation and STOT SE were open for comments in the consultation. The deadline for the adoption of an opinion is 24 December 2023.	
Acute toxicity The WG recommended to classify the substance as	**Rapporteur** to revise the opinion in accordance with the discussion

Acute Tox. 1; H330 (ATE=0.03 mg/L (dusts/mists)) and A-listing at RAC-65. *STOT SE* The WG recommended no classification (removal of the current classification as STOT SE 3; H335) and A-listing at RAC-65. The WG recommended to include an additional hazard statement EUH071 and A-listing at RAC-65. *Skin corrosion/irritation* The WG recommended to classify the substance as Skin Corr. 1; H314 based on reliable and representative animal data available for IPDI, when reliable *in vitro* data are not available. It was recommended to A-list this hazard class at RAC-65. *Serious eye damage/eye irritation* The WG recommended to classify the substance as Eye Dam. 1; H318, mainly based on animal data leading to the classification for skin corrosion, and A-listing at RAC-65. *Skin sensitisation* The WG recommended to classify the substance as Skin Sens. 1A; H317 (SCL=0.001%), based on animal data available for IPDI, and A-listing at RAC-65.	in the Working Group and to provide it to SECR. **SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for plenary discussion: none.**
4.2.6. Folpet (ISO); *N*-(trichloromethylthio)phthalimide (EC: 205-088-6; CAS: 133-07-3)	
The co-Chair welcomed the Dossier Submitter representatives and an expert accompanying the CropLife Regular Stakeholder Observer. She informed that **folpet** belongs to the class of phthalimide family and is a broad spectrum fungicide with activity against many diseases. When applied before or at the onset of fungal attack, it prevents disease infection and establishment. The substance has current Annex VI entry as Carc. 2; H351, Acute Tox. 4; H332, Eye Irrit. 2; H319, Skin Sens. 1; H317 and Aquatic Acute 1; H400 (M=10). The DS (AT) proposes <u>to retain</u> Carc. 2; H351 and Aquatic Acute 1; H400 (M=10<u>), to add</u> STOT RE 1; H372, and Aquatic Chronic 1; H410 (M=1), and initially to add Skin Irrit. 2; H315, the DS after the comments revised it to EUH066and <u>to modify</u> Acute Tox. 2; H330, Eye. Dam. 1; H318 and Skin Sens. 1A; H317. Acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE and hazardous to the aquatic environment were the hazard classes open for comments	

during the consultation. The deadline for the adoption of an opinion is 21 December 2023.	
Human Health: *Acute toxicity* The WG recommended no classification for acute toxicity via oral and dermal routes and A-listing at RAC-65. The WG recommended Acute Tox. 2; H330 (ATE=0.30 mg/L (dusts/mists)) and A-listing at RAC-65. The WG did not support the split-entry approach for acute inhalation toxicity proposed by Industry. *Skin corrosion/irritation* The WG recommended no classification, but labelling EUH066 and A-listing at RAC-65. *Serious eye damage/eye irritation* The WG recommended to classify the substance as Eye Dam. 1; H318 and A-listing at RAC-65. *Skin sensitisation* The WG recommended to classify the substance as Skin Sens. 1A; H317 with an SCL of 0.001% and A-listing at RAC-65. *Carcinogenicity* The WG recommended Carc. 2; H351 and A-listing at RAC-65. *Reproductive toxicity* The WG recommended no classification for fertility, development and lactation and A-listing at RAC-65. *Mutagenicity* The WG recommended no classification and A-listing at RAC-65. *STOT SE* The WG recommended no classification and A-listing at RAC-65.	**Rapporteurs** to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR. **SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for plenary discussion: none.**

STOT RE The WG recommended STOT RE 1; H372 with SCL of 5% for Cat. 1 and 0.5% for Cat. 2 and A-listing at RAC-65. <u>Environment</u> The WG recommended Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410 (M=10) and A-listing at RAC-65.	
The expert accompanying the CropLife Regular Stakeholder Observer commented on acute inhalation toxicity, split-entry approach, skin sensitisation, STOT RE and carcinogenicity.	
4.2.7. 2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB] (EC: 252-681-0; CAS: 35691-65-7)	
The co-Chair informed that **2-bromo-2-(bromomethyl)pentanedinitrile (DBDCB)** is used in a wide range of products for consumers and occupation use, e. g. dishwashing liquid, household cleaning products and other detergents, car care products, wax and other polishing preparations for floors, adhesives, paints, and metal working fluids. In addition, it is used in veterinary products (e. g. in dog shampoos) and as a preservative in cosmetic products at a maximum authorised concentration of 0.1 %. The substance has no current Annex VI entry. The DS (CZ) proposes to classify DBDCB as Acute Tox. 4; H302, Acute Tox. 2; H330, Eye Dam. 1; H318, Skin Sens. 1; H317, Aquatic Chronic 2; H411. Physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitization, skin sensitization, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard, aquatic hazards and hazards for the ozone layer were the hazard classes open for comments. The deadline for the adoption of an opinion is 20 October 2023.	
<u>Physical hazards</u> *Explosives* The WG recommended no classification, and A-listing at RAC-65. *Flammable solids* The WG recommended no classification and A-listing at RAC-65. *Self-reactive substances and mixtures* The WG recommended no classification, and A-listing at RAC-65. *Pyrophoric solids* The WG recommended no classification, and A-listing at RAC-65.	**Rapporteurs** to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR. **SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for plenary discussion: none.**

Self-heating substances The WG recommended no classification and A-listing at RAC-65. *Substances or mixtures which in contact with water emit flammable gases* The WG recommended no classification and A-listing at RAC-65. *Oxidising solids* The WG recommended no classification and A-listing at RAC-65. *Organic peroxides* The WG recommended no classification and A-listing at RAC-65. *Corrosive to metals* The WG recommended no classification based on lack of data, and A-listing at RAC-65. *Desensitised explosives* The WG recommended no classification and A-listing at RAC-65. <u>Human Health</u>: *Acute toxicity* The WG recommended to classify the substance as Acute Tox. 4; H302 (ATE=500 mg/kg bw) and A-listing at RAC-65. The WG recommended to classify the substance as Acute Tox. 2; H330 (ATE=0.27 mg/L (dusts or mists)) and A-listing at RAC-65. The WG recommended no classification for acute toxicity via dermal route and A-listing at RAC-65. *Skin corrosion/irritation* The WG recommended no classification and A-listing at RAC-65. *Serious eye damage/eye irritation* The WG recommended to classify the substance as Eye Dam. 1; H318 and A-listing at RAC-65. *Respiratory sensitisation*	

The WG recommended no classification and A-listing at RAC-65. *Skin sensitisation* The WG recommended to classify the substance as Skin Sens. 1A; H317 (SCL=0.001 %) and A-listing at RAC-65. *Mutagenicity* The WG recommended no classification and A-listing at RAC-65. *Carcinogenicity* The WG recommended no classification and A-listing at RAC-65. *Reproductive toxicity* The WG recommended no classification for fertility and developmental toxicity and A-listing at RAC-65. *STOT SE* The WG recommended no classification due to inconclusive data, and A-listing at RAC-65. *STOT RE* The WG recommended to classify the substance as STOT RE 2; H373 (thyroid, central nervous system), and A-listing at RAC-65. <u>Environment</u> *Hazards to the aquatic environment* The WG recommended to classify the substance as Aquatic Chronic 2; H411 and A-listing at RAC-65. *Hazards to the ozone layer* The WG recommended no classification due to a lack of data, and A-listing at RAC-65.	
4.2.8. Fluoroethylene (EC: 200-832-6; CAS: 75-02-5)	
The co-Chair welcomed the Dossier Submitter representative and informed that **fluoroethylene** has mainly been used in the production of polyvinylfluoride (PVF) and other fluoropolymers. The substance has no current Annex VI entry. The DS (FR) proposes to classify the substance as Muta 2; H341 and Carc. 1A; H350. Mutagenicity and carcinogenicity were the hazard classes open for comments in the consultation.	

The deadline for the adoption of an opinion is 31 January 2024.	
Mutagenicity The WG recommended to classify fluoroethylene as Muta. 2; H341 and A-listing at RAC-65. The Rapporteur was asked to include additional text in the revised draft opinion as to why reading-across of data from chloroethylene and bromoethylene for mutagenicity was not proposed as it was for carcinogenicity. *Carcinogenicity* Based on the animal data alone (and without consideration of the read-across from chloroethylene (vinyl chloride) as suggested by the DS) the WG supported classification of fluoroethylene with Carc. 1B. The WG discussed the appropriateness to apply Cat 1A; H350 by means of read-across from chloroethylene to fluoroethylene and agreed to continue the discussion at RAC-65. The Rapporteur will look for further relevant data to substantiate the read across from bromoethylene. The Secretariat informed that internal legal advice is also being sought on this issue. *Note D* The WG recommended to include Note D and A-listing at RAC-65.	**Rapporteur** to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR. **SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for plenary discussion: carcinogenicity.**
4.2.9. Barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]; C.I. Pigment Red 53:1 (EC: 225-935-3; CAS: 5160-02-1)	
The co-Chair welcomed the Dossier Submitter representatives. She informed that **C.I. Pigment Red 53:1** belongs to the group of β-naphthol azo lake pigments with the widespread use, especially in the imparting of colour to printing inks and plastic products, but also for coating and masterbatches. The substance has no current Annex VI entry. The DS (DE) proposes to classify the substance as Carc. 2; H351. Carcinogenicity was the hazard class open for comments during the consultation. The deadline for the adoption of an opinion is 31 January 2024.	
Carcinogenicity The WG recommended to classify the substance as Carc. 2; H351 and A-listing at RAC-65.	**SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for**

	plenary discussion: none.
4.2.10. 1,1-dichloroethylene; vinylidene chloride (EC: 200-864-0; CAS: 75-35-4)	
The Chair welcomed the Dossier Submitter representative and informed that **vinylidene chloride (VDC)** is an industrial chemical, used as an intermediate in organic synthesis reactions and as a monomer in the production of a variety of polyvinylidene chloride copolymers. Theses copolymers of vinylidene chloride have a broad spectrum of applications in the plastic industry and the major application is the production of films for food packaging. They are also used in many types of packing materials, as flame retardant coatings for fiber and carpet backing, in piping, as coating for steel pipes and in adhesive applications. The substance has current Annex VI classification as Flam. Liq. 1; H224, Carc. 2; H351, Acute Tox. 4*; H332 and Note D. The DS (FR) proposes <u>to retain</u> Flam. Liq. 1; H224 and Note D, <u>to modify</u> Carc. 1B; H350 and Acute Tox. 1; H330 (ATE=0.5 mg/L (vapours)) and <u>to add</u> Muta. 2; H341, Acute Tox. 3; H301 (ATE=200 mg/kg bw), STOT RE 1; H372 (liver, kidney, respiratory tract) and Aquatic Chronic 3; H412. Acute oral and inhalation toxicity, serious eye damage/eye irritation, mutagenicity, carcinogenicity, STOT RE and hazardous to the aquatic environment were the hazard classes open for comments in the consultation. The deadline for the adoption of an opinion is 12 October 2023.	
<u>Human Health</u> *Acute toxicity* The WG recommended Acute Tox. 1; H330 (ATE=0.5 mg/L (vapours)) and Acute Tox. 3; H301 (ATE=300 mg/kg bw) and A-listing at RAC-65. The Rapporteurs were asked to include more justification on the Jones study in the RAC opinion. *Serious eye damage/eye irritation* The WG recommended no classification based on inconclusive data and A-listing at RAC-65. *Mutagenicity* The Rapporteurs were asked to summarise in more detail in the revised draft opinion and RAC-65 presentation: 1) the comet assay including the cytotoxicity at each dose level (preferably in tabular format) and 2) to include the results of effects observed in the male reproductive system in mice and rats (the sub-chronic inhalation study, NTP, 2015). The discussion on this hazard class will continue at RAC-65.	**Rapporteurs** to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR. **SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for plenary discussion: mutagenicity.**

Carcinogenicity The WG recommended to classify the substance as Carc. 1B; H350, based on the new NTP (2015) inhalation studies, without stating the route of exposure in the hazard statement, and to A-list at RAC-65. *STOT RE* The WG recommended to classify the substance as STOT RE 1; H372 (respiratory tract, kidney, liver), based on the NTP (2015) studies, and with emphasis to the long-term 13-week studies in rats and mice. The WG recommended to A-list this hazard class at RAC-65. <u>Environment</u> The WG recommended to classify VDC as Aquatic Chronic 3; H412 and A-listing at RAC-65.	

4.2.11. Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbon dioxide (HH) (EC: 289-699-3; CAS: 89997-63-7)/ Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents (EC: 289-699-3; CAS: 89997-63-7)

The co-Chair welcomed the Dossier Submitter representatives and an expert accompanying the CropLife Regular Stakeholder Observer. He informed that *chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical CO_2 or hydrocarbon solvents, is intended to be used as insecticide against a wide range of flying and crawling pests except those that are plant parasitic, in various applications, sites in- and outdoor. Within the current CLH dossier the use against flies and mosquitoes is intended. The substance is a biocidal active substance, but also a PPP active substance under the name pyrethrins. The substance has no current Annex VI entry.

The DS (ES) proposes to classify the substance as Acute Tox. 4; H332 (ATE=700 mg/kg bw), Acute Tox. 4; H332 (ATE=2.5 mg/L (dusts and mists)), Skin Sens. 1B; H317, Aquatic Acute 1; H400 (M=100) and Aquatic Chronic 1; H410 (M=10).

Relevant physical hazards (explosives, flammable liquids, self-reactive substances, pyrophoric liquids, substances which in contact with water emit flammable gases, oxidising liquids, organic peroxides, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard, hazardous to the aquatic environment and hazardous to the ozone layer were the hazard classes open for comments in the Consultation.

The deadline for the adoption of an opinion is 31 August 2023.

RAC has discussed these dossiers at RAC-64 CLH WG and at RAC-64.	
STOT SE At RAC-64, the Committee already agreed to classify the substances as STOT SE 1; H370 (nervous system). The WG recommended no classification for STOT SE 3 narcotic effects and for respiratory tract irritation and A-listing at RAC-65. *STOT RE* The WG took into account the data on the description of the severity of the histopathological laryngeal changes in rats, as well as on the incidence of lung lesions in exposed workers, and recommended STOT RE 2; H373 (respiratory system, inhalation). The WG recommended to A-list this hazard class at RAC-65.	**Rapporteur** to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR. **SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for plenary discussion: none.**
The expert accompanying the CropLife Regular Stakeholder Observer and the CropLife Regular Stakeholder Observer commented on STOT SE and STOT RE.	

5. Article 77(3)(c)

Article 77(3)(c) request on Silanamine: review of the acute toxicity classification of Silanamine as adopted by RAC in its opinion of 5 December 2019.

The Chair welcomed an expert accompanying the CEFIC Regular Stakeholder Observer. He informed the Committee that based on the request from the Commission, RAC received an Executive Director mandate to review the RAC opinion in relation to the acute toxicity classification of **silanamine**, as adopted by RAC in its opinion of 5 December 2019.

In its opinion of 5 December 2019, RAC had concluded to classify the substance for acute toxicity by inhalation Cat. 2, with an ATE of 0.45 mg/L. Following adoption and publication of the RAC opinion, manufacturers of the substance provided an additional study which examines the mechanism for the observed acute toxicity of HMDZ-treated SAS via the inhalation route. RAC was therefore requested to review the available information on acute toxicity by inhalation, and, if appropriate, to amend the opinion of 5 December 2019 in relation to the classification for acute toxicity by the inhalation route and/or the setting of an ATE for the classification of mixtures.

A targeted consultation of the study report was organised on the ECHA website.

The deadline for the adoption of an opinion is 26 June 2023.

The WG took note of the new, OECD 436 nose-only, acute inhalation study and the analysis conducted by the Rapporteurs in the draft opinion. The WG expressed concerns regarding the study design, since the study report provides information on the deposition of the test material in the nasal cavity only for the three animals which died during the exposure period. Industry was asked for further data on the macroscopic/ microscopic findings in the study, especially for the three other animals exposed as well as information on the findings in the lower airways, not only the nose for all exposed animals. The WG also raised questions regarding the dose selection (single lethal dose only tested and no lower dose) in the new study. The WG also asked that the Rapporteurs try to further analyse the differences in findings between this new study and the older relevant studies. The WG agreed to continue the discussion at RAC-65.	**Rapporteurs** to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR. **SECR** to table the updated opinion for adoption at RAC-65. **The hazard classes going for plenary discussion: acute inhalation toxicity.**
The expert accompanying the CEFIC Regular Stakeholder commented on acute inhalation toxicity and provided more details on the study.	

6. AOB

No items were raised under Any Other Business at the meeting.

7. Adoption of the report from the Working Group

Before the Chair thanked the participants and closed the meeting, the Working Group adopted the report of its 9th Meeting, requesting the Secretariat to make any necessary editorial changes.

Annex I **Agenda of the 9th Meeting of the Committee for Risk Assessment Working Group on Harmonised Classification and Labelling**

Annex II **List of participants**

Annex III **Declarations of potential conflicts of interest**

ANNEX I: Final agenda

17 April 2023
RAC WG/A/CLH/9/2023

9th Meeting of the Committee for Risk Assessment Working Group on Harmonised Classification and Labelling (RAC-65 CLHWG)

Monday 24 April at 10:00 -
Thursday 27 April ends at 15:45

Times are Helsinki times
Virtual meeting

Final draft Agenda

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/CLH/9/2023
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Harmonised classification and labelling (CLH)

4.1. Hazard classes to be proposed for agreement without plenary debate (A-list) in RAC-65:

- 9-Octadecenoic acid (*Z*)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt: *mutagenicity, carcinogenicity, reproductive toxicity*
- 2,3-epoxypropyl isopropyl ether: *reproductive toxicity*
- Tetrahydrofurfuryl methacrylate: *STOT RE*
- Bixlozone (ISO): *acute toxicity via all routes, skin irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, hazards to the aquatic environment*
- Trimethyl phosphate: *acute toxicity via oral and dermal routes, mutagenicity, carcinogenicity, lactation*
- 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate: *acute inhalation toxicity, STOT SE, EUH071, EUH204*
- Folpet (ISO); N-(trichloromethylthio)phthalimide: *acute oral and dermal toxicity, mutagenicity, STOT SE*

- 2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB]: *acute toxicity via all routes, skin corrosion/irritation, eye damage/irritation, respiratory sensitisation, mutagenicity, carcinogenicity, hazards to the aquatic environment*
- 1,1-dichloroethylene; vinylidene chloride: *hazards to the aquatic environment*

4.2. CLH dossiers

4.2.1. Tetrahydrofurfuryl methacrylate (EC 219-529-5; CAS 2455-24-5)

4.2.2. Bixlozone (ISO); 2-(2,4-dichlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one (EC -; CAS 81777-95-9)

4.2.3. Trimethyl phosphate (EC 208-144-8; CAS 512-56-1)

4.2.4. Barium chromate (EC 233-660-5; CAS 10294-40-3)

4.2.5. 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate (EC 223-861-6; CAS 4098-71-9)

4.2.6. Folpet (ISO); *N*-(trichloromethylthio)phthalimide (EC 205-088-6; CAS 133-07-3)

4.2.7. 2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB] (EC 252-681-0; CAS 35691-65-7)

4.2.8. Fluoroethylene (EC 200-832-6; CAS 75-02-5)

4.2.9. Barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]; C.I. Pigment Red 53:1 (EC 225-935-3; CAS 5160-02-1)

4.2.10. 1,1-dichloroethylene; vinylidene chloride (EC 200-864-0; CAS 75-35-4)

4.2.11. *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide (HH) (EC: 289-699-3; CAS: 89997-63-7)/ *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents (EC: 289-699-3; CAS: 89997-63-7)

For discussion

Item 5 – Article 77(3)(c)

5.1 Article 77(3)(c) request on Silanamine: review of the acute toxicity classification of Silanamine as adopted by RAC in its opinion of 5 December 2019.

For discussion

Item 6 – AOB

Item 7 – Adoption of the Report from the WG

For discussion and agreement

ANNEX II: List of participants

RAC members	
Schulte	Agnes
Docea	Anca
Menard Srpčič	Anja
Biró	Anna
Losert	Annemarie
Pęczkowska	Beata
Piña	Benjamin
Lund	Bert-Ove
Barański	Bogusław
Murray	Brendan
Esposito	Dania
Schuur	Gerlienke
Mendas Starcevic	Gordana
Mohammed	Ifthekhar Ali
Karadjova	Irina
Angeli	Karine
Rakkestad	Kirsten Eline
Tobiassen	Lea Stine
Facchin	Manuel
Neumann	Michael
Martínek	Michal
Pribu	Mihaela
Spetseris	Nikos
Landvik Tekpli	Nina
Sørensen	Peter Hammer
Moldov	Raili
Leinonen	Riitta
Moeller	Ruth
Varnai	Veda
Rodriguez	Wendy
Užomeckas	Žilvinas

Members' advisers	
Bjørge Christine	Tekpli Nina
Capolupo Marco	Esposito Dania
Hoffmann Frauke	Schulte Agnes
Meys Catherine	Rodriguez Wendy
Moilanen Marianne	Leinonen Riitta
Russo Maria Teresa	Aquilina Gabriele
Saksa Jana	Moldov Raili
Suutari Tiina	Leinonen Riitta
Svenstrup Henrik	Tobiassen Lea Stine

Dossier submitters	Substance
Charles Sandrine	1,1-dichloroethylene; vinylidene chloride
Guillou Pauline	1,1-dichloroethylene; vinylidene chloride
Kühnert Agnes	3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate
Heiserich Lisa	Barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]; C.I. Pigment Red 53:1
Theune Loryn	Barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]; C.I. Pigment Red 53:1
Vriend Jelle	Barium chromate
Faber Melvin	Bixlozone (ISO); 2-(2,4-dichlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one
de Rivas Ana	Chrysanthemum cinerariaefolium
de la Usada Eduardo	Chrysanthemum cinerariaefolium
Deweirdt Juliette	Fluoroethylene
Fischer Alexandra	Folpet (ISO); N-(trichloromethylthio)phthalimide
Hrdina-Zoedl Bettina	Folpet (ISO); N-(trichloromethylthio)phthalimide
Losert Annemarie	Trimethyl phosphate

Regular stakeholder observers	
Barry Frank	ETUI
De Backer Liisi	Cefic
Ruelens Paul	CropLife Europe

Stakeholder experts		Substance
Richmond Emily, Exponent (CRO)	CropLife Europe	Chrysanthemum cinerariaefolium
Dekant Wolfgang, ASASP	Cefic	Article 77(3)(c) Silanamine
Kluxen Felix, Adama	CropLife Europe	Folpet
Wang Wendy, FMC	CropLife Europe	Bixlozone

European Commission		DG
Kilian	Karine	DG ENV

ECHA staff	
Bowmer (Chair of RAC)	Tim
Karjalainen (Co-chair)	Ari
Myöhänen (Co-chair)	Kirsi
Uphill (Co-chair)	Simon
Alami-Eerikinharju	Wafa
Bichlmaier Suchanová	Bohumila
Hellsten	Kati
Husa	Stine

Korjus	Pia
Lapenna	Silvia
Ludboržs	Arnis
Nygren	Jonas
O'Rourke	Regina
Perazzolo	Chiara
Rahkonen	Olli
Ryan	Paul
Sadam	Diana
Sihvola	Virve
Sobanska	Marta
Spjuth	Linda

ANNEX III: Declarations of potential conflicts of interest

The following participants, including those for whom the Chairman declared the interest on their behalf, declared potential conflicts of interest with the Agenda items (according to Art 9 (2) of RAC RoPs)

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT previous RAC plenary meeting(s)		
Harmonised classification & labelling		
1) ***Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide** 2) ***Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents** **ES**	Marieta FERNANDEZ	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Benjamin PINA	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
NEW DOSSIERS		
Harmonised classification & labelling		
1) **Bixlozone (ISO)** 2) **Barium chromate** 3) **9-Octadecenoic acid (*Z*)-, sulfonated, potassium salts a)** **NL**	Gerlienke SCHUUR	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
1) **Isophorone di-isocyanate** 2) **C.I. Pigment Red 53:1** **DE**	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1) **Fluoroethylene** 2) **Vinylidene chloride** **FR**	Karine ANGELI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Laure GEOFFROY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1) **Tetrahydrofurfuryl methacrylate** 2) **Folpet (ISO)** 3) **Trimethyl phosphate** **AT**	Annemarie LOSERT	1) and 2) Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement. 3) Dossier submitter for Trimethyl phosphate.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	Manuel FACCHIN	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB] **CZ**	Michal MARTINEK	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
2,3-epoxypropyl isopropyl ether **SE**	Bert-Ove LUND	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Ifthekhar Ali MOHAMMED	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.