

RAC WG/CLH/R/4/2022

27 January 2022

**Report
of the 4th Meeting of the Committee for Risk Assessment
Working Group on Harmonised Classification and Labelling
(RAC-60 CLH WG)**

**ECHA Conference Centre (Telakkakatu 6, Helsinki)
via Webex**

**Monday 24 January 2022 at 14.00
to
Thursday 27 January 2022 at 17.00**

Summary Record of the Proceedings

1. Welcome and apologies

The Chair of RAC, Tim Bowmer, welcomed the participants to the 4th 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 Deputy Chair of RAC Johanna Peltola-Thies and by officers of the CLH team: Ari Karjalainen, Ricardo Simoes and Simon Uphill.

Written consultations were organised on all dossiers prior to the working group meeting for RAC-60 (except for MWCNT, the draft opinion of which was made available to the working group last week).

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/CLH/4/2022), 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 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.

The Chairs then 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-60

The Working Group agreed to propose the following hazard classes to RAC-60 for A-listing (without discussing them in the WG) based on the written comments received from members during the consultation:

- **α -methyl-1,3-benzodioxole-5-propionaldehyde**: skin sensitisation
- **2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol [Disperse Blue 106]**: skin sensitisation
- **Reaction mass of: N,N'-Ethane-1,2 diylbis(decanamide) 12-Hydroxy-N-[2-[1-oxydecyl]amino]ethyl]octadecanamide N,N'-Ethane-1,2-diylbis(12-hydroxyoctadecanamide)[Thixatrol Plus]**: hazardous to the aquatic environment
- **(3E)-dec-3-en-2-one**: physical hazards, acute toxicity, skin irritation, eye irritation, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, STOT SE, STOT RE, hazardous to the aquatic environment
- **Benthiavalicarb-isopropyl (ISO)**: acute toxicity, skin irritation, eye irritation, mutagenicity, STOT RE
- **Propyl 3,4,5-trihydroxybenzoate**: skin sensitisation
- **S-metolachlor (ISO)**: mutagenicity, hazardous to the aquatic environment
- **Sulfur: acute toxicity**, skin irritation, carcinogenicity, mutagenicity, reproductive toxicity

4.2 Hazard classes for discussion

4.2.1 (3E)-dec-3-en-2-one (EC: -; CAS: 18402-84-1)

The co-Chair welcomed the Dossier Submitter representative and informed that **(3E)-dec-3-en-2-one** is intended to be used as plant growth regulator in potatoes during storage. The product is applied by hot fogging. The substance has no current Annex VI entry.

The DS (NL) proposes to classify (3E)-dec-3-en-2-one as Acute Tox. 4; H332 (ATE = 1.5 mg/L (dusts and mists)), Skin Irrit. 2; H315, Skin Sens. 1; H317, Asp. Tox. 1; H304, Aquatic Chronic 2; H411.

Physical hazards relevant for liquid substance, carcinogenicity, germ cell mutagenicity, reproductive toxicity, acute toxicity – inhalation, dermal, oral, aspiration hazard, specific target organ toxicity – single exposure, repeated exposure, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.

The legal deadline for the adoption of an opinion is 2 November 2022.

Physical hazards relevant for liquid substance

The WG recommended no classification and A-listing at RAC-60.

Human Health

Carcinogenicity

The WG recommended no classification and A-listing at RAC-60.

Mutagenicity

The WG recommended no classification and A-listing at RAC-60.

Reproductive toxicity

The WG recommended no classification and A-listing at RAC-60.

Acute oral and dermal toxicity

The WG recommended no classification and A-listing at RAC-60.

Acute inhalation toxicity

The WG recommended to support the DS and to classify (3E)-dec-3-en-2-one as Acute Tox. 4; H332 (ATE = 1.5 mg/L (dusts and mists)), and WG recommended A-listing at RAC-60.

Aspiration hazard

The WG recommended to support the DS and to classify (3E)-dec-3-en-2-one as Asp. Tox. 1; H304.

STOT SE

The WG recommended no classification and recommended for A-listing at RAC-60.

STOT RE

The WG recommended no classification and recommended for A-listing at RAC-60.

Skin irritation/corrosion

The WG supported the DS and recommended to classify (3E)-dec-3-en-2-one as Skin. Irrit. 2; H315, and also recommended A-listing at RAC-60.

Serious eye damage/eye irritation

The WG recommended no classification and A-listing

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 final discussion and adoption at RAC-60.

The hazard class going for plenary discussion: skin sensitisation.

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| <p>at RAC-60.</p> <p><i>Skin sensitisation</i></p> <p>The WG recommended to continue the discussion in the plenary on this hazard class at RAC-60. A majority of the participants in the discussion found the Buehler test results to be negative, but some reflected that overall, such test results would be inconclusive with regard to their applicability for classification. It was requested that the rapporteur would reflect on the potential steric hinderance of the benzene ring-substituted related substances. It was also requested to explore the experimental results in more detail, which were used as reference compounds in the (Q)SAR data bases.</p> <p>The WG agreed to apply an additional hazard statement EUH071: 'Corrosive to the respiratory tract' based on histopathological findings from a dose-range finding inhalation study in olfactory, respiratory and transitional epithelium, nasopharynx, trachea, tracheal bifurcation, larynx, lungs and bronchi from the 531 µg/L group dose and above. The WG recommended to A-list it.</p> <p><u>Environment</u></p> <p><i>Aquatic chronic</i></p> <p>The WG recommended to support the DS and to classify (3E)-dec-3-en-2-one as Aquatic Chronic 2; H411, and WG recommended A-listing at RAC-60.</p> | |
| <p>4.2.2. 2,3-epoxypropyl neodecanoate (EC: 247-979-2; CAS: 26761-45-5)</p> | |
| <p>The co-Chair welcomed the Dossier Submitter representatives and informed that 2,3-epoxypropyl neodecanoate is used in adhesives and sealants and has widespread uses across activities and areas by professional workers. The substance has no current Annex VI entry.</p> <p>The DS (DK) proposes to classify the substance as Skin Sens. 1A; H317 (C ≥ 0,001%) and Muta. 2; H341.</p> <p>Skin sensitisation and germ cell mutagenicity were the hazard classes open for comments during the Consultation.</p> <p>The legal deadline for the adoption of an opinion is 4 November 2022.</p> | |
| <p><i>Skin sensitisation</i></p> <p>The WG recommended to classify the substance as Skin Sens. 1A; H317 with an SCL of 0,001%. The WG recommended A-listing at RAC-60.</p> | <p>Rapporteur to revise the opinion in accordance with the discussion in the WG and to provide it to SECR.</p> |

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| <p><i>Mutagenicity</i></p> <p>The WG recommended to classify the substance as Muta. 2; H341 and A-listing at RAC-60.</p> | <p>SECR to table the updated opinion for adoption at RAC-60.</p> <p>The hazard classes going for plenary discussion: none.</p> |
| <p>4.2.3. Acetone oxime (EC: 204-820-1; CAS: 127-06-0)</p> | |
| <p>The Chair informed that acetone oxime is used as anti-skinning agent for the preparation of coatings/printing inks. The substance has no current Annex VI entry. The DS (AT) proposes to classify acetone oxime as Carc. 1B; H350, Acute Tox. 4; H312 (ATE=1100 mg/kg bw), STOT SE 3; H336, STOT RE 2; H373 (blood system), Eye Dam. 1; H318 and Skin Sens. 1B; H317.</p> <p>Acute dermal toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE and STOT RE were the hazard classes open for comments during the Consultation.</p> <p>The legal deadline for the adoption of an opinion is 8 October 2022.</p> | |
| <p><i>Acute dermal toxicity</i></p> <p>The WG recommended classification as Acute Tox. 4; H312 (ATE=1100 mg/kg bw) and A-listing at RAC-60.</p> <p><i>Skin irritation</i></p> <p>The WG recommended no classification and A-listing at RAC-60.</p> <p><i>Eye irritation</i></p> <p>The WG recommended to classify acetone oxime as Eye Dam. 1; H318 and A-listing at RAC-60.</p> <p><i>Skin sensitisation</i></p> <p>The WG recommended classification as Skin Sens. 1; H317 and A-listing at RAC-60.</p> <p><i>STOT RE</i></p> <p>The WG recommended to classify the substance as STOT RE 2; H373 (blood system) and A-listing at RAC-60.</p> <p><i>STOT SE</i></p> <p>The WG agreed with the proposed read across from butanone oxime and hence recommended STOT SE 3; H336 classification for acetone oxime. It was suggested to reflect in the draft opinion the importance of the narcotic effects for the classification. This hazard class was recommended for A-listing at</p> | <p>Rapporteurs to revise the opinion in accordance with the discussion in the WG and to provide it to SECR.</p> <p>SECR to table the updated opinion for final adoption at RAC-60.</p> <p>The hazard classes going for plenary discussion: none.</p> |

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| <p>RAC-60.</p> <p><i>Mutagenicity</i> The WG agreed with the proposed read across from butanone oxime, Wasox-MMAC2 and Wasox-VMAC2 and recommended no classification based on data for acetone oxime and read across substances.</p> <p>This hazard class was recommended for A-listing at RAC-60.</p> <p><i>Carcinogenicity</i> The WG agreed with the proposed read across from butanone oxime and recommended to classify the substance as Carc. 1B; H350 based on read across combined with data for acetone oxime itself. Several Members pointed to the uncertainties in the data for acetone oxime, however in a weight-of-evidence assessment, considered the data as supportive for the proposed classification. The Rapporteurs agreed to revise the draft opinion to reflect this matter.</p> <p>This hazard class was recommended for A-listing at RAC-60.</p> | |
| <p>4.2.4. Benthialdicarb-isopropyl (ISO); isopropyl [(S)-1-{{(R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl}carbonyl}-2-methylpropyl]carbamate (EC: -; CAS: 177406-68-7)</p> | |
| <p>The co-Chair welcomed the expert accompanying the CropLife Regular Stakeholder Observer and informed that benthialdicarb-isopropyl is an active substance used in plant protection products as a fungicide against <i>Peronosporales</i> fungi, except <i>Pythium</i> spp and <i>Phytophthora infestans</i> in potato crops. The substance has no current Annex VI entry.</p> <p>The DS (PL) proposes to classify the substance as Carc. 2; H351, Skin Sens. 1; H317 and Aquatic Chronic 2; H411.</p> <p>Selected physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.</p> <p>The legal deadline for the adoption of an opinion is 22 July 2022.</p> | |
| <p><i>Acute toxicity</i> The WG recommended no classification for acute toxicity via all routes and A-listing at RAC-60.</p> | <p>Rapporteurs to revise the opinion in accordance with the discussion in the WG and to</p> |

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| <p><i>Skin irritation</i> The WG recommended no classification and A-listing at RAC-60.</p> <p><i>Eye irritation</i> The WG recommended no classification and A-listing at RAC-60.</p> <p><i>Skin sensitisation</i> The WG recommended to classify the substance as Skin Sens. 1; H317 and A-listing at RAC-60.</p> <p><i>Mutagenicity</i> The WG recommended no classification and A-listing at RAC-60.</p> <p><i>Carcinogenicity</i> The WG recommended classifying the substance as Carc. 1B; H350 (contrary to Carc. 2; H351 proposed by the DS) mainly due to uterine tumours and hepatoblastomas. It was agreed to propose this hazard class for A-listing at RAC-60.</p> <p><i>Reproductive toxicity</i> It was agreed to discuss this hazard class further at RAC-60, after the Rapporteur has checked the available data further.</p> <p><i>STOT SE</i> The WG recommended no classification and A-listing at RAC-60.</p> <p><i>STOT RE</i> The WG recommended no classification and A-listing at RAC-60.</p> <p><i>Hazardous to the aquatic environment</i> The WG agreed with the DS that the substance does not warrant classification for acute aquatic hazards. The WG agreed to recommend classification as Aquatic Chronic 2; H411. It was agreed to propose this hazard class for A-listing at RAC-60.</p> | <p>provide it to SECR.</p> <p>SECR to table the updated opinion for final discussion and adoption at RAC-60.</p> <p>The hazard classes going for plenary discussion: reproductive toxicity.</p> |
| <p>The expert accompanying the CropLife Regular Stakeholder Observer commented on carcinogenicity and reproductive toxicity.</p> | |

4.2.5. Hexyl Salicylate (EC: 228-408-6; CAS: 6259-76-3)

The Deputy Chair welcomed the Dossier Submitter representatives and the Occasional Stakeholder Observer from IFRA with an accompanying expert. She informed that **hexyl salicylate** is a fragrance ingredient used in many fragrance compounds. It may be found in fragrances used in decorative cosmetics, fine fragrances, shampoos, toilet soaps and other toiletries as well as in non-cosmetic products such as household cleaners and detergents. Hexyl salicylate has no current Annex VI entry.

The DS (FR) proposes to classify the substance as Skin Sens. 1; H317.

Selected 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), skin sensitisation and reproductive toxicity were the hazard classes open for comments during the Consultation.

The legal deadline for the adoption of an opinion is 8 June 2022.

The dossier was discussed at RAC-59 CLH WG, where it was decided to arrange a targeted Consultation on the read across (the targeted Consultation was carried out 10 December 2021 – 18 January 2022).

The WG took note of the “Additional information report” and the other documents provided by the DS for the targeted consultation on the read across approach and of the information received from the consultation.

The Rapporteur was requested by the WG to include more data on hydrolysis and reproductive toxicity testing for the analogous substances introduced following the targeted consultation (cyclohexyl salicylate (CHS) and benzyl salicylate (BzS)), in the revised draft opinion. Also the details of the test results available on ethylhexyl salicylate (EHS) should be included in the draft opinion.

One of the Industry consortium representatives attending the meeting agreed to provide relevant data available on the substances EHS, CHS and BzS to the Rapporteurs.

The Rapporteurs were also requested to reflect the possible steric hindrance of the CHS and BzS.

It was agreed to continue the discussion and conclude on the read across in the next plenary meeting.

A majority of the WG Members expressed the view that there was sufficient data for them to accept the read across proposed by the DS, and consequently

Rapporteur to request the details of the registration data on EHS, CHS and BzS from the Industry representative attending the WG.

Rapporteur to revise the opinion in accordance with the discussion in the WG and to provide it to SECR.

SECR to organise a RAC written consultation on the revised draft opinion and to table it for final discussion and adoption at RAC-60.

The hazard class going for plenary discussion: reproductive toxicity.

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| <p>were considering to classify as Repro. 2; H361d. Others stated that a further look at the reprotoxic effects of the potential read across candidates and their rate of hydrolysis was needed in order to conclude and generally favoured no classification.</p> | |
| <p>The expert accompanying the IFRA Occasional Stakeholder Observer commented on the read across approach.</p> | |
| <p>4.2.6. Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 μm and a length ≥ 5 μm and aspect ratio $> 3:1$, including Multi-Walled Carbon Nanotubes, MWC(N)T (EC: -; CAS: -)</p> | |
| <p>The Chair welcomed the Dossier Submitter representative and informed that MWC(N)T is used in antistatic and electro-paintable thermoplastics, anti-fouling coatings, batteries (Li-ion), textiles, structural composites (e.g. for windmill blades and high performance sporting goods) and possibly printed electronics (conductive inks) and conductive coatings for displays and touch screens. The substance has no current Annex VI entry. The DS (DE) proposes to classify the substances as Carc. 1B; H350i and STOT RE 1; H372 (lung). Carcinogenicity and STOT RE were the hazard classes open for comments during the Consultation. The legal deadline for the adoption of an opinion is 4 September 2022.</p> | |
| <p><i>STOT RE</i> The WG provisionally recommended to classify MWC(N)T as STOT RE 1; H372 (lung) with an SCL of 1% for STOT RE 1 and an SCL of 0.1% for STOT RE 2 classification of MWC(N)T.</p> <p>The discussion on this hazard class will be finalised at RAC-60.</p> <p><i>Carcinogenicity</i> The WG provisionally recommended to classify MWC(N)T as Carc. 1B; H350i.</p> <p>The discussion on this hazard class (including the route) will be finalised at RAC-60.</p> | <p>Rapporteurs to revise the opinion in accordance with the discussion in the WG and to provide it to SECR.</p> <p>SECR to organise a RAC written consultation on the revised draft opinion and to table it for final discussion and adoption at RAC-60.</p> <p>The hazard classes going for plenary discussion: STOT RE, carcinogenicity.</p> |
| <p>4.2.7. Propyl 3,4,5-trihydroxybenzoate (EC: 204-498-2; CAS: 121-79-9)</p> | |
| <p>The co-Chair welcomed the Dossier Submitter representative and informed that propyl gallate is used as an antioxidant authorised as food additive. The substance has current Annex VI entry as Acute Tox. 4*; H302 and Skin Sens. 1; H317. The DS (DE) proposes <u>to modify</u> Acute Tox. 4; H302 and <u>to add</u> an oral ATE=1000 mg/kg bw (proposal changed to 1700 mg/kg bw after the Consultation) as well as Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 2; H411 (proposal changed to Aquatic Chronic 1; H410 after the Consultation). Acute oral toxicity and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.</p> | |

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| <p>The legal deadline for the adoption of an opinion is 18 November 2022.</p> | |
| <p><i>Acute oral toxicity</i> The WG agreed on classification as Acute Tox. 4; H302 with an ATE of 1700 mg/kg bw and to A-list this hazard class at RAC-60.</p> <p><i>Hazardous to the aquatic environment</i> The WG agreed to recommend classification as Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=1).</p> <p>It was agreed to propose these hazard classes for A-listing at RAC-60.</p> | <p>Rapporteurs to revise the opinion in accordance with the discussion in the WG and to provide it to SECR.</p> <p>SECR to table the updated opinion for adoption at RAC-60.</p> <p>The hazard classes going for plenary discussion: none.</p> |
| <p>4.2.8. S-metolachlor (ISO); 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide; (RaSa)-2-chloro-N-(6-ethyl-o-tolyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide [contains 80-100 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide and 0-20 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2R)-1-methoxypropan-2-yl]acetamide] (EC: -; CAS: 87392-12-9)</p> | |
| <p>The co-Chair welcomed the DS representatives and the expert accompanying the CropLife Regular Stakeholder Observer and informed that S-metolachlor is a herbicide in maize and sunflower. The substance has current entry as Skin Sens. 1; H317, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410.</p> <p>The DS (DE) proposes to <u>add</u> Carc. 2; H351, Repr. 2; H361d, STOT RE 2; H373 (skin) and M=10 for both aquatic acute and chronic hazards. The DS proposes to <u>retain</u> Skin Sens. 1; H317, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410.</p> <p>Germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT RE and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.</p> <p>The legal deadline for the adoption of an opinion is 24 November 2022.</p> | |
| <p>The WG agreed with the proposed read across from metolachlor.</p> <p><i>Mutagenicity</i> The WG recommended no classification and A-listing at RAC-61.</p> <p><i>Carcinogenicity</i> The discussion on this endpoint will be finalised at RAC-61, as the targeted consultation will be organised by ECHA on the new information on carcinogenicity received recently.</p> <p><i>Reproductive toxicity</i> The WG recommended no classification for fertility</p> | <p>SECR to organise a targeted consultation on the new carcinogenicity data received.</p> <p>Rapporteurs to revise the opinion in accordance with the discussion in the WG and to provide it to SECR.</p> <p>SECR to table the updated opinion for final discussion and adoption at RAC-61 (and April CLH WG).</p> <p>The hazard classes going</p> |

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| <p>based on inconclusive data. The WG recommended no classification for development (contrary to Repr. 2; H361d proposed by the DS). The WG recommended no classification for lactation. This hazard class was recommended for A-listing at RAC-61.</p> <p><i>STOT RE</i> The WG recommended no classification for STOT RE (contrary to STOT RE 2; H373 (skin) proposed by the DS) and recommended to apply the additional labelling statement EUH066. This hazard class was recommended for A-listing at RAC-61.</p> <p><i>Hazardous to the aquatic environment</i> The WG agreed to recommend classification as Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410 (M=10). It was agreed to propose these hazard classes for A-listing at RAC-61.</p> | <p>for plenary (RAC-61) discussion: carcinogenicity.</p> |
| <p>4.2.9. Silver (EC: 231-131-3; CAS: 7440-22-4)</p> | |
| <p>The Chair welcomed the Dossier Submitter representatives, the experts accompanying the Cefic and the Eurometaux Regular Stakeholder Observers as well as the Occasional Stakeholder Observers from EPMF and CIRFS with the accompanying experts. He informed that silver is used in biocidal products. It is used in products categorised into the following product types: disinfectants and algaecides not intended for direct application to humans or animals, food and feed area disinfection, drinking water disinfection, preservatives for liquid-cooling and processing systems. Some of these uses may result in a vast range of consumer applications. Apart from biocidal use, silver is widely used by industry, professionals and consumers. Silver has no current Annex VI entry.</p> <p>The DS (SE) proposes to classify silver as Skin Sens. 1; H317, Muta. 2; H341, Repr. 1B; H360FD, Aquatic Acute 1; H400 (M = 10) and Aquatic Chronic 1; H410 (M = 10). The DS proposes to classify nanosilver as Skin Sens. 1; H317, Muta. 2; H341, Repr. 1B; H360FD, Aquatic Acute 1; H400 (M = 1000) and Aquatic Chronic 1; H410 (M = 100).</p> <p>Selected physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment were the hazard classes open for</p> | |

comments during the Consultation.

The Committee has discussed the dossier at RAC-58 plenary meeting, at RAC-59 CLH WG and at RAC-59 plenary meeting.

The legal deadline for the adoption of an opinion is 16 March 2022.

Environment

The WG took note of the quantities reported by industry for the various uses of silver.

The WG concluded that the reasonable use of massive pure silver (≥ 1 mm) does not result in generation of particles < 1 mm.

The WG recommended the following classification for silver:

Silver ≥ 1 mm:

No classification

Silver > 100 nm < 1 mm

Aquatic Acute 1, H400, M = 10

Aquatic Chronic 1, H410, M = 10

Silver ≥ 1 nm ≤ 100 nm

Aquatic Acute 1, H400, M = 1000

Aquatic Chronic 1, H410, M = 1000

Human Health

STOT RE

The WG provisionally recommended no classification based on insufficient data, but a concern was identified for neurotoxicity and ocular argyrosis.

The WG agreed that the Rapporteur will have a look at the newly provided EOGRTS study and especially its DNT cohorts and the recent review about ocular argyrosis promised by industry to see if these have any relevant additional information for STOT RE assessment.

The discussion on this hazard class will be finalised at RAC-60 or 61.

Mutagenicity

The WG discussed the very extensive database on germ cell mutagenicity for silver and the related

Rapporteurs to revise the opinion in accordance with the discussion in the WG and to provide it to SECR.

SECR to organise a RAC written consultation on the revised draft opinion (for Human Health) and to table it for further discussion at RAC-60.

The hazard classes going for RAC-60/RAC-61: STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, ENV.

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| <p>uncertainties.</p> <p>They noted that the positive <i>in vivo</i> studies were primarily focussed on nanoparticles, and questioned whether this would also be applicable to Ag bulk forms.</p> <p>Most Members supported a Muta. 2 classification for at least the nano silver, noting that no classification might be appropriate for bulk silver. One Member supported no classification, while another supported category 1B. Another Member questioned the basis for eventually splitting the classification.</p> <p>The Rapporteur was requested, with the support of the Secretariat, to identify the key <i>in vivo</i> studies and record their quality in more detail in the draft opinion.</p> <p>The discussion on this hazard class will be finalised at RAC-60 or 61.</p> <p><i>Carcinogenicity</i></p> <p>The WG took note of the Rapporteur`s evaluation of carcinogenicity. The discussion on this hazard class will continue at RAC-60 or 61.</p> | |
| <p><u>Environment</u></p> <p>No interventions were made by Stakeholder Observers.</p> <p><u>Human Health</u></p> <p>The EPMF Occasional Stakeholder Observer and the expert accompanying the Eurometaux Regular Stakeholder Observer commented on STOT RE and germ cell mutagenicity.</p> | |
| <p>4.2.10. Sulfur (EC: 231-722-6; CAS: 7704-34-9)</p> | |
| <p>The co-Chair welcomed the expert accompanying the Eurometaux Regular Stakeholder Observer and the CIRFS Occasional Stakeholder Observer with an accompanying expert. He informed that sulfur is a fungicide and acaricide active substance used for many years in Europe on various crop.</p> <p>The substance has current Annex VI entry as Skin Irrit. 2; H315.</p> <p>The DS (FR and SL) propose to add Eye Irrit. 2; H319 and STOT SE 3; H335 and to retain Skin Irrit. 2; H315.</p> <p>Selected physical hazards (explosives, flammable solids, self-reactive substances or mixtures, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, organic peroxides, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, carcinogenicity, germ cell mutagenicity, reproductive toxicity, STOT SE and STOT RE were the hazard classes open for the Consultation.</p> <p>The legal deadline for the adoption of an opinion is 16 December 2022.</p> | |
| <p><i>General</i></p> <p>It was agreed to seek further information on the identity of the materials used for testing and include</p> | <p>Rapporteur to revise the opinion in accordance with the discussion in the WG and to</p> |

this information in the draft opinion, in order to consolidate the information on the scope of the dossier.

Physical hazards

The WG recommended no classification and A-listing at RAC-60.

Acute toxicity

The WG recommended no classification for acute toxicity via all routes and A-listing at RAC-60.

Skin irritation

The WG recommended to classify sulfur as Skin Irrit. 2, H315 and A-listing at RAC-60.

Eye irritation

Uncertainties as to the reliability of the human evidence were discussed by the WG. Details on specific exposure, including the dust formulation which was used, were requested to be added to the opinion, if available. The possible background for the statement on "well known" irritant properties should be added to the opinion.

The WG recommended concluding on this hazard class at RAC-60.

Skin sensitisation

The WG recommended no classification based on inconclusive data and A-listing at RAC-60. The draft opinion should be revised in relation to the issues raised by the WG regarding the validity of the data, especially with regard to the vehicles used.

Carcinogenicity

The WG recommended no classification and A-listing at RAC-60.

Mutagenicity

The WG recommended no classification and A-listing at RAC-60.

Reproductive toxicity

The WG recommended no classification and A-listing at RAC-60.

STOT SE

The WG considered, contrary to the DS proposal that

provide it to SECR.

SECR to table the updated opinion for final discussion and adoption at RAC-60.

The hazard classes going for plenary discussion: eye irritation, STOT SE.

sulfur, does not warrant classification for STOT SE due to uncertainties in the human data base. The discussion will be finalised at RAC-60 with further consideration of the available human evidence.

STOT RE

The WG recommended no classification for this hazard class based on the available data for oral and dermal routes, whilst the data for the inhalation are lacking. The endpoint is proposed for A-listing at RAC-60.

The expert accompanying the Eurometaux Regular Stakeholder Observer commented on physical hazards, eye irritation, skin sensitisation and STOT SE. The CIRFS Occasional Stakeholder Observer commented on eye irritation.

5. AOB

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

6. Adoption of the report from the Working Group

Before the Chair thanked the participants and closed the meeting, the Working Group adopted its report of the 4th Meeting, requesting the Secretariat to make any necessary editorial changes.

Annex I **Agenda of the of the 4th 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

18 January 2022
RAC WG/CLH/4/2022
DRAFT

**4th Meeting of the Committee for Risk Assessment Working Group on
Harmonised Classification and Labelling (RAC-60 CLHWG)**

**Monday 24 January starts at 14:00 -
Thursday 27 January ends at 18:45**

Times are Helsinki times
Virtual meeting

Final draft Agenda

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/CLH/4/2022
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Harmonised classification and labelling (CLH)

**5.1 Hazard classes to be proposed for agreement without plenary debate
(A-list) in RAC-60**

- α -methyl-1,3-benzodioxole-5-propionaldehyde: skin sensitisation
- 2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol [Disperse Blue 106]: skin sensitisation
- Reaction mass of: N,N'-Ethane-1,2 diylbis(decanamide) 12-Hydroxy-N-[2-[1-oxydecyl)amino]ethyl]octadecanamide N,N'-Ethane-1,2-diylbis(12-hydroxyoctadecanamide)[Thixatrol Plus]: hazardous to the aquatic environment
- (3E)-dec-3-en-2-one: physical hazards, acute toxicity, skin irritation, eye irritation, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, STOT SE, STOT RE, hazardous to the aquatic environment
- Bentiavalicarb-isopropyl (ISO): acute toxicity, skin irritation, eye irritation, mutagenicity, STOT RE
- Propyl 3,4,5-trihydroxybenzoate: skin sensitisation
- S-metolachlor (ISO): mutagenicity, hazardous to the aquatic environment
- Sulfur: acute toxicity, skin irritation, carcinogenicity, mutagenicity, reproductive toxicity

5.2 CLH dossiers

- 4.2.1. (3E)-dec-3-en-2-one (EC: -; CAS: 18402-84-1)
- 4.2.2. 2,3-epoxypropyl neodecanoate (EC: 247-979-2; CAS: 26761-45-5)

- 4.2.3. Acetone oxime (EC: 204-820-1; CAS: 127-06-0)
- 4.2.4. Benthialvalicarb-isopropyl (ISO); isopropyl [(S)-1-{{(R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl}carbonyl}-2-methylpropyl]carbamate (EC: -; CAS: 177406-68-7)
- 4.2.5. Hexyl Salicylate (EC: 228-408-6; CAS: 6259-76-3)
- 4.2.6. Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 μ m and a length ≥ 5 μ m and aspect ratio $> 3:1$, including Multi-Walled Carbon Nanotubes, MWC(N)T (EC: -; CAS: -)
- 4.2.7. Propyl 3,4,5-trihydroxybenzoate (EC: 204-498-2; CAS: 121-79-9)
- 4.2.8. S-metolachlor (ISO); 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide; (RaSa)-2-chloro-N-(6-ethyl-o-tolyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide [contains 80-100 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide and 0-20 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2R)-1-methoxypropan-2-yl]acetamide] (EC: -; CAS: 87392-12-9)
- 4.2.9. Silver (EC: 231-131-3; CAS: 7440-22-4)
- 4.2.10. Sulfur (EC: 231-722-6; CAS: 7704-34-9)

For discussion

Item 5 – AOB

Item 6 – Adoption of the Report from the WG

For discussion and agreement

ANNEX II: List of participants

| RAC members | |
|--------------------|---------------|
| Aquilina | Gabriele |
| Barański | Bogusław |
| Biró | Anna |
| Bjørge | Christine |
| de la Flor Tejero | Ignacio |
| Docea | Anca Oana |
| Kadiķis | Normunds |
| Geoffroy | Laure |
| Hakkert | Betty |
| Husa | Stine |
| Kadiķis | Normunds |
| Karadjova | Irina |
| Leinonen | Riitta |
| Lund | Bert-Ove |
| Martinek | Michal |
| Menard Srpčič | Anja |
| Moeller | Ruth |
| Mohammed | Ifthekhar Ali |
| Moldov | Raili |
| Murray | Brendan |
| Pęczkowska | Beata |
| Pribu | Mihaela |
| Printemps | Nathalie |
| Rodriguez | Wendy |
| Santonen | Tiina |
| Schlüter | Urs |
| Schulte | Agnes |
| Schuur | Gerlienke |
| Sogorb | Miguel |
| Sørensen | Peter Hammer |
| Stahlmann | Ralf |
| Spetseris | Nikolaos |
| Tobiassen | Lea Stine |
| Tsakovska | Ivanka |
| Tsitsimpikou | Christina |
| Uzomeckas | Zilvinas |
| Varnai | Veda Marija |

| Members' advisers | |
|--------------------------|-------------------|
| Algharably Engi | (Ralf Stahlmann) |
| Boel Els | (Wendy Rodriguez) |

| | |
|--------------------|-----------------------|
| Catone Tiziana | (Gabriele Aquilina) |
| Häschke Denise | (Ralf Stahlmann) |
| Hoffmann Frauke | (Agnes Schulte) |
| Larsen Janni | (Lea Stine Tobiassen) |
| Muller Andre | (Betty Hakkert) |
| Partosch Falko | (Ralf Stahlmann) |
| Russo Maria Teresa | (Gabriele Aquilina) |
| Sachno Dmitrij | (Ralf Stahlmann) |
| Saksa Jana | (Raili Moldov) |
| Sonnenburg Anna | (Ralf Stahlmann) |
| Suutari Tiina | (Leinonen Riitta) |
| van Herwijnen Rene | (Gerlienke Schuur) |
| Wolff Henrik | (Tiina Santonen) |

| Dossier submitters | Substance |
|---------------------------|---------------------------------|
| Birgander Pernilla (SE) | Silver |
| Boqvist Pernilla (SE) | Silver |
| Charles Sandrine (FR) | Hexyl salicylate |
| Gall Andrea (DE) | S-Metolachlor |
| Groothuis Floris (NL) | (3E)-dec-3-en-2-one |
| Guillou Pauline (FR) | Hexyl salicylate |
| Heise Tanja (DE) | S-metolachlor |
| Herzberg Frank (DE) | MWC(N)T |
| Kerkhof Odile (FR) | Hexyl salicylate |
| Kühnert Agnes (DE) | Propyl 3,4,5-trihydroxybenzoate |
| Martin Nellie (DK) | 2,3-epoxypropyl neodecanoate |
| Paludan Ditte Secher (DK) | 2,3-epoxypropyl neodecanoate |

| Regular stakeholder observers | |
|--------------------------------------|------------------------|
| De Backer | Liisi (Cefic) |
| Robinson | Jan (A.I.S.E.) |
| Ruelens | Paul (CropLife Europe) |
| Verougstraete | Violaine (Eurometaux) |
| Waeterschoot | Hugo (Eurometaux) |

| Occasional Industry stakeholder observers | |
|--|-------------------------------------|
| Alami | Anissa (EPMF) - Silver |
| Arregui | Cristina (EPMF) - Hexyl salicylate |
| Ballach | Jochen (CIRFS) - Sulphur and Silver |

| Stakeholder experts | Substance |
|----------------------------|-----------------------------------|
| Aveyard Lindsay | EPMF/GPC Consulting Ltd Silver |

| | | |
|------------------|--|--------------------|
| Battersby Rodger | Eurometaux/ EBRC Consulting | Sulphur |
| Lloyd Sara | CropLife Europe/ Syngenta | S-metolachlor |
| Martens Mark | CropLife Europe/MMTA bv on behalf Kumiai | Benthiavalicarb |
| Mertens Jelle | Cefic/EPMF | Silver |
| Neely Theresa | IFRA/ Dr Knoell Consult Ltd | Hexyl salicylate |
| Ott Wolfgang | CIRFS/Kelheim Fibres | Sulphur and Silver |
| Raffray Mark | Eurometaux/Raffray Biosciences ltd | Silver |

| European Commission | | DG |
|----------------------------|--------|-----------|
| Kilian | Karin | DG ENV |
| Pinte | Jérémy | DG GROW |

| ECHA staff | |
|----------------------|--------------------|
| Bowmer | Tim (Co-chair) |
| Bichlmaier Suchanová | Bohumila |
| Constantin | Camelia |
| Hellsten | Kati |
| Jones | Stella |
| Karjalainen | Antti (Co-chair) |
| Korjus | Pia |
| Lapenna | Silvia |
| Ludborzs | Arnis |
| Marchetto | Flavio |
| Mattiuzzo | Marco |
| Muller | Gesine |
| Myohanen | Kirsi |
| Papadaki | Lina |
| Peltola-Thies | Johanna (Co-chair) |
| Perazzolo | Chiara |
| Prevedouros | Konstantinos |
| Rahkonen | Olli |
| Ryan | Paul |
| Sadam | Diana |
| Simoes | Ricardo (Co-chair) |
| Sobanska | Marta |
| Spjuth | Linda |
| Uphill | Simon (Co-chair) |

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 | | |
| Silver SE | Bert-Ove LUND | 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. |
| | Ifthekhar Ali MOHAMMED | 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. |
| Hexyl salicylate FR | Nathalie PRINTEMPS | 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. |
| | Laure GEOFFROY | 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. |

| Dossier / DS | RAC Member | Reason for potential CoI / Working for |
|---|---------------------------|--|
| NEW DOSSIERS | | |
| Harmonised classification & labelling | | |
| Benthiavalicarb-isopropyl (ISO) PL | Boguslaw BARANSKI | 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. |
| | Beata PECZKOWSKA | 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. Personal involvement. |
| Sulfur FR | Nathalie PRINTEMPS | 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. |
| | Laure GEOFFROY | 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. |
| Thixatrol Plus ES | Ignacio de la FLOR TEJERO | 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. |

| Dossier / DS | RAC Member | Reason for potential CoI / Working for |
|--|------------------|---|
| | Miguel SOGORB | 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) Disperse Blue 106; 2) S-metolachlor (ISO); 3) Propyl 3,4,5-trihydroxybenzoate; 4) Multi-Walled Carbon Tubes 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 in no 1, 3 and 4. |
| | Urs SCHLUTER | 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. |
| | Tom Gebel | 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 in no 4. |
| Acetone oxime AT | 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. |
| | Annemarie LOSERT | Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this |

| Dossier / DS | RAC Member | Reason for potential CoI / Working for |
|---|--------------------------|--|
| | | substance - no other mitigation measures applied. Personal involvement. |
| 1) α-methyl-1,3-benzodioxole-5-propionaldehyde; 2) 2,3-epoxypropyl neodecanoate DK | Peter Hammer SORENSEN | 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. |
| | Lea Stine TOBIASSEN | 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 in no 2. |
| (3E)-dec-3-en-2-one NL | Betty HAKKERT | 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. |
| | 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. |
| Sulfur SL | Anja MENARD | 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. |