

RAC WG/CLH/R/1/2021

Final

28 April 2021

RAC/57/2021/02

**Report
of the 1st Meeting of the Committee for Risk Assessment
Working Group on Harmonised Classification and Labelling
(RAC-CLH WG-1)**

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

**Tuesday 27 April 2021 at 10.00
and
Wednesday 28 April at 16.00**

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Tim Bowmer, welcomed the participants to the 1st meeting of the RAC Working Group on CLH and reminded that RAC had agreed on the establishment of the group at RAC-56 in March 2021. Five RAC-57 cases were chosen for this WG and the RAC consultations had been organised on these prior to the WG meeting (first time in the Interact portal). The chair noted that it was the intention to have all CLH dossiers scrutinised by the working group in the future. On this occasion, a partial agenda had been prepared to allow rapporteurs more time to adapt to the new timelines. He informed that a full agenda of all scheduled dossiers would be tabled for the 3rd working group meeting in October 2021 ahead of RAC 59.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/CLH/1/2021), which was adopted with one addition under AOB (role of the Working Group in the CLH fast-track agreement process) 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. Five 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 Chair declared no potential interests related to any of the agenda points for the meeting.

4. Requests under Article 77(3)(c)

4.1 Classification for environmental toxicity of lead

The Chair welcomed the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers. He reminded that on 30 November 2018, RAC had adopted an opinion on the harmonised classification and labelling of lead, which concluded that for both the massive and the powder forms, it should be classified as Aquatic Acute 1 (M=1) and Aquatic Chronic 1 (M=10). New information had been provided by Industry on the chronic toxicity of lead in the pond snail *Lymnea stagnalis* (OECD TG 243) and RAC was requested, based on Article 77(3)(c), to review its opinion of 30 November 2018 as regards to the environmental classification of lead. The *ad hoc* consultation was carried out prior to RAC-55. The Commission's deadline for the adoption of an opinion was originally 13 May 2021, but ECHA requested an extension until 30 July 2021.

The WG took note and discussed the presentation on aquatic hazards of lead made by the co-Rapporteur, the *ad hoc* group and the SECR, as well as the presentation on the forms of lead made by the SECR.

The WG agreed that a new OECD TG 243 study in *Lymnaea stagnalis* submitted by Industry is valid and reliable but does not overrule the other data in the data set.

The WG agreed that there is no need to consider rapid environmental transformation of lead into insoluble non bioavailable forms, or bioaccumulation.

The WG agreed that the available data was generally not consistent enough – with the possible exception of *Ceriodaphnia dubia* - to allow calculation of reliable geomeans, as pH, DOC, or hardness varied between data points.

The WG agreed that the lowest value should be provisionally used as chronic Fish ERV: *Atherinops affinis*: 6.8 µg/L.

The WG agreed that based on data for the most sensitive algae specie *Pseudokirschneriella subcapitata*, the lowest value of 72 h Pb_{fit} EC₁₀ =

Co-Rapporteur, with the support from the *ad hoc* group and the SECR, to revise the opinion in accordance with the discussion in the WG and provide it to SECR.

SECR to organise a written commenting in RAC and to table the opinion for the final discussion and adoption at RAC-57.

6.1 µg/L at pH 8 should be provisionally used for algal chronic ERV.

In relation to invertebrates (*Lymnaea stagnalis*), the WG proposed to provisionally use the lowest endpoint for classification purposes the EC₁₀ = 0.48 µg/L from Munley et al 2013 but to investigate further the effect of temperature, hardness and feeding regime.

In relation to invertebrates (*Ceriodaphnia dubia*), the WG proposed to provisionally use the lowest endpoint for classification purposes the EC₁₀ = 1.7 µg/L.

In relation to “other” invertebrates, the WG proposed to provisionally use as lowest ERV the endpoint from *Philodina rapida* the EC₁₀ = 2.40 µg/L for classification purposes.

The WG recommended to further consider the option to apply the pH banding, once the most relevant endpoint for the classification has been selected.

The WG recommended to further consider the relevance and the use of the BLM modelling proposed by Industry.

The WG recommended that SSD HC5 value should be used as supporting information for the classification outcome.

The WG took note of the information on lead sheets and processing, which had recently been received and agreed to review it before RAC-57.

The SECR noted that it would continue evaluating the articles and the alloys issues.

The Commission observer, the Eurometaux Regular Stakeholder Observer and the accompanying experts of the Cefic and Eurometaux Regular Stakeholder Observers commented on different aspects of both presentations.

5. Harmonised classification and labelling (CLH)

5.1 Hazard classes to be proposed by the group for agreement (without plenary debate) by A-listing at RAC-57

The Working Group agreed to propose the following hazard classes to RAC-57 for fast-track (without discussing them in the WG):

- **Triethylamine:** acute inhalation toxicity, serious eye damage/eye irritation
- **Di-*n*-butylamine:** skin corrosion/irritation, serious eye damage/eye irritation
- **Sodium chlorate:** chronic aquatic hazards
- **Potassium chlorate:** acute inhalation toxicity, chronic aquatic hazards

5.2 Hazard classes for discussion

5.2.1 Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane (EC -; CAS -)

The Chair welcomed the DS representatives (NO). He explained that the **reaction mass** is used in inks and toners, in printing and recorded media reproduction as well as in adhesives and sealants. It has no current Annex VI entry.

The DS proposes to classify the substance as Muta. 2; H341 and Repr. 1B; H360F.

Germ cell mutagenicity and reproductive toxicity were the hazard classes open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 19 September 2021.

The group agreed to recommend to RAC-57 to adopt the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[Muta. 2; H341, Repr. 1B; H360F]

Both hazard classes are proposed to be agreed via fast track.

The WG agreed that developmental toxicity should be discussed at RAC-57.

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

SECR to table the updated opinion for adoption at RAC-57.

5.2.2 Triethylamine (EC 204-469-4; CAS 121-44-8)

The Chair explained that **triethylamine** is used in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The substance has current Annex VI entry as Flam. Liq. 2; H225, Acute Tox. 4 *; H332, Acute Tox. 4 *; H312, Acute Tox. 4 *; H302, Skin Corr. 1A; H314 and STOT SE 3; H335 (SCL ≥ 1%).

The DS (AT) proposes to modify the entry to Acute Tox. 4; H302 (ATE=500 mg/kg bw), Acute

Tox. 3; H311 (ATE=420 mg/kg bw), Acute Tox. 3; H331 (ATE=7.2 mg/L (vapours)), Eye Dam. 1; H318 and to retain Flam. Liq. 2; H225, Skin Corr. 1A; H314 and STOT SE 3; H335 (SCL ≥ 1%).

Acute toxicity via all routes and serious eye damage/eye irritation were the hazard classes open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 19 June 2021.

The WG agreed to recommend to RAC-57 to adopt the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[Acute Tox. 3; H301 (ATE=100 mg/kg bw), Acute Tox. 3; H311 (ATE=300 mg/kg bw), Acute Tox. 3; H331 (ATE=7.2 mg/L (vapours)), Eye Dam. 1; H318]

All above-mentioned hazard classes are proposed to be agreed via fast track (except for acute oral toxicity).

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

SECR to table the updated opinion for adoption at RAC-57.

5.2.3 Di-*n*-butylamine (EC 203-921-8; CAS 111-92-2)

The Chair explained that **di-*n*-butylamine** is used in manufacture, formulation or re-packing, and at industrial sites. The substance has current Annex VI entry as Flam. Liq. 3; H226, Acute Tox. 4 *; H332, Acute Tox. 4 *; H312 and Acute Tox. 4 *; H302.

The DS (AT) proposes to add Skin Corr. 1B; H314, Eye Dam. 1; H318 and STOT SE 3; H335, to modify Acute Tox. 2; H330 (ATE=1.15 mg/L), Acute Tox. 3; H311 (ATE=768 mg/kg bw) and Acute Tox. 3; H301 (ATE=220 mg/kg bw), and to retain Flam. Liq. 3; H226.

Acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation and STOT SE were the hazard classes open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 19 June 2021.

The WG agreed to recommend to RAC-57 to adopt the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[Acute Tox. 2; H330 (ATE=1.2 mg/L), Acute Tox. 3; H311 (ATE=300 mg/kg bw), Acute Tox. 3; H301 (ATE=220 mg/kg bw), Skin Corr. 1B; H314, Eye Dam. 1; H318, EUH071]

All above-mentioned hazard classes are proposed to be agreed via fast track.

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

SECR to table the updated opinion for adoption at RAC-57.

5.2.4 Sodium chlorate (EC 231-887-4; CAS 7775-09-9)

The Chair welcomed the DS representatives. He explained that **sodium chlorate** is mostly used as an intermediate in the synthesis of chlorates, perchlorates and chlorites and also in pulp and paper bleaching agent (manufacture of chlorine dioxide). The substance has current Annex VI entry as Ox. Sol 1; H271, Acute Tox. 4 *; H302 and Aquatic Chronic 2; H411. The DS (SE) proposes to modify Acute Tox. 3; H301 (ATE=100 mg/kg bw) and to remove Aquatic Chronic 2; H411.

Acute oral toxicity and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 9 October 2021.

The WG agreed to recommend to RAC-57 to adopt the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[Acute Tox. 3; H301 (ATE=100 mg/kg bw)]

The WG agreed to recommend no classification for the aquatic hazards.

Both above-mentioned hazard classes are proposed to be agreed via fast track.

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

SECR to table the updated opinion for adoption at RAC-57.

5.2.5 Potassium chlorate (EC 223-289-7; CAS 3811-04-9)

The Chair welcomed the DS representatives. He explained that **potassium chlorate** is used in the manufacture of potassium chlorate crystals, in the manufacture of pyrotechnics and matches and in the formulation of cosmetics and personal care products. The substance has current Annex VI entry as Ox. Sol. 1; H271, Acute Tox. 4 *; H302, Acute Tox. 4 *; H332 and Aquatic Chronic 2; H411.

The DS (SE) proposes to modify Acute Tox. 3; H301 (ATE=100 mg/kg bw) and to remove Acute Tox. 4 *; H332 and Aquatic Chronic 2; H411.

Acute oral and inhalation toxicity and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 9 October 2021.

The WG agreed to recommend to RAC-57 to adopt the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[Acute Tox. 3; H301 (ATE=100 mg/kg bw)]

The WG agreed to recommend no classification for acute inhalation toxicity and for the aquatic

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

SECR to table the updated opinion for adoption at RAC-57.

hazards.

All above-mentioned hazard classes are proposed to be agreed via fast track.

6. AOB: Role of the WG in fast-track agreement process

The participants discussed the role of the WG in the CLH A-listing agreement process (formerly known as fast-track). The Secretariat agreed to update the RAC Working procedure to clarify the role of the WG and to table it at RAC-57 for agreement.

7. Adoption of the report from the WG

Before the Chair thanked the participants and closed the meeting, the WG adopted its report of the 1st Meeting, requesting the Secretariat to make any necessary editorial changes.

Annex I Agenda of the of the 1st 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

27 April 2021
RAC WG/CLH/1/2021

Final Agenda
1st Meeting of the Committee for Risk Assessment
Working Group on CLH (RAC-CLH WG-1)
27-28 April 2021

Tuesday 27 April starts at 10.00
Wednesday 28 April ends at 16.00

Times are Helsinki times
Virtual meeting

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/CLH/1/2021
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Requests under Article 77(3)(c)

4.1 Classification for environmental toxicity of lead

For discussion

Item 5 – Harmonised classification and labelling (CLH)

5.1 CLH dossiers

1. Hazard classes to be proposed for agreement without plenary debate (fast-track) in RAC-57

For information

2. Hazard classes for discussion

5.1.1 Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane (EC: -; CAS: -)

- 5.1.2 Triethylamine (EC: 204-469-4; CAS: 121-44-8)
- 5.1.3 Di-*n*-butylamine (EC: 203-921-8; CAS: 111-92-2)
- 5.1.4 Sodium chlorate (EC: 231-887-4; CAS: 7775-09-9)
- 5.1.5 Potassium chlorate (EC: 223-289-7; CAS: 3811-04-9)

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	
Barański	Bogusław
Biró	Anna
Bjørge	Christine
de la Flor	Ignacio
Dobrev	Ivan
Docea	Anca
Facchin	Manuel
Geoffroy	Laure
Hakkert	Betty
Husa	Stine
Karadjova	Irina
Leinonen	Riitta
Lund	Bert-Ove
Martinek	Michal
Menard Srpčič	Anja
Moeller	Ruth
Ali Mohammed	Ifthekhar
Moldov	Raili
Murray	Brendan
Neumann	Michael
Pęczkowska	Beata
Printemps	Nathalie
Rodriguez	Wendy
Rucki	Marian
Schulte	Agnes
Schuur	Gerlienke
Sørensen	Peter Hammer
Spetseris	Nikolaos
Stahlmann	Ralf
Tobiassen	Lea Stine
Tsitsimpikou	Christina
Uzomeckas	Zilvinas

Members' advisers	
Clausen (Peter Hammer Sørensen)	Henning
Falck (Bert-Ove Lund - for Lead only)	Jonas
Hoffmann (Urs Schlueter)	Frauke
Leconte (Nathalie Printemps)	Stephane
Losert (Manual Facchin)	Annemarie
Martin (Ralf Stahlmann)	Theresa

Munch (Peter Hammer Sørensen)	Pernille
Partosch (Ralf Stahlmann)	Falko
Sedlackova (Michal Martinek)	Viktorie
Sonnenburg (Ralf Stahlmann)	Anna
Suutari (Riitta Leinonen)	Tiina

Dossier submitters		Substance
Åkerblom	Nina (SE)	Sodium Chlorate & Potassium Chlorate
Larsen	Ann Kristin (NO)	Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy) methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy) methyl)-2-hydroxymethyl butane
Witasp Henriksson	Erika (SE)	Sodium Chlorate & Potassium Chlorate

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

Stakeholder experts		Substance
Binks	Steve (International Lead association)	Article 77(3)(c) Lead
Chowdhury	Jasim (International Lead association)	Article 77(3)(c) Lead

European Commission		DG
Bintein	Sylvain	DG ENV
Kilian	Karin	DG ENV
Pinte	Jérémy	DG GROW

ECHA staff	
Bowmer	Tim (Chair)
Jones	Stella (HoU C1)
Karjalainen	Ari
Lapenna	Silvia
Myohanen	Kirsi
Nygren	Jonas
O'Rourke	Regina
Peltola-Thies	Johanna
Perazzolo	Chiara
Prevedouros	Konstantinos
Sadam	Diana
Simoes	Ricardo
Uphill	Simon
Zafeirakou	Evi

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)

Dossier / DS	RAC Member	Reason for potential CoI / Working for
Harmonised classification & labelling		
Triethylamine Di-<i>n</i>-butylamine 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.
Sodium chlorate Potassium chlorate 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.
Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane NO	Christine BJÖRGE	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.
	Stine HUSA	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation

Dossier / DS	RAC Member	Reason for potential CoI / Working for
		measures applied. No personal involvement.
Article 77.3(c)		
Classification for environmental toxicity of lead No CA involvement – the request comes from COM		