

RAC concludes on 23 scientific opinions for CLH

Helsinki, 11 December 2014

Copper compounds

Copper compounds and copper flakes are used as active substances in biocidal and plant protection products.

All 10 dossiers were submitted by France.

Copper flakes (coated with aliphatic acid)

Copper flakes do not currently have an entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by France to classify the substance as harmful if swallowed and as toxic if inhaled. RAC also proposed a harmonised classification as causing serious eye irritation. In addition, RAC agreed with France to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). However, RAC proposed an M-factor of 100 to be assigned to both the acute and the chronic hazard, while France had proposed an M-factor of 10 for the acute hazard and an M-factor of 1 for the chronic hazard.

Copper (II) oxide

Copper (II) oxide currently has no harmonised entry in Annex VI to the CLP Regulation.

RAC did not agree to the proposal by France to classify the substance for acute toxicity. As to the aquatic hazards, RAC agreed with France to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). However, RAC proposed an M-factor of 100 to be assigned to both the acute and the chronic hazard, while France had proposed an M-factor of 10 for the acute hazard and an M-factor of 1 for the chronic hazard.

Copper (I) oxide; dicopper oxide

Copper (I) oxide currently has the following harmonised classifications in Annex VI to the CLP Regulation: harmful if swallowed (minimum classification) and very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). No M-factors have been set.

RAC agreed to the proposal by France to classify the substance as harmful if swallowed and if inhaled based on data. RAC did not agree with France to classify the substance as causing

serious eye irritation, but proposed to assign the more severe classification as causing serious eye damage.

As for the aquatic hazards, RAC agreed with France to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). However, RAC proposed an M-factor of 100 to be assigned to both the acute and the chronic hazard, while France had proposed an M-factor of 100 for the acute hazard only and an M-factor of 1 for the chronic hazard.

Copper (II) hydroxide, copper dihydroxide

Copper (II) hydroxide does currently not have a harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by France to classify the substance as harmful if swallowed and fatal if inhaled (Acute Tox. 2; H330) and as causing serious eye damage.

As for the aquatic hazards, RAC agreed with France to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). However, RAC proposed an M-factor of 10 to be assigned to both the acute and the chronic hazard, while France had proposed an M-factor of 10 for the acute hazard only and an M-factor of 1 for the chronic hazard.

Copper (II) carbonate – copper (II) hydroxide (1:1), basic copper carbonate

Copper (II) carbonate – copper (II) hydroxide (1:1) does not currently have a harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by France to classify the substance as harmful if swallowed and if inhaled (H) and as causing serious eye irritation.

As for the aquatic hazards, RAC agreed with France to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) while assigning a more severe chronic aquatic classification than France who had proposed Aquatic Chronic 2. RAC also decided to assign an M-factor of 10 to both the acute and the chronic hazard, while France had proposed an M-factor of 10 for the acute hazard only.

Dicopper chloride trihydroxide, copper oxychloride

Dicopper chloride trihydroxide does not currently have a harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by France to classify the substance as toxic if swallowed and harmful if inhaled.

As for the aquatic hazards, RAC agreed to the proposal by France to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) while assigning a more severe chronic aquatic classification than France who had proposed Aquatic Chronic 2. RAC also decided to assign an M-factor of 10 to both the acute and the chronic hazard, while France had proposed an M-factor of 10 for the acute hazard only.

Copper thiocyanate

Copper thiocyanate currently has the following harmonised classifications in Annex VI to the CLP Regulation: harmful if swallowed, in contact with skin and if inhaled (minimum classifications) and as harmful to aquatic life with long lasting effects (Aquatic Chronic 3; H412). In addition, the supplemental hazard statement EUH032 ("Contact with acids liberates very toxic gas.") is assigned in Annex VI.

RAC agreed to the proposal by France to retain the supplemental hazard statement EUH032 based on data. RAC did not form an opinion on acute toxicity, as no data were provided in the CLH report.

As for the aquatic hazards, RAC agreed with France to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) while assigning a more severe chronic aquatic classification than France who had proposed Aquatic Chronic 2. RAC also decided to assign an M-factor of 10 to both the acute and the chronic hazard, while France had proposed an M-factor of 10 for the acute hazard only.

Copper sulphate pentahydrate

Copper sulphate pentahydrate currently has the following harmonised classifications in Annex VI to the CLP Regulation: harmful if swallowed (minimum classification), irritant to skin and eyes and as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). No M-factors have been set.

RAC agreed to the proposal by France to classify the substance as harmful if swallowed based on data and as causing serious eye damage.

As for the aquatic hazards, RAC agreed with France to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) while assigning a more severe chronic aquatic classification than France who had proposed Aquatic Chronic 2. RAC also decided to assign an M-factor of 10 to both the acute and the chronic hazard, while France had proposed an M-factor of 10 for the acute hazard only.

Tetracopper hexahydroxide sulphate [1], tetracopper hexahydroxide sulphate hydrate [2]

Tetracopper hexahydroxide sulphate and its hydrate do currently not have a harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by France to classify the substance as harmful if swallowed.

As for the aquatic hazards, RAC agreed with France to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) while assigning a more severe chronic aquatic classification than France who had proposed Aquatic Chronic 2. RAC also decided to assign an M-factor of 10 to both the acute and the chronic hazard, while France had proposed an M-factor of 10 for the acute hazard only.

Bordeaux mixture, reaction products of copper sulphate with calcium dihydroxide

Bordeaux mixture currently has no harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by France to classify the substance as harmful if inhaled and as causing serious eye damage.

As for the aquatic hazards, RAC agreed to the proposal by France to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) while assigning a more severe chronic aquatic classification than France who had proposed Aquatic Chronic 2. RAC also decided to assign an M-factor of 10 to both the acute and the chronic hazard, while France had proposed an M-factor of 10 for the acute hazard only.

2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide (Acetochlor (ISO))

Acetochlor (ISO) is a pesticide active substance. The substance currently has the following harmonised classifications in Annex VI to the CLP Regulation: harmful if inhaled (minimum

classification), irritant to the respiratory tract, skin irritant, skin sensitiser and as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). No M-factors have been set.

RAC agreed to the proposal by Spain to retain the harmonised classification as skin irritant, irritant to the respiratory tract and as very toxic to aquatic life with long lasting effects. RAC also agreed to confirm the classification as harmful if inhaled based on available data, to add classifications as a substance which may cause cancer (Carc. 2; H351) and to assign an M-factor of 1 000 to the acute aquatic hazard and an M-factor of 100 to the chronic aquatic hazard. RAC also concluded that acetochlor is a substance which may cause damage to kidney through prolonged or repeated exposure. Finally, although not proposed by Spain, RAC decided to classify acetochlor as a substance which is suspected of damaging fertility (Repr. 2; H361f). RAC also decided that sub-categorisation for skin sensitisation, as proposed by Spain, was not justified, but decided instead to retain the current classification as Skin Sens. 1. In addition, RAC decided that the data in the dossier were not sufficient to conclude on a classification for acute oral toxicity.

2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl] benzenesulphonamide (Chlorsulfuron (ISO))

Chlorsulfuron (ISO) is a pesticide active substance. The substance is currently classified as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) in Annex VI to the CLP Regulation. No M-factors were assigned.

RAC agreed to the proposal by Poland to assign an acute M-factor of 1 000 to the acute aquatic hazard and an M-factor of 100 to the chronic aquatic hazard.

1-[(4-chlorophenyl)methyl]-1-cyclopentyl-3-phenylurea (Pencycuron (ISO))

Pencycuron (ISO) is a herbicidal active substance. The substance currently has no harmonised classification in Annex VI to the CLP Regulation. RAC agreed with the proposal by the Netherlands to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410), but also proposed to assign the hazard category Aquatic Acute 1; H400. RAC decided to assign an M-factor of 1 to both the acute and the chronic aquatic hazard. RAC concluded not to classify for human health hazards.

Tert.-butyl hydroperoxide (TBHP)

Tert.-butyl hydroperoxide (TBHP) is primarily used in the chemical industry, as a starting material, intermediate and as a reactive ingredient (catalyst, initiator or curing agent). The substance currently has no harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by the Netherlands to classify the substance as suspected of causing genetic defects (Muta. 2; H341).

Dicyclohexylphthalate (DCHP)

Dicyclohexylphthalate (DCHP) is a common plasticiser ingredient in the production of nitrocellulose, ethyl cellulose, chlorinated rubber and polymer resins. The substance currently has no harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Sweden to classify the substance as sensitising to skin without further sub-categorisation (Skin Sens. 1; H317) and as a substance which may damage the unborn child (Repr. 1B; H360D). However, RAC did not agree with Sweden to classify for effects on sexual function and fertility.

Diisobutylphthalate (DIBP)

Diisobutylphthalate (DIBP) is used as a plasticiser. DIBP already has a harmonised classification as a substance which may damage fertility and the unborn child (Repr. 1B, H360Df), with specific concentration limits of 25% for developmental effects and 5% for effects on sexual function and fertility, in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Germany to remove the specific concentration limit from Annex VI based on updated ECHA guidance on the setting of SCLs for reproductive toxicity. This means that generic concentration limits of 0.3% for developmental effects and of 3 % for effects on sexual function and fertility apply.

Two glass microfibres

RAC adopted opinions on two glass microfibres, namely on E-glass microfibres of representative composition and on glass-fibres of representative composition. Both fibres have uses in insulation and for special purposes. None of these fibres have had an entry in Annex VI to the CLP Regulation.

E-glass microfibres of representative composition¹

RAC agreed to the proposal by France to classify the E-glass microfibres as a substance which may cause cancer through inhalation (Carc. 1B; H350i). It was also decided to assign Note A, whereas Note R and Note Q were not considered justified.

Glass microfibres of representative composition²

RAC agreed to the proposal by France to classify the glass microfibres as a substance which is suspected of causing cancer through inhalation (Carc. 2; H351 (inhalation)). It was also decided to assign Note A, whereas Note R and Note Q were not considered justified.

N-{2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethyl}-2-(trifluoromethyl)benzamide (Fluopyram (ISO))

Fluopyram (ISO) is a fungicide. Plant protection products containing Fluopyram (ISO) are applied as foliar spray in agriculture, horticulture and viticulture. Fluopyram (ISO) currently has no harmonised classification in Annex VI to the CLP Regulation.

RAC disagreed to the proposal by Germany to classify Fluopyram (ISO) as a substance which is suspected of causing cancer (Carc. 2; H351) and concluded that classification for carcinogenicity was not warranted. RAC agreed with the proposal to classify the substance as toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411).

N-[9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide (Benzovindiflupyr (ISO))

Benzovindiflupyr (ISO) is a new active substance which is proposed for use as a fungicide in the EU. It currently has no harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by France to classify Benzovindiflupyr (ISO) as toxic if swallowed and if inhaled, and as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400

¹ Calcium-aluminium-silicate fibres with random orientation with the following representative composition (% given by weight): SiO₂ 50.0- 56.0%, Al₂O₃ 13.0-16.0%, B₂O₃ 5.8-10.0%, Na₂O <0.6%, K₂O <0.4%, CaO 15.0-24.0%, MgO <5.5%, Fe₂O₃ <0.5%, F₂ <1.0% with note R. Process: typically produced by flame attenuation and rotary process.

² Calcium-aluminium-silicate fibres with random orientation with the following composition (% given by weight): SiO₂ 55.0-60.0%, Al₂O₃ 4.0-7.0%, B₂O₃ 8.0-11.0%, ZrO₂ 0.0-4.0%, Na₂O 9.5-13.5%, K₂O 0.0-4.0%, CaO 1.0-5.0%, MgO 0.0-2.0%, Fe₂O₃ <0.2%, ZnO 2.0-5.0%, BaO 3.0-6.0%, F₂ <1.0% with note R. Process: typically produced by flame attenuation and rotary process.

and Aquatic Chronic 1; H410) with an M-factor of 100 to be assigned to both the acute and the chronic hazard.

5,6-dimethyl-2-dimethylamino-pyrimidin-4-yl N,N-dimethylcarbamate (Pirimicarb (ISO))

Pirimicarb (ISO) is a pesticide active substance; in the EU, it is used as a selective aphicide. Pirimicarb (ISO) currently has the following harmonised classifications in Annex VI to the CLP Regulation: toxic if swallowed (minimum classification) and very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). No M-factors have been set.

RAC agreed to the proposal by the United Kingdom to classify Pirimicarb (ISO) as a substance which is suspected of causing cancer (Carc. 2; H351), as toxic if swallowed and if inhaled, as a skin sensitiser without further sub-categorisation (Skin Sens. 1; H317), and as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) with an M-factor of 10 to be assigned to the acute hazard and an M-factor of 100 to the chronic hazard.

(1E)-N-[4-chloro-2-(trifluoromethyl)phenyl]-1-(1Himidazol-1-yl)-2-propoxyethanimine (Triflumizole (ISO))

Triflumizole (ISO) is a pesticide active substance; it is used as a fungicide which inhibits the biosynthesis of ergosterol. Triflumizole (ISO) currently has no harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by the Netherlands to classify Triflumizole (ISO) as a substance which may damage the unborn child (Repr. 1B; H360D), which may cause damage to the liver through prolonged or repeated exposure, as harmful if swallowed, sensitising to skin without further sub-categorisation due to potency (Skin Sens. 1; H317) and as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410), with an M-factor of 1 to be assigned to both the acute and the chronic hazard.

3,7-dimethylocta-2,6-dienenitrile (Geranonitril)

Geranonitril is used as a fragrance. It currently has no harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Germany to classify geranonitril as a substance which may cause genetic defects (Muta. 1B; H340).

Tetrapropylphenol (TPP)

At the request of the ECHA's Executive Director, RAC reviewed the information submitted by industry for setting higher specific concentration limits for the reproductive toxicity hazard class.

Tetrapropylphenol is a UVCB substance used in chemical synthesis processes which convert this alkylphenol into other chemical derivatives. RAC had adopted an opinion on TPP in December 2013, proposing a harmonised classification as a substance which may damage fertility (Repr. 1B: H360D), with the generic concentration limit of 0.3% to apply.

RAC confirmed the applicability of the generic concentration limit of 0.3% as concluded in its former opinion.

Further information

The opinions will be available at the following link in the near future:

[Opinions](#)

Background Information

The role of RAC in EU regulatory processes

The Committee is responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions and proposals for harmonised classification and labelling. RAC also prepares opinions on specific questions relating to risks of chemicals to human health or the environment and on any other aspects concerning the safety of substances at the Executive Director's request. The final decision for proposals for harmonised classification and labelling, for proposals for restrictions as well as on applications for authorisation will be taken by the European Commission through a committee procedure.

[Further information about RAC](#)