

[Annex to news alert ECHA/NA/15/37](#)

Helsinki, 9 December 2015

[More information about the adopted opinions](#)

Restriction proposal on methanol

RAC adopted its opinion, in support of Poland's proposal to restrict the concentration of methanol in windscreen washing fluids and denaturated ethanol. The proposed restriction is intended to prevent poisoning caused by the consumption of windshield washing fluids and denaturated alcohol containing methanol. Ingestion of methanol may cause permanent blindness and death. In its opinion, RAC supported a lower concentration limit of 0.6%, compared with the original proposal.

Applications for authorisation

RAC agreed on three draft opinions for uses of 1,2-dichloroethane (EDC), sodium chromate and sodium dichromate, including: EDC as a process and extracting solvent in the manufacture of pharmaceutical ingredients; sodium chromate as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators; and sodium dichromate in copper/lead separation in concentrators handling complex sulphide ores.

Carcinogenicity dose-response relationship reference values setting for SVHCs

RAC discussed and agreed in principle to an amendment to the RAC note "*Application for Authorisation: Establishing a reference dose-response relationship for carcinogenicity of hexavalent chromium*" to include Derived No Effect Levels (DNEL) for the intrinsic property "Toxic to reproduction" of the Cr(VI) compounds".

Proposals for harmonised classification and labelling

Three formaldehyde releasing substances:

Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2; MBO), reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1; HPT) and 4,4'-methylene-dimorpholine (MBM)

The formaldehyde-releasing UVCB substances MBO, HPT and MBM have bactericidal and fungicidal properties; they are used in biocidal products. None of the substances has an existing entry in Annex VI to the CLP Regulation.

Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2; MBO)

RAC agreed to Austria's proposal to classify MBO as causing severe skin burns and eye damage (Skin Corr. 1B; H314) and Eye Dam. 1; H318), as a substance which may cause an allergic skin reaction (Skin Sens. 1A; H317), which may cause cancer (Carc. 1B; H350) and which is suspected of causing genetic defects (Muta. 2; H341).

In addition to the dossier submitter's proposal, RAC also agreed to classify MBO as toxic in contact with skin (Acute Tox. 3; H311), as harmful if swallowed and if inhaled (Acute 4; H302 and H332) and as a substance which may cause damage to the gastrointestinal and the respiratory tract (STOT RE 2; H373; gastrointestinal tract, respiratory tract). RAC also decided to assign the supplemental labelling as corrosive to the respiratory tract (EUH071). RAC also recommended to classify the substance as toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411).

Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1; HPT)

RAC agreed with Austria's proposal to classify HPT as a substance which may cause an allergic skin reaction (Skin Sens. 1A; H317), which may cause cancer (Carc. 1B; H350) and which is suspected of causing genetic defects (Muta. 2; H341).

In addition to the dossier submitter's proposal, RAC agreed to classify MBO as harmful if swallowed and if inhaled (Acute Tox. 4; H302 and H332) and as a substance which may cause damage to the gastrointestinal and the respiratory tract (STOT RE 2; H373; gastrointestinal tract, respiratory tract). RAC also agreed to the Austrian proposal to classify HPT as causing severe skin burns and eye damage (Skin Corr. 1C; H314 and Eye Dam. 1; H318) whereas Austria had proposed category 1B for skin corrosion. RAC finally decided to assign the supplemental labelling as corrosive to the respiratory tract (EUH071).

Finally, RAC recommended to classify HPT as toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411).

4,4'-methylene-dimorpholine (MBM)

RAC agreed to Austria's proposal to classify MBM as causing severe skin burns and eye damage (Skin Corr. 1B; H314) and as a substance which may cause cancer (Carc. 1B; H350) and which is suspected of causing genetic defects (Muta. 2; H341).

In addition to the dossier submitter's proposal, RAC agreed to classify MBM as harmful if swallowed, if inhaled and if in contact with skin (Acute 4; H302, H312 and H332) and as a substance which may cause damage to the gastrointestinal and the respiratory tract (STOT RE 2; H373; gastrointestinal tract, respiratory tract).

Finally, RAC also recommended to assign the supplemental labelling corrosive to the respiratory tract (EUH071) and to classify MBM as a substance which may cause an allergic skin reaction (Skin Sens. 1; H317), but did not assign sub-category A as proposed by the dossier submitter.

Triadimenol; α -tert-butyl- β -(4-chlorophenoxy)-1H-1,2,4-triazole-1-ethanol

Triadimenol is used as a fungicidal seed and foliar spray treatment in agricultural applications within the EU. The substance currently has no entry in Annex VI to CLP.

RAC agreed to the United Kingdom's proposal to classify triadimenol as harmful if swallowed (Acute Tox. 4; H302) as a substance which may damage fertility or the unborn child (Repr. 1B; H360) and which may cause harm to breastfed children (Lact.; H362).

In relation to aquatic toxicity, RAC also decided to classify triadimenol as toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411) as was proposed by the UK.

Silver zinc zeolite

The proposed group entry in Annex VI covers 'LTA' framework type zeolite which have been surface-modified with both silver and zinc ions at contents Ag⁺ 0.5%-6%, Zn²⁺ 5%-16%, and potentially with phosphorus, NH₄⁺, Mg²⁺ and/or Ca²⁺ each at levels <3%].

Silver zinc zeolites form a group of silver ion-based biocidal active substances used as antimicrobials for a wide variety of industrial, professional and consumer applications. The group of silver zinc zeolites currently has no entry in Annex VI to CLP.

RAC agreed to Sweden's proposal to classify silver zinc zeolites as irritant to skin (Skin Irrit. 2; H315), as causing serious eye damage (Eye Dam. 1; H318) and as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410), with M=100 for both hazards.

In contrast to Sweden's proposal, RAC did not consider harmonised classifications for specific target organ toxicity and carcinogenicity to be justified.

In relation to reproductive toxicity, RAC also decided on a less severe classification than proposed by Sweden, namely to classify as a suspected developmental toxicant (Repr. 2; H361d).

Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts

Nonadecafluorodecanoic acid (PFDA) is used in the chemicals industry as a lubricant, wetting agent, plasticiser and corrosion inhibitor. The substance and its sodium and ammonium salts do not currently have an entry in Annex VI to CLP.

RAC agreed to Sweden's proposal to classify PFDA and its sodium and ammonium salts as substances which may damage the unborn child and which are suspected of damaging fertility (Repr. 1B; H360Df), which are suspected of causing cancer (Carc. 2; H351) and which may cause harm to breastfed children (Lact; H362).

Medetomidine; (RS)-4-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole

Medetomidine is an antifouling agent registered under the biocidal product type 21. It is also used within the EU as an anaesthetic in veterinary medicine and as an analgesic in human medicine. The substance currently has no entry in Annex VI to CLP.

RAC agreed to the United Kingdom's proposal to classify medetomidine as fatal if swallowed and if inhaled (Acute Tox. 2; H300 and H330), as a substance which may cause drowsiness or dizziness (STOT SE 3; H336) and as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410), with M=1 for the acute and M=100 for the chronic aquatic hazard.

In addition to the proposal by the dossier submitter, RAC also agreed to classify medetomidine as causing damage to eyes (STOT SE 1; H370 (eyes)) and as causing damage to organs through prolonged or repeated exposure (STOT RE 1; H372).

Three cadmium compounds: cadmium carbonate, cadmium hydroxide, cadmium nitrate

The cadmium compounds cadmium carbonate, cadmium hydroxide and cadmium nitrate are used for the production of inorganic and organic compounds and pigments, as laboratory agents, as additives, in batteries/fuels and as components for polymer-matrices, plastics and related preparations.

All three cadmium compounds are currently included in the group entry 048-001-00-5 in Annex VI where they have been assigned harmonised classifications as harmful if swallowed, if inhaled and in contact with skin (minimum classifications) and as very toxic to aquatic life

with long-lasting effects (Aquatic Acute 1 and Aquatic Chronic 1) while no M-factors have been set.

RAC agreed to Sweden's proposal to create separate entries in Annex VI for the three substances, including the existing harmonised classifications from the group entry for acute toxicity (all routes) and aquatic toxicity.

In addition, all three cadmium compounds would be classified as substances which may cause genetic defects (Muta. 1B; H340), which may cause cancer (Carc. 1B; H350) and which cause damage to kidney and bones through prolonged or repeated exposure (STOT RE 1; H372 (kidney, bone)). For cadmium nitrate, RAC also decided to set a specific concentration limit of 0.01% for carcinogenicity.

Hexaflumuron (ISO); 1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea

Hexaflumuron (ISO) is a biocidal active substance which is used as termiticide in confined bait stations. The substance has currently no entry in Annex VI to CLP.

RAC agreed to Portugal's proposal to classify the substance as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410), with M=1 000 for the acute and M=10 000 for the chronic aquatic hazard.

Penthiopyrad; (RS)-N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)pyrazole-4-carboxamide

Penthiopyrad is a pesticide used as a foliar fungicide on pome fruit, tomato, aubergines, cucurbits, cucumbers, courgettes and cereals. The substance currently has no entry in Annex VI to CLP.

RAC agreed to the United Kingdom's proposal to classify penthiopyrad as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1 and Aquatic Chronic 1), with M=1 for both hazards.

Clethodim (ISO); (5RS)-2-[(1EZ)-1-[(2E)-3-chloroallyloxyimino]propyl]-5-[(2RS)-2-(ethylthio) propyl]-3-hydroxycyclohex-2-en-1-one

Clethodim (ISO) is an active substance used in plant protection products. The substance currently has no entry in Annex VI to CLP.

RAC agreed to the proposal by the Netherlands to classify Clethodim (ISO) as harmful if swallowed (Acute Tox. 4; H302), as a skin sensitiser (Skin Sens. 1; H317) and as harmful to aquatic life with long-lasting effects (Aquatic Chronic 3; H412).

On the basis of the dossier submitter's proposal, RAC also decided to assign the supplemental labelling as a substance to which repeated exposure may cause skin dryness or cracking (EUH066).

3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea (Complex Soap TH28)

3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea is used for lubrication or as a lubrication additive. The substance has an existing entry in Annex VI to CLP where it is classified as a skin sensitiser (Skin Sens. 1; H317) and as a substance which may cause long-lasting harmful effects to aquatic life (Aquatic Chronic 4; H413).

RAC agreed with the proposal from Germany to remove the classification as a skin sensitiser from Annex VI to CLP. However, RAC decided to retain the current classification as a substance

which may cause long-lasting harmful effects to aquatic life (Aquatic Chronic 4; H413) whereas Germany had originally proposed to remove this classification from Annex VI.

2,3-epoxypropyl methacrylate (GMA)

2,3-epoxypropyl methacrylate (GMA) is an ester of methacrylic acid and a common monomer used in the creation of epoxy resins. The substance has an existing entry in Annex VI to CLP where it is classified as harmful if swallowed, if inhaled and in contact with skin (minimum classifications for all routes of exposure), as a skin and eye irritant and as a skin sensitiser (Skin Sens. 1; H317). Note D applies.

RAC agreed to the proposal by the Netherlands to classify 2,3-epoxypropyl methacrylate as harmful if swallowed (Acute Tox. 4; H302) and as toxic in contact with skin (Acute Tox. 3; H311) based on data, to remove the classification for acute inhalation toxicity based on data and to classify the substance as causing severe skin burns and eye damage (Skin Corr. 1C and Eye Dam. 1; H314). As the hazard statement H314 already reflects serious damage to eyes, it was also agreed to remove the hazard statement H318 from Annex VI.

RAC further concluded that harmonised classifications as a skin sensitiser (Skin Sens. 1; H317), as a substance which may cause cancer (Carc. 1B; H350), which may damage fertility (Repr. 1B; H360F) and which is suspected of causing genetic defects (Muta. 2; H341) are justified.

As for specific target organ toxicity, RAC decided on classifications as a substance which may cause respiratory irritation (STOT SE 3; H335) and as causing damage to the respiratory tract through prolonged or repeated exposure by inhalation (STOT RE 1; H372 (respiratory tract)(inhalation)). The Netherlands had proposed a classification as causing damage to the respiratory tract by inhalation (STOT SE 1; H370 (respiratory tract) (inhalation)).

9,10-anthraquinone; anthraquinone

Anthraquinone is a high-volume chemical which is mainly used in the paper and pulp industry and as an intermediate for the synthesis of other chemicals. The substance currently has no entry in Annex VI to CLP.

RAC agreed to Germany's proposal to classify anthraquinone as a substance which may cause cancer (Carc. 1B; H350).

Reaction mass of isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n = 5 or 6 isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol (Tinuvin 171/571)

Tinuvin 171/571 is used in coatings. It has a harmonised classification as toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411) in Annex VI to CLP.

RAC did not agree to Germany's proposal to declassify Tinuvin 171/571 and remove the entry from Annex VI to CLP, but concluded that a harmonised classification as Aquatic Chronic 4; H413 was justified.

Further information

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

[Committee for Risk Assessment](#)

[Authorisation under REACH](#)

[Restriction under REACH](#)

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 is available on the ECHA website.