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Annex to a news alert

RAC concludes on 10 scientific opinions for harmonised classification and labelling – ECHA/NA/17/23

Helsinki, 27 September 2017

The Committee for Risk Assessment (RAC) concluded on 10 opinions for harmonised classification and labelling, including cobalt metal, titanium dioxide and metaldehyde. RAC and the Committee for Socio-economic Analysis (SEAC) also agreed on four draft opinions on two applications for authorisation and adopted one final opinion.

Ethylene oxide, oxirane

Ethylene oxide, oxirane is used for polymer production, as an intermediate and as laboratory agent. It is also used in coatings and sealings and as a plant protection product.

It has an existing entry in Annex VI to the CLP Regulation as a flammable gas (Flam. Gas 1; H220), gas under pressure (Press. Gas; H280), toxic via the inhalation route of exposure (Acute Tox. 3*; H331 – minimum classification), skin irritant (Skin Irrit. 2; H315), serious eye irritant (Eye Irrit. 2; H319), a substance which may cause genetic defects (Muta. 1B; H340), a substance which may cause cancer (Carc. 1B; H350), and a substance which may cause respiratory irritation (STOT SE 3; H335).

RAC agreed to the proposal by Austria to add a classification for acute toxicity via the oral route of exposure (Acute Tox. 3; H301), to retain acute toxicity via inhalation (Acute Tox. 3; H331 – confirmation of minimal classification), to add a classification as a substance which causes severe skin burns and eye damage (Skin Corr. 1B; H314 and Eye Dam. 1; H318) and to add classification as a substance that causes damage to the nervous system through prolonged or repeated exposure (STOT RE 1; H372 (nervous system)).

Contrary to the proposal by Austria, RAC did not agree to classify the substance for skin sensitisation and as a substance that may cause drowsiness or dizziness (STOT SE 3; H336). The Committee additionally agreed on classification in category 1B as a substance that may damage fertility and as suspected of damaging the unborn child (Repr. 1 B; H360Fd).

Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl)derivatives

Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivatives are used in the manufacture of plastic products, including compounding and conversion.

The substance does not have an existing Annex VI entry.

RAC agreed to the proposal by the Netherlands to classify the substance as toxic to reproduction that may damage the unborn child (Repr. 1B; H360D).

Acid Black 210 Na

Acid Black 210 Na is used in water-based formulations mainly for industrial leather dyeing as well as in textile and paper formulation.

The substance has an existing entry in Annex VI to the CLP Regulation for serious eye damage (Eye Dam. 1; H318) and for environmental hazards (Aquatic Chronic 3; H412).

RAC agreed to the proposal from Italy to remove the existing classifications based on new information provided in the framework of the REACH Regulation.

Cobalt metal

Cobalt has many uses including as an intermediate and for the production of magnets, varistors, batteries, alloys and catalysts.

The substance has an existing entry in Annex VI to the CLP Regulation for skin and respiratory sensitisation (Skin Sens. 1; H317, Resp. Sens. 1; H314) and for aquatic chronic toxicity (Aquatic Chronic 4; H413).

RAC agreed to the proposal from the Netherlands to additionally classify cobalt for carcinogenicity (Carc. 1B; H350 with a specific concentration limit (SCL) of 0.01 %), for mutagenicity (Muta. 2; H341) and for toxicity to reproduction with regard to effects on sexual function and fertility (Repr. 1B; H360F).

Metalddehyde (ISO)

Metalddehyde (ISO) is an active substance used in plant protection products as a molluscicide for controlling slugs and snails.

The substance has an existing entry in Annex VI to the CLP Regulation as a flammable solid (Flam. Sol. 2; H228) and as harmful via the oral route of exposure (Acute Tox. 4; H302).

RAC agreed to the proposal from Austria to classify the substance as a flammable solid (Flam. Sol. 2; H228), toxic via the oral route of exposure (Acute Tox. 3; H301). After discussion, RAC agreed to classify for reproductive toxicity (Repr. 2, H361f) and not to classify as toxic to specific target organs (oral) through prolonged or repeated exposure (STOT RE 2; H373).

In contrast to the original proposal from Austria, who proposed no classification for hazards to the aquatic environment, RAC agreed to classify the substance for chronic aquatic toxicity (Aquatic Chronic 3; H412).

Halosulfuron-methyl (ISO)

Halosulfuron-methyl (ISO) is an active substance used in plant protection products as a herbicide.

The substance has no existing Annex VI entry.

RAC agreed to the proposal from Italy to classify the substance for aquatic acute and aquatic chronic toxicity (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with an M-factor of 1 000 for both). In addition, contrary to the proposal from Italy, RAC agreed to classify the substance for reproductive toxicity as a substance that may damage the unborn child (Repr. 1B; H360D).

Nickel (II) sulphide [1]; nickel sulphide [2]; millerite [3] and nickel bis(sulfamidate)

Both nickel compounds have existing Annex VI entries to the CLP Regulation for carcinogenicity, mutagenicity and – for nickel bis(sulfamidate) – for toxicity to reproduction.

RAC did not agree to the proposals by Industry, based on read-across to add classifications for acute toxicity via inhalation (Acute Tox. 4; H332) for both nickel compounds in the absence of relevant information for this hazard. RAC supported the proposal from Industry to add classification for acute toxicity via the oral route of exposure for nickel bis(sulfamidate) (Acute Tox. 4;

H302) and additionally agreed on acute toxicity estimates (ATEs) to be used to classify mixtures containing nickel bis(sulfamate).

Dodecyl methacrylate

Dodecyl methacrylate is used to manufacture polymers with applications in lubricant additives, paint resins, floor care products, sizing agents for paper, reactive adhesives and reactive coatings.

It has an existing Annex VI entry to the CLP Regulation as Skin Irrit. 2; H315, Eye Irrit. 2; H319, STOT SE 3; H335 and for environmental hazards (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410).

Based on data registered under REACH, RAC agreed with the proposal from Germany to remove the Skin Irrit. 2; H315, Eye Irrit. 2; H319 and the environmental (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) classifications, but to retain the STOT SE 3; H335 classification.

Titanium dioxide

Titanium dioxide is a high volume inorganic substance manufactured from mineral ores or from iron titanate or titanium slag.

The substance has no existing entry in Annex VI to the CLP Regulation.

At RAC 41, RAC did not agree to the proposal from France to classify the substance in category 1B as presumed to have carcinogenic potential for humans, but agreed to classify titanium dioxide in category 2 as a suspected human carcinogen Carc. 2; H351 (inhalation), i.e. not by the oral or dermal routes. The final RAC opinion was adopted in written procedure before RAC 42.

The opinions will be available on ECHA's website in the near future:

<http://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment>

Background information

The role of the Committee for Risk Assessment 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 ECHA's website at the link below:

<http://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment>