Annex

Annex to news alert ECHA/NA/16/10

Helsinki, 15 March 2016

More information about the adopted opinions

Restriction proposal on octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5)

RAC adopted its opinion, in support of the proposal by the United Kingdom to restrict the placing on the market of D4 and D5. Both substances are high tonnage substances in Europe and have direct uses in personal care products, cosmetics, cleaning products and a wide range of other uses. D4 is a persistent, bioaccumulative and toxic (PBT) substance and D5 is a vvery persistent, very bioaccumulative (vPvB) substance as agreed by the Member State Committee (MSC).

Due to these properties, they have a potential to accumulate in the environment and cause effects that are unpredictable in the long term and are difficult to reverse. The restriction is targeted at the use of D4 and D5 in personal care products that are intended to be used or disposed with water, e.g. shower gels, shaving foams and shampoos. These uses are a major source of these substances to the aquatic environment in the EU.

Applications for authorisation

RAC agreed on three draft opinions on the uses of chromium trioxide in functional chrome plating, functional chrome plating with decorative character, and etching.

RAC also discussed the key issues identified in the 27 applications for authorisation (mainly concerned with chromates) received at the November 2015 submission window.

Proposals for harmonised classification and labelling

Amisulbrom (ISO); 3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)-*N*,*N*-dimethyl-1*H*-1,2,4-triazole-1-sulfonamide

Amisulbrom (ISO) is a pesticidal active substance which is used as a fungicide on grapes and potatoes within the EU. The substance currently has no entry in Annex VI to CLP.

RAC agreed to the proposal by the United Kingdom to classify Amisulbrom (ISO) as a substance which is irritant to eyes (Eye Irrit. 2; H319), which is suspected of causing cancer (Carc. 2; H351) and which is very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410), with M=10 for both aquatic hazards.

Flutianil (ISO); (2*Z*)-{[2-fluoro-5-(trifluoromethyl)phenyl]thio}[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene]acetonitrile

Flutianil (ISO) is a thiazolidine fungicide. The substance currently has no entry in Annex VI to CLP.

RAC agreed to the proposal by the United Kingdom to classify Flutianil (ISO) as a substance which is very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1; H410), with M=100. In contrast to the UK's proposal to classify Flutianil (ISO) for reproductive toxicity, RAC considered that the evidence provided was not robust enough for classification.

Chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol

Chlorocresol is a biocidal active substance. It has an existing entry in Annex VI to CLP, where it is classified as harmful if swallowed and if in contact with skin (Acute Tox. 4*; H302 and H312; minimum classifications), as causing serious eye damage (Eye Dam. 1; H318), as a skin sensitiser (Skin Sens. 1; H317) and as very toxic to aquatic life (Aquatic Acute 1; H400), with no M-factor set.

RAC agreed to the proposal by France to classify chlorocresol as harmful if swallowed (Acute Tox 4; H302), to remove the classification for acute dermal toxicity, to retain the classification as causing serious eye damage (Eye Dam. 1; H318) and for acute aquatic toxicity (Aquatic Acute 1; H400) while adding an M-factor of 1. RAC also agreed to add a classification as irritant to the respiratory tract (STOT SE 3; H335) and as harmful to aquatic life with long-lasting effects (Acute Chronic 3; H412). RAC also agreed to add harmonised classification as corrosive to skin (Skin Corr. 1C; H314). RAC also agreed to amend the classification as a skin sensitiser into Skin Sens. 1B (H317) based on the available data.

Salicylic acid

Salicylic acid has a wide range of industrial uses, including as an intermediate, in the manufacture of resins, separation of salts, tyre manufacturing, in fertiliser formulations and as cleaning agents, as well as consumer uses (in cosmetics and cleaning agents). The substance currently has no entry in Annex VI to CLP.

RAC agreed to the proposal by industry to classify salicylic acid as harmful if swallowed (Acute Tox. 4; H302) and as causing serious eye damage (Eye Dam. 1; H318). RAC agreed to classify salicylic acid as a substance which is suspected of damaging the unborn child (Repr. 2; H361d); the dossier submitter had proposed no classification.

Isoeugenol; racemic mixture of 2-methoxy-4-((E)prop-1-enyl)phenol and 2-methoxy-4-((Z)prop-1-enyl)phenol

Isoeugenol is used as a fragrance and flavouring agent in numerous non-food and food products and as an anaesthetic for fish. The substance currently has no entry in Annex VI to CLP.

Isoeugenol is a racemic mixture of two diastereomers. The proposed Annex VI entry covers the racemic mixture as well as both isomers, i.e. 2-methoxy-4-((E)prop-1-enyl)phenol and 2-methoxy-4-((Z)prop-1-enyl)phenol.

RAC agreed to the proposal by the Netherlands to classify isoeugenol as a strong skin sensitiser (Skin Sens. 1A; H317). RAC also decided to set a specific concentration limit of 0.01%. Therefore, when present at concentrations equal to or greater than 0.001% in a mixture, the name of the substance must be indicated on the label.

Pyroxsulam (ISO); *N*-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide

Pyroxsulam is a member of the triazolopyrimidine sulfonamides, a class of herbicides known to inhibit the plant enzyme acetolacate synthase (ALS). The substance currently has no entry in Annex VI to CLP.

RAC agreed to the proposal by the United Kingdom to classify Pyroxsulam (ISO) as a skin sensitiser (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 M=100 for both aquatic hazard classes.

2-methylisothiazol-3(2*H*)-one (ISO); MIT (ISO)

MIT (ISO) is used as a bactericide and broad-spectrum antimicrobial substance in biocidal products. It currently has no entry in Annex VI to CLP.

RAC agreed to the proposal by Slovenia to classify MIT (ISO) as fatal if inhaled (Acute Tox. 2; H330) and as toxic if swallowed and if in contact with skin (Acute Tox. 3; H301 and H311), as causing severe skin burns and eye damage (Skin Corr. 1B; H314), as a highly potent skin sensitiser (Skin Sens. 1A; H317) with an specific concentration limit (SCL) of 0.0015% (15 ppm), and as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410), with M=10 for the acute and M=1 for the long-term aquatic hazard. RAC also decided to assign the supplemental hazard statement “Corrosive to the respiratory tract” (EUH071).

Reaction mass of 5-chloro-2-methyl-2*H*-isothiazol-3-one and 2-methyl-2*H*-isothiazol-3-one (3:1); C(M)IT/MIT

C(M)IT/MIT is used in biocidal products. It has an existing entry in Annex VI to CLP, where it is classified as toxic if swallowed, if in contact with skin and if inhaled (Acute Tox. 3; H301, H311, H331; minimum classifications), as causing severe skin burns and eye damage (Skin Corr. 1B; H314) with a specific concentration limit (SCL) of 0.6 %, as a skin sensitiser (Skin Sens. 1; H317) with an SCL of 0.0015% (15 ppm), and as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410), with no M-factors set.

RAC agreed to the proposal by France to classify C(M)IT/MIT as fatal if inhaled and if in contact with skin (Acute Tox. 2; H330 and H310), as toxic if swallowed (Acute Tox. 3; H301), to amend the skin corrosion classification to Skin Corr. 1C (H314) while retaining the SCL of 0.6% and to amend the classification as a skin sensitiser to Skin Sens. 1A (H317), retaining the current SCL of 0.0015% (15 ppm). RAC also concurred with the dossier submitter in assigning M-factors of 100 to both the acute and the long-term aquatic classifications as well as the supplemental hazard statement “Corrosive to the respiratory tract” (EUH071) to C(M)IT/MIT.

Further information

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

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

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 at the link below:

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