ECHA
EUROPEAN CHEMICALS AGENCY

Annex

Annex to News alert ECHA/NA/16/30

Helsinki, 21 September 2016

More information about the adopted opinions

Proposals for harmonised classification and labelling

Acetaldehyde; ethanal

Acetaldehyde, while occurring widely in nature, is produced at large industrial scale, e.g. as an intermediate in the production of acetic acid, in the production of cellulose acetate, pyridine derivates, perfumes, paints (aniline dyes), plastics, synthetic rubber and a range of further products. The substance has an existing entry in Annex VI to CLP, where it is classified as extremely flammable liquid and vapour (Flam. Liq. 1; H224), irritant to eyes (Eye Irrit. 2; H319), irritant to the respiratory tract (STOT SE 3; H335) and as a substance which is suspected of causing cancer (Carc. 2; H351).

RAC agreed to the proposal by the Netherlands to assign a more severe classification for carcinogenicity (Carc. 1B; H350) and to classify acetaldehyde also as a substance which is suspected of causing genetic defects (Muta. 2; H341).

Pinoxaden (ISO); 8-(2,6-diethyl-4-methylphenyl)-7-oxo-1,2,4,5-tetrahydro-7H-pyrazolo[1,2-*d*][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropanoate

Pinoxaden (ISO) is a pesticide active substance which is used as a grass-weed control herbicide. The substance currently has no entry in Annex VI to CLP.

RAC agreed to the proposal by the United Kingdom to classify Pinoxaden (ISO) as harmful if swallowed and inhaled (Acute Tox 4; H302 and H332), irritant to eyes (Eye Irrit 2; H319), irritant to the respiratory tract (STOT SE 3; H335), as highly potent skin sensitiser (Skin Sens 1A; H317) and as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 with an M-factor of 1 and Aquatic Chronic 3; H412). In addition to the hazard classes proposed by the Dossier Submitter, RAC decided to assign a harmonised classification as suspected of damaging the unborn child (Repr. 2; H361d).

Tetramethrin (ISO); (1,3-dioxo-1,3,4,5,6,7-hexahydro-2*H*-isoindol-2-yl)methyl 2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate

d-trans-tetramethrin; (1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl (1R-trans)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate

Tetramethrin (ISO) and d-trans-tetramethrin are active substances used in plant protection and in biocidal products. They have currently no entry in Annex VI to CLP.

RAC agreed to the proposal by Germany to classify tetramethrin (ISO) and d-trans-tetramethrin as harmful if swallowed (Acute Tox. 4; H302), as a substance which may cause damage to the nervous system through inhalation (STOT SE 2; H371 (nervous system)(inhalation)) and which is suspected of causing cancer (Carc. 2; H351) 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 100 for both hazards.

2-benzyl-2-dimethylamino-4'-morpholinobutyro-phenone

2-benzyl-2-dimethylamino-4'-morpholinobutyro-phenone (BDMBP) is an industrial chemical. It is used as a photosensitive agent in printing inks, pigmented coatings and photopolymers for imaging applications. BDMBP already has an entry in Annex VI to CLP where it is classified 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 did not agree to the proposal by Industry (BASF SE) to classify BDMBP as suspected of damaging the unborn child (Repr. 2; H361d), but concluded on the more severe classification as a substance which may cause damage to the unborn child (Repr. 1B; H360D).

Pyrocatechol; 1,2-dihydroxybenzene

Pyrocatechol is a chemical intermediate mainly used for the synthesis of other chemicals including pesticides, flavours, and fragrances. The substance has an existing entry in Annex VI to CLP where it is classified as harmful if swallowed and in contact with skin (Acute Tox. 4*; H302 and Acute Tox. 4*; H312; minimum classifications) and as irritant to skin (Skin Irrit. 2; H315) and irritant to eye (Eye Irrit. 2; H319).

RAC agreed to the proposal by France to retain the classifications as skin and eye irritant (Skin Irrit. 2; H315 and Eye Irrit.; H319), to change the minimum classifications to toxic if swallowed and in contact with skin (Acute Tox. 3; H301, Acute Tox. 3; H311) and to add harmonised classifications as suspected of causing genetic defects (Muta. 2; H341) and for carcinogenicity into a more severe category than proposed by France (Carc. 1B; H350).

Maleic anhydride

Maleic anhydride is mainly used for synthesizing e.g. unsaturated polyester resins, coatings, pharmaceuticals, pesticides, lubricating-oil additives and foodstuff additives. The substance has an existing entry in Annex VI to CLP where it is classified as harmful if swallowed (Acute Tox. 4*; H302, minimum classification), as corrosive to skin (Skin. Corr. 1B; H314), as skin sensitiser (Skin. Sens. 1; H317) and as respiratory sensitiser (Resp. Sens. 1; H334).

RAC agreed to the proposal by Austria to retain the classification for acute oral toxicity based on data (Acute Tox. 4; H302), as corrosive to skin (Skin. Corr. 1B; H314) and as a respiratory sensitiser (Resp. Sens. 1; H334). RAC also decided to assign a more severe hazard category for skin sensitisation based on potency (Skin. Sens. 1A; H317) with a specific concentration limit of 0.001% and to add a harmonised classification as a substance which causes damage to the respiratory system through prolonged or repeated exposure through inhalation (STOT RE 1; H372 (respiratory system) (inhalation), as causing serious eye damage (Eye Dam. 1; H318) and a supplementary labelling to indicate corrosivity to the respiratory tract (EUH071). RAC did

not agree to also assign a harmonised classification as STOT RE 2 to reflect damage to the kidney, as was proposed by the Dossier Submitter.

Succinic anhydride

Succinic anhydride is used as a monomer for the production of resins. The substance has an existing entry in Annex VI to CLP where it is classified as harmful if swallowed (Acute Tox. 4*; H302, minimum classification), as irritant to eyes (Eye Irrit. 2; H319) and as a substance which may cause respiratory irritation (STOT SE 3; H335). Specific concentration limits for both irritation hazards are displayed in Annex VI as well.

RAC agreed to the proposal by Austria to retain the classification for acute oral toxicity based on data (Acute Tox. 4; H302). Concurring with the Dopssier Submitter, RAC also decided to assign harmonised classifications as corrosive to skin (Skin Corr. 1; H314), as skin sensitiser (Skin Sens. 1; H317) and as respiratory sensitiser (Resp. Sens. 1; H334) whereas the STOT SE 3 classification for respiratory irritation was removed. RAC finally decided to upgrade the classification for eye effects to serious eye damage (Eye Dam. 1; H318) and to add the supplementary labelling as corrosive to the respiratory tract (EUH071).

Further information

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

http://echa.europa.eu/web/guest/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling

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

Role of SEAC in EU regulatory processes

The committee is responsible for preparing the opinion of the Agency on applications for authorisation and proposals for restrictions. SEAC also prepares opinions on specific questions relating to socio-economic issues and on any other aspects concerning the safety of substances on their own, in preparations or in articles at the Executive Director's request. The final decision 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 SEAC is available on the ECHA website at the link below:

https://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis