20 March 2019

Annex to a news release

RAC concludes on 16 opinions for harmonised classification and labelling and SEAC adopts its opinion on a restriction of substances used in tattoo inks.

Helsinki, 20 March 2019

The Committee for Socio-economic Analysis (SEAC) agreed on one restriction proposal.

Substances used in tattoo inks and permanent make-up

SEAC adopted its final opinion in support of ECHA's proposal (prepared in collaboration with Denmark, Italy and Norway) to restrict the placing on the market and use of tattoo inks and permanent make-up containing a wide range of chemicals, e.g. carcinogens, mutagens, reprotoxicants, sensitisers and irritating substances.

The Committee for Risk Assessment (RAC) adopted 16 opinions on harmonised classification and labelling

1,4-dioxane

The substance 1,4-dioxane is an industrial chemical mainly used as a solvent in the manufacture of other chemicals and as a stabiliser in the transport of halogenated hydrocarbons.

The substance has an existing entry in Annex VI to the CLP Regulation as suspected of causing cancer (Carc. 2; H351).

RAC agreed to the proposal by the Netherlands to classify 1,4-dioxane as a substance that may cause cancer (Carc. 1B; H350). Contrary to the proposal by the Netherlands, RAC did not agree to classify the substance as suspected of causing genetic defects (Muta. 2; H341).

Flumioxazin (ISO); N-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2H-1,4-benzoxazin-6-yl)cyclohex-1-ene-1,2-dicarboximide

The substance flumioxazin (ISO) is an active substance used in plant protection products as a herbicide.

The substance has an existing entry in Annex VI to the CLP Regulation as Repr. 1B; H360D and for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1 with multiplying factor of 1 000 for both endpoints).

RAC agreed to the proposal by the Czech Republic to reduce the concern for developmental toxicity of the substance on the basis of new mechanistic information. RAC agreed to classify flumioxazin (ISO) as a substance suspected of damaging the unborn child (Repr. 2; H361d).

Prothioconazole (ISO); 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione

The substance prothioconazole (ISO) is an active substance used in plant protection products as a fungicide.

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

RAC agreed to the proposal by the United Kingdom to classify prothioconazole as very toxic to

aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (aquatic Chronic 1) with multiplying factors of 10 and 1 respectively.

Thiophanate-methyl (ISO); dimethyl (1,2- phenylenedicarbamothioyl)biscarbamate; dimethyl 4,4'-(o-phenylene)bis(3-thioallophanate)

The substance thiophanate-methyl (ISO) is an active substance used in plant protection products as a fungicide.

The substance has an existing entry in Annex VI to the CLP Regulation for acute inhalation toxicity (Acute Tox. 4*, minimum classification), for skin sensitisation (Skin Sens. 1), for mutagenicity (Muta. 2; H341) and for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1).

RAC agreed to the proposal by Sweden to classify thiophanate-methyl (ISO) as harmful if inhaled (Acute Tox. 4) with an acute toxicity estimate (ATE; inhalation) of 1.7 mg/L for mixtures containing the substance, as a substance that may cause an allergic skin reaction (Skin. Sens. 1) and for hazards to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 10 for both endpoints.

Contrary to the proposal by Sweden, RAC did not agree to classify thiophanate-methyl (ISO) as a substance that may cause genetic defects (Muta 1B; H340), but agreed that the existing classification as suspected of causing genetic defects (Muta 2; H341) was more appropriate. In addition, RAC did not agree to the proposal by Sweden to classify thiophanate-methyl (ISO) as a substance that may cause damage to the thyroid through prolonged or repeated exposure (STOT RE), but instead classified the substance as suspected of causing cancer (Carc. 2; H351).

(RS)-1-{1-ethyl-4-[4-mesyl-3-(2-methoxyethoxy)-o-toluoyl]pyrazol-5-yloxy}ethyl methyl carbonate; tolpyralate

The substance tolpylarate is a new active substance used in plant protection products as a herbicide.

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

RAC agreed to the proposal by the United Kingdom to classify tolpyralate as a substance suspected of causing cancer (Carc. 2; H351), that is suspected of damaging fertility and the unborn child (Repr. 2; H361fd), that may cause damage to the eye through prolonged or repeated exposure (STOT RE 2) and for hazards to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 10 and 100 respectively.

1-isopropyl-4-methylbenzene; p-cymene

The substance p-cymene is an industrial chemical which is also used as an active substance in the plant protection product terpenoid blend QRD-460.

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

RAC agreed to the proposal by the Netherlands to classify p-cymene as flammable liquid (Flam. Liq. 3), as toxic if inhaled (Acute Tox. 3) with an acute toxicity estimate of 3 mg/L (vapour) to classify and label mixtures containing the substance and as a substance that may pose an aspiration toxicity hazard to humans i.e. it may be fatal if swallowed and enters the airways (Asp. Tox. 1).

In addition, RAC classified p-cymene as toxic to aquatic life with long lasting effects (Aquatic Chronic 2) contrary to the proposal by the Netherlands to classify as harmful to aquatic life with long lasting effects (Aquatic Chronic 3).

(R)-p-mentha-1,8-diene; d-limonene

The substance d-limonene is an industrial chemical which is also used as an active substance in the plant protection product terpenoid blend QRD-460.

The substance has an existing entry in Annex VI to the CLP Regulation as flammable liquid (Flam. Liq. 3), as a substance causing skin irritation (Skin Irrit. 2), that may cause allergic skin reaction (Skin Sens. 1) and for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1).

RAC agreed to the proposal by the Netherlands to classify d-limonene as a substance that may pose an aspiration toxicity hazard to humans i.e. it may be fatal if swallowed and enters the airways (Asp. Tox. 1), to modify the existing classifications for skin sensitisation by adding a subcategory (Skin Sens. 1B) and for aquatic environment with long lasting effects (Aquatic Chronic 3). In addition, RAC agreed to add a multiplying factor of 1 for aquatic acute toxicity.

p-mentha-1,3-diene; 1-isopropyl-4-methylcyclohexa-1,3-diene; alpha-terpinene

The substance alpha-terpinene is an industrial chemical which is also used as an active substance in the plant protection product terpenoid blend QRD-460.

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

RAC agreed to the proposal by the Netherlands to classify alpha-terpinene as flammable liquid (Flam. Liq. 3) and as a substance that may pose an aspiration toxicity hazard to humans i.e. it may be fatal if swallowed and enters the airways (Asp. Tox. 1). RAC did not agree to the proposal by the Netherlands to classify the substance for toxicity to reproduction and for acute aquatic hazards.

In addition, contrary to the proposal by the Netherlands, RAC classified alpha-terpinene as harmful if swallowed (Acute Tox. 4) with an acute toxicity estimate (ATE) of 1 680 mg/kg to classify and label mixtures containing the substance. RAC also classified alpha-terpinene as toxic to aquatic life with long lasting effects (Aquatic Chronic 2) contrary to the proposal by the Netherlands to classify as harmful to aquatic life with long lasting effects (Aquatic Chronic 3).

1,2,4-triazole

The substance 1,2,4-triazole is an industrial chemical used as an intermediate and as a fertiliser.

The substance has an existing entry in Annex VI to the CLP Regulation as Acute Tox. 4*, Eye Irrit. 2 and as Repr. 2; H361d***.

RAC agreed to the proposal by Belgium to classify 1,2,4-triazole as harmful if swallowed (Acute Tox. 4) with an acute toxicity estimate (ATE; oral) of 1 320 mg/kg bw to classify and label mixtures containing the substance and agreed to re-classify as a substance that may damage fertility and the unborn child (Repr. 1B; H360FD).

Sedaxane; N-{2-[[1,1'-bi(cyclopropyl)]-2-yl]phenyl}-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide

The substance sedaxane is an active substance used in plant protection products as a fungicide.

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

RAC agreed to the proposal by France to classify sedaxane as suspected of causing cancer (Carc. 2; H351); for effects to aquatic environment as very toxic to aquatic life (Aquatic Acute 1) with multiplying factor of 1 and as toxic to aquatic life with long lasting effects (Aquatic Chronic 2).

Tolclofos-methyl (ISO); O-(2,6-dichloro-p-tolyl) O,O-dimethyl thiophosphate

The substance tolclofos-methyl (ISO) is an active substance used in plant protection products as a fungicide.

The substance has an existing entry in Annex VI to the CLP Regulation as skin sensitiser (Skin Sens. 1) and for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1).

RAC agreed to the proposal by Sweden to modify the existing classification of tolclofos-methyl (ISO) for skin sensitisation by adding a subcategory (Skin Sens. 1B). In addition, RAC agreed to the proposal by Sweden to add multiplying factors of 1 to the aquatic hazard classifications.

Mancozeb (ISO); manganese ethylenebis(dithiocarbamate) (polymeric) complex with zinc salt

The substance mancozeb (ISO) is an active substance used in plant protection products as a fungicide.

The substance has an existing entry in Annex VI to the CLP Regulation as Repr. 2; H361d***, Skin Sens. 1 and for hazards to aquatic environment (Aquatic Acute 1 with an M factor of 10).

RAC agreed to the proposal by the United Kingdom to retain the classification of mancozeb as a substance that may cause an allergic skin reaction (Skin. Sens. 1), and for hazards to aquatic environment (Aquatic Acute 1 with an M factor of 10).

RAC also agreed to the proposal by the United Kingdom to classify mancozeb as a substance that may cause damage through prolonged or repeated exposure to thyroid and nervous system (STOT RE 2), but did not agree to specify the route of exposure for STOT RE 2; and for chronic aquatic hazard (Aquatic Chronic 1) with a multiplying factor of 10, contrary to that of 100 as proposed by the United Kingdom.

RAC also agreed, contrary to the proposal by the United Kingdom, to classify mancozeb as a substance that may damage the unborn child (Repr. 1B; H360D) and in addition, to classify mancozeb as suspected of causing cancer (Carc. 2; H351).

Benzyl salicylate

The substance benzyl salicylate is an industrial chemical used as an ultraviolet absorbing substance in air care products, as a biocides (e.g. disinfectants, pest control products), in perfumes and fragrances, polishes and waxes, and washing and cleaning products.

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

RAC agreed to the proposal by Germany to classify benzyl salicylate as a substance that may cause an allergic skin reaction (Skin. Sens. 1B).

Trinickel disulfide; nickel subsulfide; [1] heazlewoodite [2]

The substance trinickel disulphide is an industrial chemical used in articles, in formulations, and in re-packing at industrial sites and in manufacturing.

The substance has an existing entry in Annex VI to the CLP Regulation as a substance that may cause cancer (Carc. 1A; H350), is suspected of causing genetic defects (Muta. 2; H341), causing damage to organs through prolonged or repeated exposure (STOT RE 1) and that may cause an allergic skin reaction (Skin Sens. 1). It is also classified for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1).

RAC did not agree to the proposal by Industry to re-classify trinickel disulphide as harmful if

inhaled (Acute Tox. 4), but instead agreed to classify as toxic if inhaled (Acute Tox. 3) with an acute toxicity estimate (ATE) of 0.92 mg/L to classify and label mixtures containing the substance.

N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide; pydiflumetofen

The substance pydiflumetofen is an active substance used in plant protection products as a fungicide.

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

RAC agreed to the proposal by France to classify pydiflumetofen for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 1.

In addition, contrary to the proposal by France, RAC classified pydiflumetofen as a substance suspected of causing cancer (Carc. 2; H351) and as suspected of damaging fertility (Repr. 2; H361f).

2-(4-*tert*-butylbenzyl)propionaldehyde; lysmeral

The substance lysmeral is an industrial chemical used as a fragrance.

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

RAC did not agree to the proposal from industry (BASF) to classify the substance as a suspected human reproductive toxicant (category 2), but instead agreed to classify lysmeral as substance that may damage fertility and as suspected of damaging the unborn child (Repr. 1B; H360Fd).

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

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 ECHA's website at the link below:
http://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment

Background information

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 ECHA’s website at the link below:
http://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis