

14 October 2020

Details of adopted CLH opinions – annex to ECHA Weekly communication

RAC adopted 10 opinions on harmonised classification and labelling

Pyridalyl (ISO); 2,6-dichloro-4-(3,3-dichloroallyloxy)phenyl 3-[5-(trifluoromethyl)-2-pyridyloxy]propyl ether (EC -; CAS 179101-81-6)

The substance pyridalyl (ISO) is an active substance used in plant protection products as an insecticide. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by the Netherlands to classify pyridalyl (ISO) as a substance that may cause an allergic skin reaction (Skin Sens. 1; H317), is very toxic to aquatic life (Aquatic Acute 1; H400, M=1000) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=100).

2,4,6-tri-tert-butylphenol (EC 211-989-5; CAS 732-26-3)

The substance 2,4,6-tri-tert-butylphenol is an industrial chemical used in indoor closed systems (e.g. cooling liquids in refrigerators, oil-based electric heaters) and outdoor closed systems (e.g. hydraulic liquids in automotive suspension, lubricants in motor oil and break fluids). The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Belgium to classify 2,4,6-tri-tert-butylphenol as a substance which is harmful if swallowed (Acute Tox. 4; H302, ATE = 500 mg/kg bw), may cause an allergic skin reaction (Skin Sens. 1B; H317) and may cause damage to the liver (STOT RE 2; H373). RAC also concluded it should be classified as a substance which may damage the unborn child (Repr. 1B; H360D) (Belgium had proposed classification in category 2 for this effect).

Pendimethalin (ISO); N-(1-ethylpropyl)-2,6-dinitro-3,4-xylidine (EC 254-938-2; CAS 40487-42-1)

The substance pendimethalin (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 a substance that may cause an allergic skin reaction (Skin Sens. 1; H317) and for hazards to the aquatic environment as very toxic to aquatic life (Aquatic Acute 1; H400) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410).

RAC agreed to the proposal by the Netherlands to add to the classification that the substance is suspected of damaging the unborn child (Repr. 2; H361d). RAC also agreed to add M-factors for the aquatic hazards (Aquatic Acute 1; H400, M=100 and Aquatic Chronic 1; H410; M=10). Contrary to the proposal of the dossier submitter, RAC decided to remove from the existing classification that the substance may cause an allergic skin reaction (Skin Sens. 1; H317).

Ammonium bromide (EC 235-183-8; CAS 12124-97-9)

The substance ammonium bromide is an industrial chemical used as a flame retardant and as a precursor for biocidal active substances. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Sweden to classify ammonium bromide as a substance that causes serious eye irritation (Eye Irrit. 2; H319), may damage fertility and the unborn child

(Repr. 1B; H360FD), may cause harm to breast-fed children (Lact.; H362) and may cause drowsiness or dizziness (STOT SE 3; H336). RAC also concluded that classification as STOT RE 1, H372 with the nervous system as the target organ after repeated exposure was warranted (Sweden had proposed classification in category 2 for this effect). RAC did not agree with the proposal by Sweden to state the thyroid as a target organ after repeated exposure.

Methyl methacrylate; methyl 2-methylprop-2-enoate ; methyl 2-methylpropenoate (EC 201-297-1; CAS 80-62-6)

The substance methyl methacrylate is an industrial chemical with several uses, including as an adhesive and sealant, as a monomer for polymerisation or intermediate in synthesis of other chemicals, manufacturing of acrylic sheets and in the manufacture of resins.

The substance has an existing entry in Annex VI to the CLP Regulation as a highly flammable liquid or vapour (Flam. Liq. 2; H225), as a substance that causes skin irritation (Skin Irrit. 2; H315), that may cause an allergic skin reaction (Skin Sens. 1; H317) and respiratory irritation (STOT SE 3; H335) and note D.

RAC agreed to the proposal by France to add to the existing classifications that methyl methacrylate may also cause allergy or asthma symptoms or breathing difficulties if inhaled (Resp. Sens. 1; H334).

Pyridine-2-thiol 1-oxide, sodium salt; pyrithione sodium; sodium pyrithione (EC 223-296-5; CAS 3811-73-2)

The substance sodium pyrithione is an active substance in biocidal products used against bacteria, moulds, yeast, actinomycetes. It has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Sweden to classify sodium pyrithione as a substance which is harmful if swallowed (Acute Tox. 4; H302, ATE = 500 mg/kg bw), toxic in contact with skin (Acute Tox. 3; H311, ATE = 790 mg/kg bw, instead of the proposed classification as harmful in contact with skin, Acute tox 4), toxic if inhaled (Acute Tox. 3; H331, ATE = 0.5 mg/L (dusts or mists)), causes skin irritation (Skin Irrit. 2; H319), may cause an allergic skin reaction (Skin Sens. 1; H317), causes serious eye irritation (Eye Irrit. 2; H319) and causes damage to nervous system (STOT RE 1; H372) and to add labelling as toxic by eye contact (EUH070). Furthermore, RAC also agreed with the dossier submitter to classify the substance as very toxic to aquatic life (Aquatic Acute 1; H400, M=100) and toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411).

N-(5-chloro-2-isopropylbenzyl)-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazole-4-carboxamide; isoflucypram (EC -; CAS 1255734-28-1)

The substance isoflucypram is an active substance in plant protection products used as a fungicide. It has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by the United Kingdom¹ to classify isoflucypram as a substance which is harmful if inhaled (Acute Tox. 4; H332, ATE = 2.2 mg/L (dusts or mists)), may cause an allergic skin reaction (Skin Sens. 1B; H317), is very toxic to aquatic life (Aquatic Acute 1; H400, M=10) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=1). In addition, contrary to the proposal by the dossier submitter, RAC concluded that classification as a substance suspected of damaging fertility (Repr. 2; H361f) is warranted.

¹ This dossier was declared in accordance on 04/04/2019 after which any active role of the UK as dossier submitter had ceased.

2-(2-methoxyethoxy)ethanol; diethylene glycol monomethyl ether (EC 203-906-6; CAS 111-77-3)

The substance 2-(2-methoxyethoxy)ethanol is an industrial chemical primarily used as an intermediate or industrial processing aid and an additive in aviation fuels. It has an existing entry in Annex VI to the CLP Regulation as suspected of damaging the unborn child (Repr. 2; H361d***).

RAC agreed to the proposal by the Netherlands to modify the classification to a substance which may damage the unborn child (Repr. 1B; H360D, SCL = 3%).

Bisphenol A; 4,4'-isopropylidenediphenol; BPA (EC 201-245-8; CAS 80-05-7)

The substance bisphenol A is an industrial chemical used for the manufacture of plastic products, chemicals and epoxy resins. The substance has an existing entry in Annex VI to the CLP Regulation as a substance that may damage fertility (Repr. 1B; H360F), may cause respiratory irritation (STOT SE 3; H335), skin sensitisation (Skin Sens. 1; H317) and serious eye damage (Eye Dam. 1; H318).

RAC agreed to the proposal by Germany to classify BPA also as very toxic to aquatic life (Aquatic Acute 1; H400, M=1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=10).

Dimoxystrobin (ISO); (2E)-2-{2-[(2,5-dimethylphenoxy)methyl]phenyl}-2-(methoxyimino)-N-methylacetamide; (E)-2-(methoxyimino)-N-methyl-2-[a-(2,5-xylyloxy)-o-tolyl]acetamide (EC -; CAS 149961-52-4)

The substance dimoxystrobin (ISO) is an active substance in plant protection products used as a fungicide. It has an existing entry in Annex VI to the CLP Regulation as suspected of causing cancer (Carc. 2; H351), as suspected of damaging the unborn child (Repr. 2; H361d***) and as harmful if inhaled (Acute Tox. 4*; H332). The substance is also classified for hazards to the aquatic environment as very toxic to aquatic life (Aquatic Acute 1; H400) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410).

RAC agreed to the proposal by Hungary to retain the category 4 classification for acute toxicity via the inhalation route (adding an ATE value of 1.3 mg/L (dusts or mists)) and to add classifications for hazards to the aquatic environment (Aquatic Acute 1; H400, M=100 and Aquatic Chronic 1; H410, M=100). The Committee did not agree with the proposal by Hungary to classify dimoxystrobin as a substance which may cause harm to breast-fed children or which may cause damage to the blood through repeated exposure. However, contrary to the proposal of the dossier submitter, RAC recommended to retain the existing classification for dimoxystrobin (ISO) as suspected of damaging the unborn child (Repr. 2; H361d).

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>