

6 May 2020

Details of adopted CLH opinions on 4 May 2020

cyfluthrin (ISO); α -cyano-4-fluoro-3-phenoxybenzyl-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate

Cyfluthrin (ISO) is an active substance used in biocidal products as an insecticide.

The substance has an existing entry in Annex VI to the CLP Regulation as fatal if swallowed (Acute Tox. 2*) and toxic if inhaled (Acute Tox. 3*) (minimum classifications) and for hazards to the aquatic environment as very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1) with a multiplying factor of 1 000.

RAC agreed to the proposal by Germany to classify cyfluthrin (ISO) as fatal if swallowed (Acute Tox. 2) with an acute toxicity estimate (ATE; oral) of 14 mg/kg bw and fatal if inhaled (Acute Tox. 2) with an acute toxicity estimate (ATE; inhalation) of 0.14 mg/L (for dusts or mists), and as a substance that may cause harm to breast-fed children (Lact.).

Furthermore, RAC agreed to classify the substance as causing damage to the nervous system after single exposure (STOT SE 1). RAC also agreed to retain the classification of Aquatic Acute 1 and Aquatic Chronic 1 and to assign a multiplying factor of 1 000 000 for both.

beta-cyfluthrin (ISO); reaction mass of *rel*-(*R*)-cyano(4-fluoro-3-phenoxyphenyl)methyl (1*S*,3*S*)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate and *rel*-(*R*)-cyano(4-fluoro-3-phenoxyphenyl)methyl (1*S*,3*R*)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate

Beta-cyfluthrin (ISO) is an active substance used in plant protection products as an insecticide.

The substance has an existing entry in Annex VI to the CLP Regulation as fatal if swallowed (Acute Tox. 2*) and fatal if inhaled (Acute Tox. 2*) (minimum classifications) and for hazards to the aquatic environment as very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1).

RAC agreed to the proposal by Germany to classify beta-cyfluthrin (ISO) as fatal if swallowed (Acute Tox. 2) with an acute toxicity estimate (ATE; oral) of 11 mg/kg bw and fatal if inhaled (Acute Tox. 2) with an acute toxicity estimate (ATE; inhalation) of 0.081 mg/L (for dusts or mists), and as a substance that may cause harm to breast-fed children (Lact.).

Furthermore, RAC agreed to classify the substance as causing damage to the nervous system after single exposure (STOT SE 1). RAC also agreed to retain the classification of Aquatic Acute 1 and Aquatic Chronic 1 and to assign a multiplying factor of 1 000 000 for both.

acetamiprid (ISO); (1*E*)-*N*-[(6-chloropyridin-3-yl)methyl]-*N'*-cyano-*N*-methyl-*ylethanimidamide*; (1*E*)-*N*1-[(6-chloro-3-pyridyl)methyl]-*N*2-cyano-*N*1-methylacetamidine

Acetamiprid (ISO) is an active substance in plant protection products used as an insecticide.

The substance has an existing entry in Annex VI to the CLP Regulation as harmful if swallowed (Acute Tox. 4* (minimum classification)) and for hazards to the aquatic environment as harmful to aquatic life with long lasting effects (Aquatic Chronic 3).

RAC agreed to the proposal by the Netherlands to classify acetamiprid (ISO) as toxic if swallowed (Acute Tox. 3) with an acute toxicity estimate (ATE; oral) of 140 mg/kg bw, and also as a suspected human reproductive toxicant by causing adverse effects on development (Repr. 2).

Contrary to the proposal by the Netherlands, RAC did not find the classification of acetamiprid (ISO) as suspected of causing cancer (Carc. 2) warranted. RAC agreed with the dossier submitter regarding acute aquatic hazards, concluding that acetamiprid warrants classification as Aquatic Acute 1, M=10. However, they did not agree with the dossier submitter regarding chronic aquatic hazards and concluded that acetamiprid warrants classification as Aquatic Chronic 1, M=10.

silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide

Silanamine is an active substance in biocidal products used as an insecticide. RAC adopted its opinion on the silanamine dossier, submitted by France, at RAC-51 in December 2019 (by simple majority), which included a conclusion on harmonised classification and labelling as fatal if inhaled (Acute Tox. 2) with an acute toxicity estimate (ATE; inhalation) of 0.45 mg/L.

It was also agreed that ECHA would launch an *ad hoc* consultation on the data not included in the CLH dossier that led to the conclusion on the classification on acute toxicity by inhalation. This consultation was carried out in February 2020 and ECHA decided to re-open the discussion on this endpoint in RAC. The Committee took note of the outcome of the *ad hoc* consultation but decided that this did not change its classification conclusion.

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 RAC in EU regulatory processes

The committee is responsible for preparing scientific opinions related to the risks of chemicals to human health and the environment for the following processes:

- applications for authorisation;
- proposals for restrictions;
- proposals for harmonised classification and labelling; and
- occupational exposure limits (OELs).

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 decisions are taken by the European Commission through a comitology procedure.

Further information:

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