

Nitric acid

Nitric acid is used as a pre-cursor for organic nitrogen compounds and in cleaning products.

Nitric acid already has a harmonised classification in Annex VI to the CLP Regulation as an oxidising liquid, i.e. as a substance which may intensify fire or act as an oxidiser and which causes severe skin burns and eye damage.

RAC agreed with the proposal by Germany to classify nitric acid into a more severe category for oxidising liquids (Oxid. Liq. 2) and as a substance which is fatal if inhaled (Acute Tox. 1). RAC also agreed with Germany to assign supplemental labelling as corrosive to the respiratory tract (EUH 071).

Etridiazole

Etridiazole is used as a fungicide.

Etridiazole already has harmonised minimum ("asterisk") classifications in Annex VI to the CLP Regulation for acute toxicity, i.e. as toxic if inhaled, and as harmful if swallowed and in contact with skin. It also has harmonised classifications as a substance which is suspected of causing cancer and as very toxic to aquatic life with long lasting effects.

RAC agreed with the proposal from the Netherlands to classify etridiazole as a substance which may cause an allergic skin reaction but did not consider a further sub-categorisation warranted (Skin Sens. 1). RAC also confirmed the current harmonised classification as harmful if swallowed (Acute Tox. 4) and agreed to remove the classifications as toxic if inhaled and as harmful if in contact with skin from Annex VI as proposed by the Netherlands. RAC did not consider the evidence sufficient to classify the substance for respiratory irritation.

The Committee re-confirmed the harmonised classification of etridiazole as a substance which is suspected of causing cancer (Carc. 2). Finally, RAC agreed with the dossier submitter to assign an M-factor of 1 to both the acute and the chronic aquatic (Aquatic Acute 1 and Aquatic Chronic 1) classification in Annex VI.

Metosulam

Metosulam is used as a herbicide in agriculture.

The classification and labelling of metosulam has so far not been harmonised at EU level.

RAC agreed with the proposal from France to classify metosulam as a substance which is suspected of causing cancer (Carc. 2) and which may cause damage to organs through prolonged or repeated exposure (STOT RE 2). RAC also agreed with the proposal to classify the substance as very toxic to aquatic life with long lasting effects, assigning an M-factor of 1 000 to acute aquatic and an M-factor of 100 to chronic aquatic effects (Aquatic Acute 1 and Aquatic Chronic 1).

Octanoic acid

Octanoic acid is a linear, unbranched fatty acid, used as an active substance in biocidal and pesticidal products.

The classification and labelling of octanoic acid has so far not been harmonised at EU level.

RAC agreed with the proposal by Austria to classify octanoic acid as a substance which causes severe skin burns and eye damage (Skin Corr. 1C), but decided not to assign specific concentration limits as the available data was insufficient to do so.

As for environmental hazards, RAC agreed to the proposal by Austria to classify the substance as harmful to aquatic life with long lasting effects (Aquatic Chronic 3).

Nonanoic acid

Nonanoic acid is a linear, unbranched fatty acid, used as an active substance in biocidal and pesticidal products.

Nonanoic acid already has a harmonised classification as a substance which causes severe skin burns and eye damage in Annex VI to the CLP Regulation.

RAC agreed to change the classification for irritation/corrosion and classify nonanoic acid for skin and eye irritation. While the agreed classification in relation to skin is the same as proposed by Austria (Skin Irrit. 2), the classification in relation to eyes is less severe (Eye Irrit. 2) than the classification for serious eye damage which had originally been proposed by the dossier submitter (Eye Dam. 1).

As for environmental hazards, RAC agreed to the proposal by Austria to classify the substance as harmful to aquatic life with long lasting effects (Aquatic Chronic 3).

Decanoic acid

Decanoic acid is a linear, unbranched fatty acid, used as an active substance in biocidal and pesticidal products.

The classification and labelling of decanoic acid has so far not been harmonised at EU level.

RAC agreed to classify decanoic acid for skin and eye irritation. While the agreed classification in relation to skin is the same as proposed by Austria (Skin Irrit. 2), the classification in relation to eyes is less severe (Eye

Irrit. 2) than the classification for serious eye damage which had originally been proposed by the dossier submitter (Eye Dam. 1).

As for environmental hazards, RAC agreed to the proposal by Austria to classify the substance as harmful to aquatic life with long lasting effects (Aquatic Chronic 3).

1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear

The substance is used as lubricant in steering fluid and as a plasticiser.

The classification and labelling of 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear has so far not been harmonised at EU level.

RAC agreed to the proposal by Sweden to classify 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear as a substance which may damage fertility and the unborn child (Repr. 1B). RAC also decided to specify the effects on fertility and development explicitly in the hazard statement. This opinion was based on read across of data on reproduction from other C4 to C8 dialkylphthalates, including di-n-hexyl phthalate, which RAC had previously classified as Repr. 1B.

Imazalil

Imazalil is a fungicide intended for post-harvest use on fruits.

The substance already has harmonised minimum ("asterisk") classifications as harmful if swallowed and if inhaled, as seriously damaging to the eye and as very toxic to aquatic life with long lasting effects (Aquatic Acute 1 and Chronic 1), in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Germany to classify the substance as toxic if swallowed (Acute Tox. 3), to delete the acute aquatic classification and to include an M-factor of 10 for the chronic aquatic classification. RAC also agreed with Germany to add a classification as suspected of causing cancer (Carc. 2). Further to the proposal by Germany, RAC confirmed that the substance should be classified as harmful if inhaled (Acute Tox. 4) and as seriously damaging to the eye (Eye Dam. 1).

Tebuconazole

Tebuconazole is a fungicide for foliar and seed treatment applications on a wide range of different crops.

The substance already has a harmonised classification as suspected of damaging the unborn child (Repr. 2), as harmful if swallowed (Acute Tox. 4, minimum classification) and as toxic to aquatic life with long lasting effects (Aquatic Chronic 2).

RAC agreed to the proposal by the Netherlands to upgrade the aquatic classification, i.e. to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Acute 1 and Aquatic Chronic 1) with an acute M-factor of 1 and a chronic M-factor of 10 and to confirm the classification as harmful if swallowed (Acute Tox. 4).

Dimethenamid-P

Dimethenamid-P is composed of two enantiomers; the S-enantiomer is used as a herbicide in plant protection products.

The classification and labelling of dimethenamid-P has so far not been harmonised at EU level.

RAC agreed to the proposal by Germany to classify the substance as a skin sensitiser (Skin Sens. 1), as harmful if swallowed (Acute Tox. 4) and as very toxic to aquatic life with long lasting effects (Aquatic Acute 1 and Aquatic Chronic 1), together with an M-factor of 10 for both acute and chronic aquatic toxicity.

Carvone

Carvone is found naturally in many essential oils. It is composed of two enantiomers, which are used in agriculture as plant growth regulators and as pesticide active substances. Carvone is also used as a flavouring agent in food and in personal care products.

The classification and labelling of carvone has so far not been harmonised at EU level.

RAC agreed to the proposal by the Netherlands to classify the substance as a skin sensitiser (Skin Sens. 1). The Committee agreed not to classify the substance for skin irritation.

Tembotrione

Tembotrione is used as an herbicide against grasses and broad leaved weeds.

The classification and labelling of this substance has so far not been harmonised at EU level.

RAC agreed with the proposal from Austria to classify tembotrione as a substance which may cause an allergic skin reaction (Skin Sens. 1) as well as damage to organs through prolonged or repeated exposure (STOT RE 2). In addition, RAC proposed to classify the substance as suspected of damaging fertility or the unborn child (Repr. 2). RAC also agreed to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1 and Aquatic Acute 1). While RAC supported the proposal to assign an M-factor of 10 to chronic hazards, it increased the proposed M-factor for the acute hazard from 10 to 100.

Flonicamid

Flonicamid is an insecticide used on e.g. potatoes, wheat and apples.

The classification and labelling of this substance has so far not been harmonised at EU level.

RAC agreed with the proposal from France to classify flonicamid as a substance which is harmful if swallowed (Acute Tox. 4). RAC also agreed with the dossier submitter proposal not to classify flonicamid for environmental endpoints. As the conclusion on the discussion on carcinogenicity properties, the RAC decided to not classify this substance as suspected of causing cancer, finding the supporting data insufficiently strong.

Phenolic benzotriazoles (UV-320 and UV-328)

At the request of ECHA's Executive Director, RAC assessed information related to specific target organ toxicity of two phenolic benzotriazoles (UV-320 and UV-328) provided in the SVHC Annex XV dossiers submitted by Germany. RAC adopted an opinion that UV-320 may cause damage to the liver and UV-328 may cause damage to the liver and kidneys through prolonged or repeated exposure (STOT RE2).

The request was triggered by the need of the Member State Committee to assess whether the proposed substances fulfil the criteria of Annex XIII of REACH for a Persistent, Bioaccumulative and Toxic (PBT) substance, recognising that UV-320 and UV-328 currently have no entry in Annex VI of the CLP Regulation which would cover specific target organ toxicity.