Annex to a news alert

RAC agrees on two opinions on occupational exposure and discusses 11 harmonised classification cases ECHA/NA/17/15

Helsinki, 14 June 2016

The Committee for Risk Assessment (RAC) adopted 10 opinions on harmonised classification and labelling, and agreed on 14 draft opinions and adopted nine final opinions on applications for authorisation.

Harmonised classification and labelling

N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (DTPA-H5), pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo) pentaacetate (DTPA-Na5), pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5), Diethylenetriaminepentaacetic acid and its Na and K salts (DTPA-H5, DTPA-Na5 and DTPA-K5) are substances used in a wide number of applications and products including in the pulp and paper industries, laundry detergents, cleaners, soaps, and textiles.

None of the three substances has an existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposals by industry to classify them as harmful if inhaled (Acute Tox. 4; H332) and as substances which may cause damage to organs through prolonged or repeated exposure through the inhalation route of exposure (STOT RE 2; H373 (inhalation)). RAC also concurred with industry to assign a harmonised classification as an eye irritant (Eye Irrit. 2; H319) to DTPA-H5 and DTPA-K5.

With regard to toxicity to reproduction, RAC did not agree with the dossier submitter's proposal to classify the three substances as suspected of damaging the unborn child (Repr. 2; H360d), but instead agreed to assign a more severe classification, namely as substances that may damage the unborn child (Repr. 1B; H360D).

Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide is used as a photo initiator. The substance has an existing entry in Annex VI to the CLP Regulation for skin sensitisation (Skin. Sens. 1; H317) and for environmental hazards (Aquatic Chronic 4; H413).

RAC agreed to the proposal by Germany to modify the existing skin sensitisation classification to Skin Sens. 1A; H317. Contrary to the dossier submitter's proposal, RAC agreed to retain the existing environmental classification.

Diisohexyl phthalate (DIHP)

Diisohexyl phthalate (DIHP) does not have an existing Annex VI entry.
The proposal by Sweden was based on hazard data from other 'transitional' phthalates, which have been classified as presumed human reproductive toxicants (Repr. 1B; H360FD).
RAC agreed to the proposal by Sweden to classify DIHP as a substance that may damage

fertility and the unborn child (Repr. 1B; H360FD).

N,N-diethyl-m-toluamide (DEET)

DEET is an active substance used in biocidal products as an insect repellent. It has an existing entry in Annex VI to the CLP Regulation for acute oral toxicity (Acute Tox. 4*; H302) for eye and skin irritation (Eye Irrit. 2; H319, Skin Irrit. 2; H315) and for aquatic hazards (Aquatic Chronic 3; H412).

RAC agreed to the proposal by Sweden to confirm the classification of DEET as harmful if swallowed (Acute Tox. 4; H302) and to remove the existing environmental classification.

Benzo[rst]pentaphene
dibenzo[b,def]chrysene, dibenzo[a,h]pyrene

Dibenzo[rst]pentaphene and dibenzo[b,def]chrysene are polycyclic aromatic hydrocarbons (PAHs). PAHs occur in certain petroleum streams and can therefore be emitted in the atmosphere. It is also present in elastomer/rubber materials, and potentially also in plastics, lacquers/varnishes, or coatings. None of the two substances has an existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Germany to classify benzo[rst]pentaphene and dibenzo[b,def]chrysene as substances suspected of causing genetic defects (Muta. 2; H341) and substances that may cause cancer (Carc. 1B; H350).

4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH_4Cl), pentachlorophosphorane and phenol

The substance has an existing Annex VI entry as Aquatic Chronic 4; H413.

RAC agreed to the proposal by Germany to remove the existing environmental classification.

Fludioxonil (ISO)

Fludioxonil (ISO) is an active substance used in biocidal products. It does not have an entry in Annex VI to the CLP Regulation. Thus in accordance with Article 36(2) of CLP all hazard classes needed to be assessed.

RAC agreed to the proposal by Denmark to classify fludioxonil (ISO) as very toxic to aquatic life with long lasting effects except that the chronic M-factor was agreed to be M=10 instead of M=1 (Aquatic Acute 1; H400, M=1 and Aquatic Chronic 1; H410, M=10).

Titanium dioxide

Titanium dioxide is a high volume inorganic substance manufactured from mineral ores or from iron titanate or titanium slag.

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

RAC concluded that the available scientific evidence meets the criteria in the CLP Regulation to classify titanium dioxide as a substance suspected of causing cancer through the inhalation route (Carc. 2; H351 (inhalation)). The opinion will be formally adopted later by written procedure or at the September meeting.

Applications for authorisation

RAC continued its work on 12 applications for authorisation. The committee agreed in total on 14 draft opinions on the uses of chromium (VI) substances, 1,2-dichloro-ethane (EDC), bis(2-methoxyethyl) ether (diglyme) and 2,2'-dichloro-4,4'-methylene-dianiline (MOCA).

According to the REACH Regulation, the agreed draft opinions will be sent to the applicants for comments before final adoption.

The committee also finalised its work on one application for authorisation by adopting the opinion on the use of diglyme as a process solvent in the manufacture of an intermediate for an active pharmaceutical ingredient (API) (application submitted by ISOCHEM).

In between the March and May/June 2017 plenary meetings, the committee adopted eight opinions on four applications for authorisation on the uses of chromium (VI) substances and EDC. In these cases, the applicants did not wish to comment on the draft opinions of the committees, which were agreed earlier in 2017.

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