Annex to a news alert ECHA/NA/16/37

Helsinki, 13 December 2016

Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) adopted 19 final opinions for recommending authorisation:

Brenntag UK Ltd (lead applicant with two other co-applicants) on the uses of sodium dichromate:

- In the formulation of mixtures,
- For surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites and sealings of anodic films,
- For the electrolytic passivation of tin plated steel for the packaging industry.

Brenntag UK Ltd on the uses of potassium dichromate:

- In the formulation of mixtures,
- For surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealings of anodic films.

Henkel AG & Co. KGaA (lead applicant with another co-applicant) on the uses of dichromium tris(chromate):

- In the formulation of mixtures,
- For surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealings of anodic films.

AKZO Nobel Car Refinishes B.V. (lead applicant with nine other co-applicants) on the uses of strontium chromate:

- In the formulation of mixtures,
- On application of paints, primers and specialty coatings containing strontium chromate in the construction of aerospace and aeronautical parts, including aeroplanes / helicopters, spacecraft, satellites, launchers, engines, and for the maintenance of such constructions.

PPG Industries (UK) Ltd (lead applicant with four other co-applicants) on the uses of potassium hydroxyoctaoxodizincatedichromate:

- In the formulation of mixtures,
- In paints, in primer, sealants, and coatings (including as wash primers).

Robert Bosch GmbH on the use of acids generated from chromium trioxide and their oligomers:

- In hard chrome plating for gasoline and diesel injection applications.

Federal Mogul Burscheid GmbH on the use of chromium trioxide:

- In functional chrome plating of piston rings for automotive engines as applied in the segments light vehicle petrol, light vehicle diesel, middle range diesel and heavy duty.

Federal-Mogul Friedberg GmbH on the use of chromium trioxide:

- In functional chrome plating of piston rings for two-stroke and four-stroke large bore engines as applied in the industrial sectors construction and industry, power generation, railway and maritime.

Federal-Mogul Valvetrain GmbH on the use of chromium trioxide:

- In functional chrome plating of valves for the use in petrol and diesel engines for light- and heavy duty vehicles.

Akzo Nobel Pulp and Performance Chemicals AB on the uses of sodium dichromate:

- As an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of sodium chlorate with or without subsequent production of chlorine dioxide,

- As an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of potassium chlorate.

ARKEMA FRANCE on the use of sodium dichromate:

- As an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of sodium chlorate with or without subsequent production of chlorine dioxide or sodium chlorite.

CROMOMED S.A. (lead applicant with four other co-applicants) on the use of chromium trioxide:

- In functional chrome plating.

Committee for Risk Assessment (RAC) adopted 11 opinions on harmonised classification and labelling:

1-vinylimidazole

1-vinylimidazole is used in industrial settings as a monomer for further polymerization. The polymerized products serve as lubricants, coating additives and emulsifiers. 1-vinylimidazole does currently not have an entry in Annex VI to CLP.

RAC agreed to the proposal by BASF to classify 1-vinylimidazole as a substance which may damage the unborn child (Repr. 1B; H360D). Further to the Dossier Submitter's proposal, the Committee also decided to assign a specific concentration limit of 0.03%.

Colecalciferol (cholecalciferol, vitamin D3)

Colecalciferol is intended to be used in the context of Regulation (EC) No 528/2012 as a new

biocidal active substance under Directive 98/8/EC for use as rodenticide (Product type 14).

Colecalciferol already has an entry in Annex VI to CLP where it is classified as Acute Tox. 3* (H301 and H311; minimum classifications), Acute Tox. 2* (H330; minimum classification) and as STOT RE 1 (H372**).

RAC agreed to the proposal by Sweden to classify colecalciferol as fatal if swallowed, if inhaled and in contact with skin (Acute Tox. 2; H300, 310, 330), and as causing damage to organs through prolonged or repeated exposure (STOT RE 1; H372), but with a specific concentration limit of 3% which is higher than the limit proposed by Sweden. In deviation to the Dossier Submitter's proposal, RAC did not consider that classifications for germ cell mutagenicity and carcinogenicity were justified.

Mesosulfuron-methyl; methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl] sulfamoyl}-4-{[(methylsulfonyl)amino]methyl}benzoate

Mesosulfuron-methyl is used as a sulfonylurea herbicide for post-emergence use in cereals (soft and durum wheat, triticale). The substance does currently not have an entry in Annex VI to CLP. This means that all hazard classes had to be evaluated.

RAC agreed to the proposal by France to classify mesosulfuron-methyl as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) with an M-factor of 100 for both hazards. In relation to human health hazards, the Committee agreed with the Dossier Submitter that the substance does not meet any of the human health hazard classification criteria.

Potassium permanganate

Potassium permanganate is a highly oxidative agent; its primary uses are in control of odour and taste, remove of colour, control of biological growth and remove of iron and manganese. It is used by industrials, professionals and consumers as a laboratory and water treatment chemical in various sectors.

Potassium permanganate has an existing entry in Annex VI to the CLP Regulation as Ox. Sol. 2 (H272), as Acute Tox. 4* (H302; minimum classification) and as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with no M-factors set.

RAC agreed to the proposal by France to add a harmonised classification for reproductive toxicity to the entry in Annex VI. Nevertheless, RAC decided to classify potassium permanganate in a lower category than proposed by France, namely as a substance which is suspected of damaging the unborn child (Repr. 2; H360d). The Committee did not concur with France to classify the substance for effects on fertility.

Propane-1,2-diol

Propane-1,2-diol is, among many other uses, commonly used to produce artificial smoke with generators in theatres, discotheques, emergency trainings or is used as a liquid for vaporisation in electronic cigarettes. The substance does currently not have an entry in Annex VI to CLP.

RAC did not agree to the proposal by Germany to classify the substance as respiratory irritant (STOT SE 3; H335).

Propiconazole (ISO); (2*RS*,4*RS*;2*RS*,4*SR*)-1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1*H*-1,2,4-triazole; Propiconazole (ISO)

Propiconazole (ISO) is a fungicidal active substance. It has an existing entry in Annex VI to the CLP Regulation where it is classified as Acute Tox. 4 * (H302; minimum classification), Skin Sens. 1 (H317) and as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with no M-factors set.

RAC agreed to the proposal by Finland to confirm the classification as harmful if swallowed (Acute Tox. 4; H302) and to assign an M-factor of 1 to both the acute and the chronic aquatic classifications. RAC further agreed to add a harmonised classification for reproductive toxicity to the entry in Annex VI in a higher category than proposed by Finland, namely as a substance which may damage the unborn child (Repr. 1B; H360D).

Reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-({[2-(2-aminobutoxy)ethoxy]methyl}propoxy)but-2-ylamine ("XTJ-568")

XTJ-568 is a polyetherdiamine of high molecular weight. It is designed to be a slower epoxy curing agent than conventional polyetheramines for applications such as fabrication of large composite parts where longer pot life is desirable. The substance does currently not have an entry in Annex VI to CLP.

RAC agreed to the proposal by Belgium to classify XTJ-568 as harmful if swallowed (Acute Tox. 4; H302), corrosive to skin (Skin Corr. 1B; H314) and causing serious eye damage (Eye Dam. 1; H318), as a substance which is suspected of damaging fertility (Repr. 2; H361f). In deviation from the Dossier Submitter's proposal, RAC did not consider that a classification for developmental effects was justified. Beyond the proposal from Belgium, RAC also agreed to assign supplemental labelling with "corrosive to the respiratory tract" (EUH071).

Sodium methyl [(4-aminophenyl)sulphonyl]carbamate; sodium methyl (EZ)-sulfanilylcarbonimidate; asulam-sodium

Asulam-sodium is a pesticide active substance; it is an herbicide which is effective against annual and perennial weeds, both monocotyledons and dicotyledons, and on some perennial pteridophytes. The substance does currently not have an entry in Annex VI to CLP. This means that all hazard classes had to be evaluated.

RAC agreed to the proposal by the United Kingdom to classify the substance as skin sensitiser (Skin Sens 1; H317) and as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410), with an M-factor of 1 for both aquatic hazards.

Spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate]

Spirodiclofen (ISO) is currently (since August 2010) approved as an active substance for authorisation in plant protection products. The substance does currently not have an entry in Annex VI to CLP. This means that all hazard classes had to be evaluated.

RAC agreed to the proposal by the Netherlands to classify Spirodiclofen (ISO) as a substance which may cause cancer (Carc. 1B; H350), which is suspected of damaging fertility (Repr. 2; H361f) and as a substance which may cause damage to organs through prolonged or repeated exposure (STOT RE 2; H373), as a skin sensitiser (Skin Sens. 1B; H317) and as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410) with an M-factor of 10.

Thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl- 1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate

Thifensulfuron-methyl (ISO) (TSM) is an herbicidal active substance. It has an existing entry in

Annex VI to the CLP Regulation where it is classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with no M-factors set.

RAC agreed to the proposal by the United Kingdom to assign an M-factor of 100 to both the acute and the chronic aquatic classifications.

Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate (Uvinul ® T 150)

Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate is predominantly used in cosmetic and personal care products. It has an existing entry in Annex VI to the CLP Regulation where it is classified as Aquatic Chronic 4 (H413).

RAC agreed to the proposal by Germany to remove the current classification from Annex VI.

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 the ECHA website at the link below:

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

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 the ECHA website at the link below:

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