New Classification for Stearic Acid, Cobalt Salt; Resin Acids and Rosin Acids, Cobalt Salts; Naphthenic Acids, Cobalt Salts; Neodecanoic Acid, Cobalt Salt; and Cobalt, Borate Neodecanoate Complexes

Industry Actions for Responsible Assessment and Classification of Cobalt Compounds

The members of the Cobalt Institute (CI) and the Cobalt REACH Consortium (CoRC) have (1) taken the decision to **self-classify** the following substances under the UN Globally Harmonized System for Classification and Labelling of Chemicals (UN GHS) as specific target organ toxicants following repeated exposure (**STOT RE 1 (GI Tract); H372**) and (2) taken the decision to remove previous interim Repr. 2; H361f self-classifications[1] where appropriate:

• Stearic acid, cobalt salt	EC No. 237-016-4; CAS No. 13586-84-0
	EC No. 213-694-7; CAS No. 1002-88-6
• Resin and rosin acids, cobalt salts	EC No. 273-321-9; CAS No. 68956-82-1
• Naphthenic acids, cobalt salts[1]	EC No. 263-064-0; CAS No. 61789-51-3
	EC No. 285-220-7; CAS No. 85049-49-6
• Neodecanoic acid, cobalt salt[1]	EC No. 248-373-0; CAS No. 27253-31-2
	EC No. 257-798-0; CAS No. 52270-44-7
• Cobalt, borate neodecanoate complexes[1]	EC No. 270-601-2; CAS No. 68457-13-6

with the following comments,

- Using the UN GHS mixture rules, it is not foreseen to implement a specific concentration limit. Instead, the generic concentration limit should apply, resulting in all mixtures containing ≥ 10% of the above cobalt compounds carrying the same STOT RE 1 (H372) classification and all mixtures containing ≥ 1% carrying a STOT RE 2 (H373) classification.
- Companies are responsible for their own self-classification, labelling and communication within their supply chains (e.g. Safety Data Sheets), as appropriate for their products.

An updated self-classification table for these substances is listed at the end of this document.

BACKGROUND

There are 12 cobalt substances registered by the CoRC under the EU REACH[2] Regulation that are chemically defined as 'inorganic cobalt substances with organic ligands' and are collectively known as the 'cobalt carboxylates'. Of these substances, five are considered to have 'long-chain' organic ligands – defined as a straight chain length of more than six carbons, with measured or predicted surface activity. These five long-chain cobalt carboxylates (named

[1] The removal of the Repr. 2; H361f self-classifications relates to these substances; the other substances of this list were not classified as Repr.2; H361f.
[2] Registration, evaluation, authorisation and restriction of chemicals.

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in this classification update) were placed in a separate read-across group, as repeated-dose oral toxicity studies indicate that the most sensitive toxicological effect of these compounds is severe irritation of the gastrointestinal (GI) tract.

An evaluation of the available repeated-dose toxicity data for this group was performed, in which toxicity study effect levels were compared to the EU CLP[3] regulation classification criteria for specific target organ toxicity after repeated exposure. It was determined that the substances listed in this classification update fit the criteria for classification as STOT RE category 1, based on severe GI tract irritation observed in repeated dose toxicity studies and use of recommended guidance values (taking into account duration of exposure and dose that produced the effect).

In addition, of the five substances listed in this self-classification update, three of these (cobalt salts with naphthenic and neodecanoic acids and borate neodecanoate complexes), had interim self-classifications as Repr. 2; H361f, which are no longer considered appropriate. Repeated exposure to these substances, at levels which will deliver the Co ion in doses known to cause adverse effects on male fertility, is predicted to cause severe GI tract-related morbidity. There are four guideline compliant screening level studies (3 OECD 422 and 1 OECD 407) on substances of this group, with negative findings for reproductive toxicity at MTD (maximum tolerated dose[4]) – lending further support that reproductive toxicity is not exerted by these substances in the absence of other toxic effects (GI-tract related morbidity).

As a result of these considerations, the members of the CI and CoRC have taken the decision to self-classify stearic acid, cobalt salt; Resin acids and Rosin acids, cobalt salts; naphthenic acids, cobalt salts; neodecanoic acid, cobalt salt; and cobalt, borate neodecanoate complexes as **STOT RE 1 (GI tract); H372**. In addition, the members of the CI and CoRC have taken the decision to remove the self-classification of Repr. 2; H361f from naphthenic acids, cobalt salts; neodecanoic acid, cobalt salts; and cobalt, borate neodecanoate complexes.

Substance	**Self-Classifications**
Stearic acid, cobalt salt	STOT RE 1; H372, Skin Sens. 1; H317, Aquatic Chronic 3; H412
Resin acids and Rosin acids, cobalt salts	Self Heat. 2; H252, STOT RE 1; H372, Skin Sens. 1A; H317, Resp. Sens. 1B; H334, Aquatic Chronic 3; H412
Naphthenic acids, cobalt salts	STOT RE 1; H372, Skin Sens. 1; H317, Aquatic Chronic 3; H412
Neodecanoic acid, cobalt salt	STOT RE 1; H372, Skin Sens. 1; H317, Acute Tox. 4; H302, Aquatic Chronic 3 ; H412
Cobalt, borate neodecanoate complexes	STOT RE 1; H372, Eye Irrit. 2; H319, Skin Sens. 1; H317, Acute Tox. 4; H302, Aquatic Acute 1 ; H400 (M=1), Aquatic Chronic 2; H411

October 2018

[3] Classification, labelling and packaging
[4] MTD is generally defined as the highest dose to produce toxic effects without causing death, and at which decreases in body weight gain of no more than 10% relative to the controls are observed.

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