

EU Classification of Co metal as from 1 October 2021

October 2021 – Corrigendum2

Nature of correction in Corrigendum 1: Footnote 2 in Self-classification line of Human Health Classification table has been added following a response received from the ECHA Helpdesk on 20 October.

Nature of correction in Corrigendum 2: Specification that the Repr. 2 (H361d2) is an addition to the Harmonized classification, resulting in the overall reproductive toxicity classification of Repr. 1B (H360Fd).

Following the review of the harmonized classification applicable to Cobalt (Co) metal in the 14th Adaptation to Technical Progress (ATP) to the EU Classification, Labeling and Packaging (CLP) Regulation, the Co metal EU REACH registration file was updated to reflect the new harmonized human health classification and the related hazard statements. These are: Carcinogenicity 1B (H350) ‘all routes’, Mutagenicity 2 (H341), and Reproductive toxicity 1B (H360F). The latter is completed with the following Industry self-classification: Reproductive toxicity 2, H361 (developmental).

The overall **HUMAN HEALTH CLASSIFICATION** for **Cobalt metal**, including harmonized classification endpoints and Industry self-classifications for those endpoints where no (complete) harmonized classification exists in Annex VI of CLP, is now:

| | Massive (≥ 1 mm) | Non-Respirable Powder (< 1 mm) | Respirable Powder¹ |
|---|---|--|--|
| Harmonized classification (Annex VI of CLP and REACH Dossier) | <ul style="list-style-type: none"> • Resp. Sens. 1 (H334) • Skin Sens. 1 (H317) • Carc. 1B (H350) “all routes” • Muta. 2 (H341) • Repr. 1B (H360F²) | <ul style="list-style-type: none"> • Resp. Sens. 1 (H334) • Skin Sens. 1 (H317) • Carc. 1B (H350) “all routes” • Muta. 2 (H341) • Repr. 1B (H360F²) | <ul style="list-style-type: none"> • Resp. Sens. 1 (H334) • Skin Sens. 1 (H317) • Carc. 1B (H350) “all routes” • Muta. 2 (H341) • Repr. 1B (H360F²) |
| Additional self-classification endpoints or self-classification endpoints derived based on evidence not reflected in the harmonized classification (in EU REACH dossier) | Harmonized classification complemented with: <ul style="list-style-type: none"> • Resp. Sens. 1B (H334) • Acute Tox. 4 (H302) • Repr. 2 (H361d²) | Harmonized classification complemented with: <ul style="list-style-type: none"> • Resp. Sens. 1B (H334) • Eye Irrit. 2 (H319) • Acute Tox. 4 (H302) • Repr. 2 (H361d²) | Harmonized classification complemented with: <ul style="list-style-type: none"> • Resp. Sens. 1B (H334) • Eye Irrit. 2 (H319) • Acute Tox. 4 (H302) • Acute Tox 1 (H330) • Repr. 2 (H361d²) |

¹ Only applicable to Co metal powder containing ≥ 0,01% w/w respirable size powder, following the Size Weighted Relevant fine Fraction (SWeRF) calculation.

² The “d” is added from the Repr. 2 (H316d) self-classification. According to the ECHA Helpdesk, adding the “d” is not a deviation from the harmonised classification because the absence of the “d” amounts to no classification for developmental toxicity and “no classification” is not a harmonised classification. The overall resulting reproductive toxicity classification is Repr. 1B (H360Fd).

Following this revised **CMR** classification, according to Appendices 2 and 6 of EU REACH Annex XVII, please note that:

- **Co metal shall not be placed on the market**, or used, as a substance, as a constituent of other substances, or, in mixtures, **for supply to the general public when the individual concentration of Co metal in the substance or mixture is $\geq 0,1$ %**.
- Suppliers shall ensure before the placing on the market that the packaging of such Co metal containing substances and mixtures is marked visibly, legibly and indelibly as follows: ***'Restricted to professional users'***.

As regards the **ENVIRONMENTAL CLASSIFICATION** for **Co metal**, there is one unique harmonized classification applicable to both massive and powder forms of Co metal, and two different Industry self-classifications, one for the massive form of Co metal, and one for its powder form:

| | Massive (≥ 1 mm) | Respirable and Non-Respirable Powder (< 1 mm) |
|---|---|---|
| Harmonized classification (Annex VI of CLP and REACH Dossier) | Aquatic Chronic 4, no M-Factor | Aquatic Chronic 4, no M-Factor |
| Additional self-classification endpoints or self-classification endpoints derived based on evidence not reflected in the harmonized classification (in EU REACH dossier) | Aquatic Chronic 3, no M-Factor (H412) | Aquatic Acute 1 (M-Factor = 10) (H400) Aquatic Chronic 1 (M-Factor = 1) (H410) |

The self-classifications deviate from the harmonized classification. Based on external legal advice, the CI recommends companies placing Co metal as a substance or in mixtures on the **EU market** to:

- implement the classification as provided in Annex VI of the CLP regulation (harmonized classification);
- provide safety recommendations based on the more severe self-classification in the following sections of the extended Safety Data Sheet (eSDS): 2.3. Other hazards, 6.2. Environmental precautions, 7. Handling and storage, 12. Ecological information, and 16. Other information; and
- communicate these more conservative risk management measures for each use also via the tailored exposure scenarios attached to the eSDS, as applicable.

Please note that eSDS supplied by EU REACH registrants of Co metal should normally comply with the above recommendations.

When supplying **Co metal containing mixtures or alloys** to the **EU market**, when there is **insufficient data on the mixture itself** to classify the mixture, two approaches are possible:

- When there is **sufficient** hazard and/or classification data on the individual components **and** on similar mixtures: Bridging principles (including the dilution approach, which, if applicable, allows for classification equivalent to the original tested mixture or substance)
- When there is **sufficient** hazard and/or classification data on the components of the mixture: Summation method

Note that in the above two methods, when supplying the EU market, harmonized classifications should be used, where applicable, for the components of the mixture, including for Co metal.

More information on these two possible approaches is available in the ECHA Guidance on the Application of CLP criteria (Figure 4.1.2 on page 528 in version 5.0 – July 2017 of the Guidance) available at: https://echa.europa.eu/documents/10162/2324906/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5.

Please note that when following the summation method, the resulting classification for the mixture may result in **no classification** for any environmental endpoint, in which case the mixture would be supplied without the proper hazard and precautionary statements (e.g., H413: May cause long lasting harmful effects to aquatic life and P273: Avoid release to the environment). Although this may be legally compliant, it could go against liability and best/duty of care practice.

To ensure proper protection of the environment, in the EU or elsewhere, it is recommended to communicate the relevant self-classification-based safety recommendations, when these are more stringent than those from any mandatory classification, and as allowed by applicable legislation.