

## Cobalt metal harmonised classification

### CLP 14<sup>th</sup> ATP

#### Q & A

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## What is the new harmonised EU classification of cobalt metal?

The 14<sup>th</sup> Adaptation to Technical Progress (14<sup>th</sup> ATP) to the EU CLP Regulation updates the existing harmonised EU classification of Co metal with the following endpoints:

- carcinogenicity category 1B – presumed human carcinogen (proven in animals)
  - hazard phrase H350; for all routes of exposure (inhalation, oral, dermal)
- mutagenicity category 2 – suspected of causing genetic defects
  - hazard phrase H341
- reproductive toxicity category 1B – presumed human reproductive toxicant
  - hazard phrase H360F; effects on fertility

The harmonised classification applies to all physical forms of Co metal (i.e. massives, granules and powders). The full updated entry is shown in Table 1 below. All manufacturers, importers and downstream users of Co metal and Co-containing alloys in the EU must classify, label and package accordingly, to communicate the hazards and help ensure a high level of protection of human health and the environment throughout the supply chain.

Table 1. Full harmonised EU classification of Co metal (all physical forms).

Index No	Chemical name	EC No	CAS No	Hazard class and Category Code(s)	Hazard Statement Code(s)	Suppl. Hazard statement Code(s)	Pictogram, Signal Word Code(s)	SCLs, M-factors and ATEs
027-001-00-9	cobalt	231-158-0	7440-48-4	Carc 1B Muta 2 Repr 1B Resp Sens 1 Skin Sens 1 Aq Chronic 4	H350 H341 H360F H334 H317 H413		GHS08 Dgr	<b><i>[Interim GCL for carcinogenicity; 0.1 %]</i></b>

## From when does the new harmonised classification apply?

The 14<sup>th</sup> ATP was published in the EU's Official Journal on 18<sup>th</sup> February 2020, and entered into force on 9<sup>th</sup> March. The provisions of the ATP will apply from 1<sup>st</sup> October 2021, from which date Co metal and alloys containing Co metal must be classified, labelled and packaged according to the harmonised EU classification. However, companies may already classify, label and package Co metal according to the ATP prior to 1<sup>st</sup> October 2021.

## **Is cobalt metal now a Substance of Very High Concern (SVHC)?**

No, Co is not automatically listed as an SVHC. The identification of a substance as an SVHC is instigated by an EU Member State submitting an Annex XV dossier to ECHA. Any proposal to list a substance as an SVHC should be preceded by a comprehensive risk management options analysis (RMOA) which demonstrates that this is the most appropriate approach to address any risks that the substance poses to human health and/or the environment.

## **Is there now a restriction on sale of cobalt metal to the general public?**

Yes, Co metal will become subject to the restriction on the sale of carcinogenic, mutagenic or toxic to reproduction (CMR) substances to the general public as set out in REACH Annex XVII provisions 28-30. The European Commission will issue a Regulation adding Co metal to the lists of substances that are classified as carcinogenic category 1B (Appendix 2) and toxic to reproduction category 1B (Appendix 6) and subject to these provisions. From 1<sup>st</sup> October 2021, Co metal will no longer be allowed to be placed on the market on its own or in alloys (above the concentration limits in Table 3 below) for supply to the general public and must be labelled as 'Restricted to professional users'. However, articles containing Co metal are not subject to this restriction, nor is the supply of Co metal or alloys for professional use.

## **Will cobalt metal be added to the proposed restriction on cobalt salts?**

No, Co will not be added to the proposed REACH restriction, which is currently undergoing discussion at ECHA's Committee for Risk Assessment (RAC) and Committee for Socio-Economic Assessment (SEAC). As with the identification of a substance as an SVHC, any proposal to restrict the marketing and use of Co metal, and to place it on REACH Annex XVII, needs to be preceded by a comprehensive RMOA which demonstrates that this is the most appropriate approach to address any risks that the substance poses to human health and/or the environment.

## **Did cobalt metal have a harmonised classification previously?**

Yes, the classification of Co metal was previously harmonised under the EU's predecessor to CLP, the Dangerous Substances Directive (67/548/EEC). Co metal was previously classified by this Directive for respiratory and skin sensitisation (both category 1), and chronic aquatic toxicity (category 4), and these classifications were transposed into the Annex VI entry when CLP was adopted in 2008. The classifications for these endpoints have not changed.

## Does the cobalt industry agree with the harmonised classification?

No, not with all aspects of the classification. Of particular note, there is a concern about the designation of the carcinogenicity classification (Carc 1B) to all routes of exposure. It is correct that Co metal powder is carcinogenic following inhalation exposure in rodents, leading to tumours in the lung. The classification Carc 1B (inhalation route) is therefore supported by data. There are however no data indicating that non-inhalable Co metal would be carcinogenic following oral or dermal exposure. Although there were some systemic tumours following the inhalation exposure to Co metal, these are not considered relevant for human hazard assessment by the cobalt industry. Furthermore the animals were exposed to Co metal powder in whole body inhalation chambers, where exposure to the fur and skin occurs, as well as significant exposure to the whole gastrointestinal (GI) tract following grooming. Despite these exposures, there were no skin or GI tract tumours, supporting the interpretation that Co metal powder is an inhalation carcinogen only.

The “all routes” carcinogenicity is a presumed, and not a known, hazard. The CLP text foresees that the assumption of carcinogenicity by all exposure routes must be made, unless there is a negative carcinogenicity study showing that Co does not cause cancer following oral (or dermal) exposure. The legal text states: “In certain instances, route-specific classification may be warranted, if it can be conclusively proved that no other route of exposure exhibits the hazard.” The Co industry (CI) is committed to carry out an oral carcinogenicity study to fill this knowledge gap (see below, “What is the cobalt industry doing to address the classification?”)

There are also concerns about the classification of Co metal as mutagenic (category 2). Only a few older studies, not conducted according to the guidelines for mutagenicity testing, have shown that the Co ion has direct toxic effects to genetic material (mutagenic effects). These effects occurred following non-relevant routes of exposure (injection) or in study designs no longer considered suitable to detect mutagenicity. Industry is taking the concern of mutagenicity very seriously and has conducted a whole range of studies following modern laboratory procedures and OECD guidelines for testing this particular endpoint. These data have been reviewed by the OECD in the CoCAM Programme ([OECD Existing Chemicals Database](#)) and have been published ([Kirkland et al, 2015](#)), with further state-of-the-art tests investigating the genotoxicity and mutagenicity of many Co compounds currently being written up for publication. These studies have unanimously shown that Co metal and the Co ion are not mutagenic.

## What is the cobalt industry doing to address the classification?

### Carcinogenicity (Carc 1B, all routes)

The precautionary classification of Co metal as carcinogenic by “all routes” highlights a knowledge gap regarding the carcinogenicity of Co following oral or dermal exposure, and necessitates the generation of data to answer this question. The Co industry, together with other stakeholders, is currently preparing for the conduct of an oral carcinogenicity study with a highly bioavailable form of Co, and is committed to carrying out this study, should the relevant testing proposal be granted by the EU authorities. This study will enable the Co industry and other stakeholders to answer the question of an “all routes” carcinogenic hazard and risk posed by Co metal.

How will an oral carcinogenicity study help with determining a carcinogenic hazard or risk by the dermal route? This question is being addressed by comparing the bioavailability of Co following oral versus dermal exposure. There are reliable data showing that Co is many orders of magnitude more bioavailable by the oral route, compared with the dermal route of exposure. If Co is not carcinogenic following oral exposure, or has an effect only at high doses, this can be translated to a theoretical dose required by dermal exposure. That way it can be assessed whether a hazard or risk realistically exists by exposure to the skin.

### Mutagenicity (Muta 2)

The database on the genotoxicity of Co following inhalation exposure is also being further improved by generating data on local in vivo genotoxicity following inhalation exposure to Co. This has been highlighted by EU authorities as the last remaining data gap related to the mutagenicity/genotoxicity of Co. Pending approval of a testing proposal by the EU authorities, the Co industry is committed to fill this knowledge gap and generate the relevant data.

## How does self-classification differ from the harmonised entry?

One requirement of the CLP Regulation (Article 4, paragraph 3) is for manufacturers, importers and downstream users to assess the hazard classes that were not covered by the harmonised classification, and to self-classify accordingly.

The evaluations of the hazard properties of Co metal by the EU authorities only addressed the endpoints sensitisation, carcinogenicity, mutagenicity, reproductive toxicity and aquatic toxicity. However CI and CoRC have generated test data for the acute oral toxicity, acute inhalation toxicity, and skin and eye irritation properties of a range of different Co substances, and concluded that Co metal meets the criteria for classification in several of these hazard classes.

All manufacturers, importers and downstream users of Co metal are obliged to self-classify and label with the classifications in Table 2 below, in addition to the harmonised EU classification outlined above.

For some hazard classes, such as acute inhalation toxicity, the effect cannot be caused by some physical forms, therefore industry self-classifies differently for different physical forms.

Table 2. Self-classifications to be applied in addition to the harmonised EU classification.

Massive Co metal	Co powder (non-respirable)	Co powder (respirable)
Acute Tox. 4; H302 (oral)	Acute Tox. 4; H302 (oral) Eye Irrit. 2B; H320	Acute Tox. 4; H302 (oral) Acute Tox. 1; H330 (inh.) Eye Irrit. 2B; H320

## How should cobalt metal be classified in the EU for aquatic toxicity?

The recent evaluation of Co metal by the EU authorities did not cover the aquatic hazard classification, only the carcinogenicity, mutagenicity and reproductive toxicity endpoints. The Aquatic Chronic 4 classification is not new, in fact this was applied under the EU Dangerous Substances Directive (67/548/EEC) as R53, and translated to the CLP Annex VI entry in 2008. This Aquatic Chronic 4 classification is the “safety net” classification, applied to metals for which the soluble salts are hazardous but which do not have “transformation/dissolution” data at the time of evaluation to enable assignment to the appropriate aquatic classification category.

Aquatic classification of metals may be split into “massive” and “powder”, based on particle size, with the cut-off being 1 mm. The CI has generated toxicity data and transformation/dissolution data on both massive Co metal and Co metal powders, and applied the classification criteria to determine the scientifically appropriate classification, which is:

- Massive cobalt metal – Aquatic Chronic 3; H412
- Cobalt metal powder – Aquatic Acute 1; H400 (M = 10)  
Aquatic Chronic 1; H410 (M = 1)

However, in the EU the labels and SDS must be based on the legal Aquatic Chronic 4 classification. CI and CoRC recommend that the appropriate self-classification is also described in the “Other information” section of the SDS, to ensure proper communication of the known hazard of Co metal to the aquatic environment, and that Co metal continues to be packaged and transported appropriately to the relevant self-classifications.

## How should mixtures containing cobalt be classified in the EU?

In the EU, mixtures need to be self-classified based on the content in percent of a hazardous component. For mixtures containing Co metal, the concentration limits in Table 3 apply, above which the mixture as a whole needs to carry the relevant classification:

Table 3. Concentration limits for classification of mixtures containing Co metal.

Endpoint	Category	Mixture concentration limit	Comments
Carc	1B	≥ 0.1 %	This concentration limit, the "Generic Concentration Limit" (GCL) applies ad interim; only until an ECHA expert group has concluded on an appropriate way to calculate the carcinogenic potency of inorganic dusts that are carcinogenic via the inhalation pathway. The current methodology may not be suitable for this exposure route and/or these types of chemicals and is currently being reviewed by the expert group. A conclusion is not expected before end of 2020. If no alternative way to calculate the carcinogenic potency of Co metal is found or developed, then the CLP would implement a "Specific Concentration Limit" (SCL) of 0.01%, as originally proposed by the dossier submitter.
Repr	1B	≥ 0.3 %	
Muta	2	≥ 1 %	
Resp Sens	1	≥ 1 %	
Skin Sens	1	≥ 1 %	
Eye Irrit	2	≥ 10 %	
Acute tox (inhalation)	1	Apply additivity formula in CLP Annex I section 3.1.3.6.1	Industry guidance being developed

## How can bioavailability be taken into account in mixture classification?

Mixtures and alloys (considered “special mixtures” under REACH) need to be self-classified under CLP following the mixture rules, as outlined in the table above. However, there are “Specific cases requiring further evaluation” referred to in Article 12 of the CLP regulation. Article 12 (b) states that such a specific case is a mixture for which “conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable”.

How can such a “special case” be made? If it can be shown that a hazardous component is not biologically available from a certain mixture as from the pure component, it may be possible to assess the hazard of this mixture not based on the nominal content of the hazardous component, but based on its bioavailable concentration. While bioavailability is measured in vivo, the release of the component from the mixture can be measured in vitro (bioaccessibility). Bioaccessibility is a conservative estimate of bioavailability as not all the component that is released will be absorbed and become bioavailable. Thus a “bioaccessible concentration” of a component such as Co metal in a mixture (e.g. alloy) can be calculated based on measurements made using a bioelution protocol. This can indicate whether the matrix of the mixture affects the release of the components. Currently, efforts are under way to obtain an OECD test guideline for the oral bioelution protocol.

In the interim, and without the official OECD guideline, anyone having to self-classify a mixture may make a case that the mixture or individual components of the mixture are not biologically available. This case can be made by collection data on the bioaccessibility of the mixture (or component thereof) and demonstrating that the hazardous component (Co ion) is not detectable in this test.

## Does the new classification affect workplace risk management?

The harmonised EU classification of Co metal already included respiratory and skin sensitisation, which requires minimisation of exposure by inhalation and to skin in the workplace. Furthermore the self-classification of Co metal has included inhalation carcinogenicity since December 2013. However under the EU Carcinogens and Mutagens at Work Directive the new inclusion of the oral route as relevant to the Carc 1B hazard may result in the need for additional risk management measures.

Additionally more substances and mixtures containing Co will now be classified for dermal hazard, as the concentration limit for carcinogenicity (0.1 %) is lower than that for skin sensitisation (1.0 %), triggering the risk management of these dermal hazards in a greater range of workplaces.



## How should cobalt metal be self-classified outside the EU?

The CI and CoRC have evaluated all the available scientific information on the hazard properties of Co metal and other Co substances, and have agreed on the self-classifications for all endpoints covered by the UN Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS). These classifications should be applied by all companies globally (except where local or regional regulations require otherwise), ensuring the communication of the hazards to enable protection of human health and the environment in use, transport and disposal. The latest table of UN GHS self-classifications for Co substances is available on the CI website:

<https://www.cobaltinstitute.org/globally-harmonized-system.html>

## Any further questions on cobalt metal?

Please email us at [hsande@cobaltinstitute.org](mailto:hsande@cobaltinstitute.org), and we will attempt to address your enquiry.