Fact Sheet

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MERAG

Fact Sheet

Metals Environmental Risk Assessment Guidance



Classification: Introduction to the Environmental Classification of Metals and Metal Compounds (Principles and Application)

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Introduction

01



The general strategy for classifying chemical substances, compounds and mixtures for the aquatic environment is a hazard-based approach which takes into account the intrinsic properties (aquatic toxicity, solubility, degradation, and bioaccumulation) of the substance or those of its components (OECD 2001a).

The United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS) and its regional implementation in the EU, the European Union's Classification, Labelling and Packaging (EU CLP[1]) are two important pieces of legislation setting out procedures and guidance on how to determine the correct environmental hazard classification of a substance or mixture of substances through classification schemes that can be used in a straightforward manner.

Environmental aquatic hazard classification focuses on both the short-term (acute) and long-term (chronic) hazards of substances and mixtures. Within these two hazard classes there are several categories, each representing a different level of hazard:

Acute Category 1	Hereafter referred to as Aq.Acute 1.
Acute Category 2	GHS, not CLP[1]; hereafter referred to as Aq.Acute 2.
Acute Category 3	GHS, not CLP[1]; hereafter referred to as Aq.Acute 3.
Chronic Category 1	Hereafter referred to as Aq.Chronic 1.
Chronic Category 2	Hereafter referred to as Aq.Chronic 2.
Chronic Category 3	Hereafter referred to as Aq.Chronic 3.
Chronic Category 4	Hereafter referred to as Aq.Chronic 4.

Under GHS the evaluation of both short-term and long-term aquatic hazard potentials of a metal or metal compound under investigation is achieved using appropriate standard Ecotoxicity Reference Values (ERVs) as determined with a soluble metal salt (Acute and Chronic ERV) and comparison of these ERVs with the classification cut-off values (Acute: 1–100 mg/L ; Chronic: 0.01–1 mg/L).

One of the key principles for the hazards assessment of metals and metal compound is that the aquatic toxicity of a metal is determined by the concentration of soluble metal ion,[2] irrespective of the original metal species/ compound that was released in the aquatic environment. Consequently metal-specific ERVs are typically expressed as µg Me/L, even for those metals that do not occur as a simple ion in solution (eg molybdate, selenite and selenate, vanadate, etc). ERVs expressed as µg Me/L are used as the starting point for the determination of ERVs for metal compounds, using the molecular weight ratio correction ($MW_{compound}/MW_{metal\ ion}$) for translation from ion to compound (UN GHS 2017, Rev.11, p. 524). This translation from metal ion to metal compound, however, is only valid when the counter-ion does not contribute significantly to the overall toxicity. For pure metals (massive, powder), the ERVs expressed as metal ion concentration is equal to the ERV_{metal}.

A number of problems are, however, encountered when trying to use the same methodology (developed for soluble substances) to classify insoluble metals, sparingly soluble metal compounds (SSMC) (OECD, Ottawa Workshop 1995; UN GHS 2025-Rev.11) and Complex Inorganic Materials (CIMs) such as 'More than One Constituent' substances (MOCs) which include Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB), Ores & Ore Concentrates (hereafter called O&C) and special inorganic mixtures like alloys.

1. The CLP is the EU implementation of the UN GHS, though there are some significant differences in the applied environmental classification categories between both regulations, eg Acute 2 and Acute 3 categories have been omitted from the EU-CLP regulation.
2. Or metal ionic species for metals that do not possess a dissolved metal ion as such (eg MeO_4^{3-}).

A correct hazard classification for such materials requires that their chemical and physical specificities are properly considered. Some of these metal-specific properties have already been recognised and addressed in Annexes 9 and 10 of the UN GHS (UN GHS 2025-Rev.11), as well as in regional implementations of this guideline document. For example, the rate and extent to which metals, SSMCs and CIMs can produce soluble ionic and other metal-bearing species in aqueous media are determined using a Transformation/ Dissolution protocol (T/Dp) (OECD No. 29). This test is aimed at evaluating whether the rate and extent of the formation of soluble metal ions are sufficient to be of concern. As such, the T/Dp facilitates estimation of the aquatic toxicity of SSMCs, metals, and CIMs (Annex 10 of the UN GHS 2025, Rev.11). Annex 9 (UN GHS 2025-Rev.11) also provides guidance for classifying hazards based on the Critical Surface Area (CSA) approach. The CSA methodology recognises the main properties of the testing material that will dictate the extent and rate of metal release in a T/Dp test:

— The size and specific surface area of the particles under evaluation.

— The mass or surface area loading of the metal in the test medium.

The CSA concept explains why different particle sizes of the same substance exhibit different release rates and, consequently, may have a different environmental hazard classification.

The derivation of an ERV using species sensitivity distributions, normalisation for bioavailability, metal removal through metal partitioning from the water column and extension of these concepts towards the classification of metallic alloys are some of the new components discussed further in this Fact Sheet. These concepts are not currently covered in the OECD, UN GHS, or EU CLP classification systems. They are however used in practice and could be embedded in future guidance.

The unique chemical properties that need to be taken into account in determining hazard classifications for metals, SSMCs and CIMs such as UVCBs, O&Cs and alloys are outlined in more detail in **Section 3** of this Fact Sheet. More detailed information and guidance on the general principles and methodologies of a number of concepts that are used in this Fact Sheet (eg summation method) can be found in the general guidance provided under EU CLP (2008) and UN GHS (2025, Rev.11). It should be noted that some of the proposed methodologies in this Fact Sheet have not yet been included in existing regulatory guidance documents, and some of the proposed principles will still have to be discussed in a regulatory context with the appropriate regulatory bodies. They can, however, be used for self-classification when proper scientific justification is provided.

Only metal compounds that contain an organic component (organometals) but that dissociate easily in water or dissolve as the metal ion should be treated in the same way as metal compounds and these are therefore covered by this guidance (eg metal acetates and citrates). The strategy for environmental classification of metals and inorganic metal-containing compounds, as outlined in this Guidance Document, accounts for the metal fraction of these readily dissociated organic metal salts. For organic metal compounds that do not dissolve into a metallic and organic component and organometals (ie metal compound containing at least one direct bond between a carbon atom of an organic ligand and the metal atom like metal carboxylates), ecotoxicity potentials are to be evaluated on a case-by-case basis. This assessment also considers potential bioaccumulation or persistence hazards for organometals. Detailed guidance on this topic can be found in the OECD Series on Testing & Assessment No.212 (2015).

This Fact Sheet consists of several sections and annexes:

Section 1	Introduction
Section 2	Classification of Metals and Metal Compounds – General Principles
Section 3	Environmental Hazard Classification of CIMs
Section 4	Classification of CIMs with the Metals Classification Tool (MeClas)
Annex 1	Acute and Chronic ERV Derivation in Accordance with the Principles of the CLP Regulation
Annex 2	Transformation/Dissolution Test Protocol and Implementation for Setting Acute and Chronic Hazard Classes for Metals and Metal Compounds
Annex 3	Critical Surface Area Approach
Annex 4	Characterisation and Identification of CIMs
Annex 5	Classification of CIMs – Summation Method
Annex 6	Classification of CIMs – Substance Approach-Based on Transformation/Dissolution Data

Section 2 provides a concise overview of some of the scientific metal-specific principles that are relevant for a basic understanding for classification of inorganic substances and materials. More detailed in-depth information in these principles is provided in Annexes 1–3.

Section 3 provides a concise overview of some of the challenges that are encountered regarding the environmental classification of CIMs and MOCs, as well as practical schemes and guidance on what to measure (and how to classify). More detailed in-depth information on the procedures and science is provided in Annex 4. At this point in time, current legislation does not always provide sufficiently detailed guidance on how to self-classify CIMs. The main goal of this section is therefore to provide a science-based methodology that takes both existing classification procedures and the specific properties of some of these materials into account.

Section 4 provides additional guidance on how to incorporate the data of your CIM/MOC into MeClas, allowing for an automated calculation of the environmental hazard classification, thereby using the most recent and up-to-date ERVs and harmonised classifications.

Classification of Metals and Metal Compounds – General Principles

02



Implementing the principles underpinning the concepts outlined below is essential for the classification of metals, metal compounds, and the various CIMs and inorganic MOCs.

— Derivation of relevant Acute and Chronic Ecotoxicity Reference Values (ERVs).
— The Transformation/Dissolution test protocol.
— CSA concept.

General Information on each of these concepts is provided in the main body of this document; more detailed information on the concepts is provided in the Annexes of this document. In addition, some of the scientifically sound principles that have not (yet) been embedded in the current legislations, but which are considered to be relevant for the self-classification of metals and metal compounds, are also discussed in this section: 'Environmental transformation', which is the metallic equivalent of the 'rapidly degradable' concept for organics (discussed in principle). Finally, a separate section focuses on the bioaccumulation and regulation of essential and non-essential metals in biota, and how this information may affect the classification of metals and metal compounds. More details can also be found in the EU REACH Guidance on the Application of the CLP criteria (2024), eg in Annex I (Aquatic Toxicity) and Annex IV (Metals and inorganic metal compounds).

Based on the information and guidance that is provided in this Fact Sheet, the reader should a) understand the rationale behind the existing self-classification of inorganic substances, and b) be able to self-classify. It should be noted that for all metal compounds that have been placed on the EU market by a producer or importer at a yearly volume of 1 tonne/year or more, there is a legal obligation under EU REACH to self-classify the substance in line with the CLP Regulation in the EU. Each of these self-classifications can be found in ECHA's Classification and Labelling (C&L) Inventory. Hence, in most cases the need for determining a (new) self-classification only applies to low-tonnage metal compounds.

The procedures for the derivation of a self-classification that are described in this document, are – in theory – also followed by the competent authorities when setting a legally binding harmonised environmental hazard classification for a specific substance. In practice a modified approach is sometimes followed, and modifications to the derivation methods can result in ERVs that differ from those determined by either EU REACH registrants or C&L Inventory notifiers in the EU. In this context it is essential to point out that the hazard classification classes that are adopted in a harmonised classification proposal are legally binding, but this is not the case for the underlying ERV presented in this Fact Sheet: for example, ERVs can change over time when new ecotoxicity data become available and thus trigger a different (more or less stringent) self-classification.

Hence, when it comes to establishing a self-classification of a metal compound, if a metal-specific ERV has already been calculated within the context of an EU harmonised classification for that metal (or another compound of that metal), then a justified deviation from that ERV can only be made if:

— New ecotoxicological information has been identified;
— There is evidence that one or more critical studies used for the ERV derivation in the harmonised classification proposal are not reliable/relevant;
— It can be demonstrated that the followed ERV calculation procedure in the harmonised classification proposal is not in line with the procedures and guidelines provided in the CLP Regulation.

This self-derived ERV (expressed as µg Me/L) can then be used for the self-classification of each metal-containing substance that is not subject to a harmonised classification.

2.1. Derivation and use of the ecotoxicity reference values

As for any other chemical, the hazard classification of metal compounds and (multi-) metallic materials is based on acute and chronic Ecotoxicity Reference Values (ERVs). These ERVs are derived from available data for fish, crustaceans, and algae/aquatic plants (ie taxa accepted as representative of aquatic fauna and flora). In general, both freshwater and marine species toxicity data are considered suitable for use in classification provided the test methods used are equivalent and are preferable to be derived using OECD Test Guidelines or equivalent according to the principles of Good Laboratory Practices (GLP) (EU CLP 2008; UN GHS 2025, Rev.11). To establish a proper basis for comparison of classifications between substances, preference is given to data obtained on standard test organisms specified in internationally recognised test guidelines, when available.

Detailed information on how an Acute and Chronic ERV is determined, including an overview on the type of information that is required for this derivation, is provided in **Annex 1** of this Fact Sheet. The scheme below represents a concise overview of the different steps that are followed.

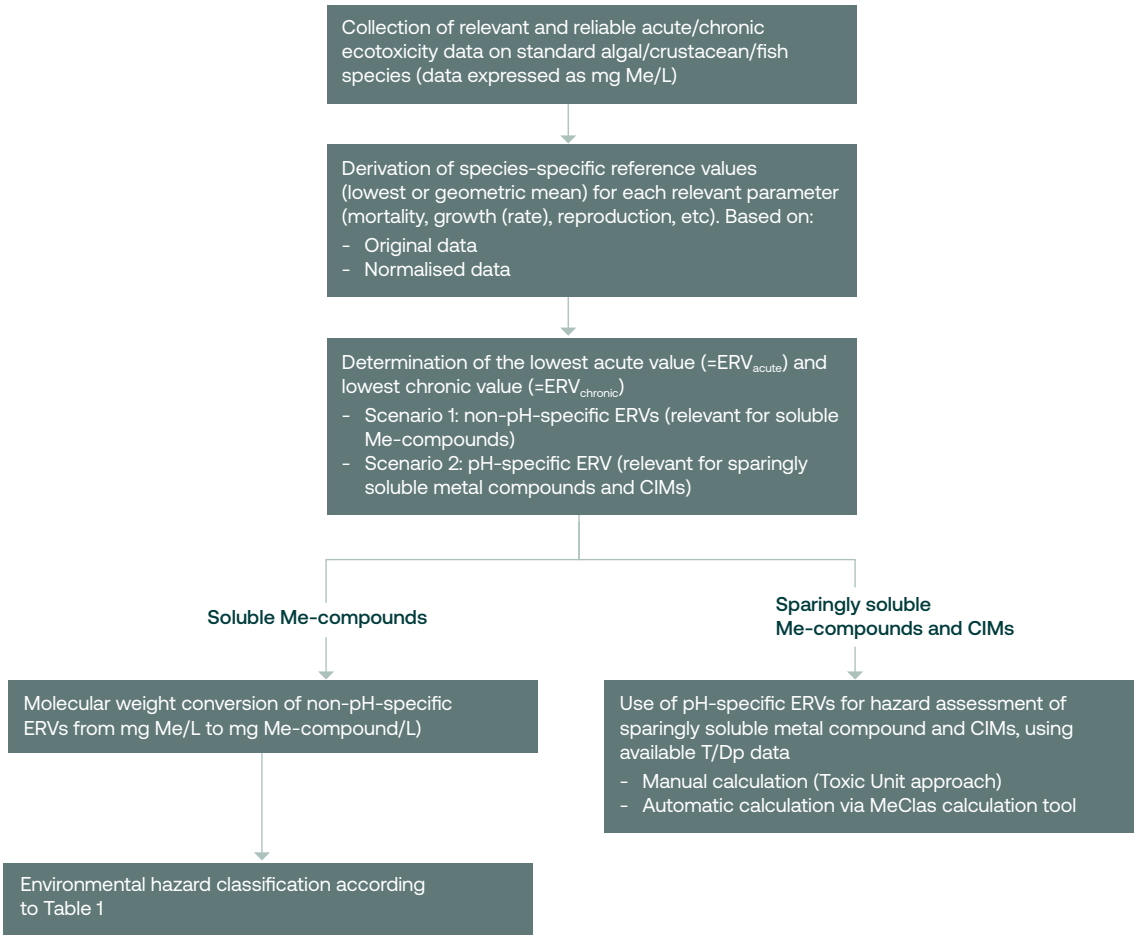


Figure 1. Generic Schematic overview of ERV derivation and implementation for soluble metal compounds, sparingly soluble metal compounds and CIMs

It is important to ensure that the data point used as basis for the classification (ie the ERV) is expressed as the weight of the molecule of the metal compound to be classified. This is known as correcting for molecular weight (MW). Thus, an ERV expressed as mg Me/L needs to be adjusted to the corresponding weight of the metal compound. For pure metals (massive, powder), the ERV_{metal} is equal to the $ERV_{metal\ ion}$:

$$Acute\ ERV_{metal\ compound} = Acute\ ERV_{metal\ ion} \times \frac{MW_{metal\ compound}}{n \times MW_{metal}}$$

$$Chronic\ ERV_{metal\ compound} = Chronic\ ERV_{metal\ ion} \times \frac{MW_{metal\ compound}}{n \times MW_{metal}}$$

(n = number of metal ions in the metal compound)

Once the Acute and Chronic ERVs are determined and converted into compound-specific ERVs, the correct hazard classification can be assigned to each compound according to the rules that are outlined in Table 1. More detailed information on the classification methodology can also be found in EU CLP 2008; UN GHS 2025, Rev.11).

The hazard classes that are assigned to a metal or metal compound are subsequently used for the derivation of the environmental hazard classification of a mixture in which the metal and/or metal compound is present, following the mixture rules that are described in EU CLP (2008) and UN GHS (2025, Rev.11).

Table 1: Translation of ERVs into an environmental hazard classification

	Aquatic Acute classification	Aquatic Chronic classification		Aquatic Chronic classification in absence of $ERV_{chronic}$
		Non-rapidly removed and/or BCF ≥500	Rapidly removed substance	
ERV_{acute}				
> 100 mg/L	Not classified			Not classified
> 10 – ≤ 100 mg/L	Cat.3 (GHS only)			Cat.3(1)
> 1 – ≤ 10 mg/L	Cat.2 (GHS only)			Cat.2(1)
≤ 1 mg/L	Cat.1 (CLP, GHS), M-factor 1 or higher			Cat.1, M-factor 1 or higher(1)
$ERV_{chronic}$				
> 1 mg/L		Not classified	Not classified	
> 0.1 – ≤ 1 mg/L		Cat.2	Cat. 3	
> 0.01 – ≤ 0.1 mg/L		Cat.1, M-factor 1	Cat.2	
≤0.01 mg/L		Cat.1, M-factor 10 or higher	Cat.1, M-factor 1 or higher	

(1) and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500; otherwise, no classification is required

2.2. Transformation/Dissolution test protocol

As previously stated, one of the key principles for the hazards assessment of metals (massive, powder) and metal compounds is that the aquatic toxicity is determined by the concentration of soluble metal ion.

As such, the environmental hazard of (poorly soluble) metals, sparingly soluble metal compounds and CIMs will depend on the extent and rate that these substances release metal ions into the environment. Overall, the interactions that these substances undergo with their surrounding media will determine the release and fate of the metal ion, partitioning from the water column and the chemical species of the metal ion(s) that exist in the water column. The environmental hazard of metals, sparingly soluble metal compounds and CIMs is therefore not determined by its total metal content, but by its dissolved metal fraction, and it is only that fraction that should be considered for the determination of an environmental hazard classification.

Thus, when conducting an environmental hazard assessment, it is necessary to quantify the metal ions that are formed, and whether the rate of dissolution is sufficient to cause concern (UN GHS 2025, Rev.11). These compound-specific properties can be assessed through a Transformation/Dissolution protocol test (T/Dp). Guidance on how to conduct a T/Dp test is given in Annex 10 of the UN GHS Document (2025, Rev.11), and more detailed, additional information is also provided in Annex 6 of this Fact Sheet.

Threshold concentrations that trigger a specific environmental hazard classification (See Table 1) are:

- 100 mg/L (Aq.Acute Cat.3, GHS).
- 10 mg/L (Aq.Acute Cat.2, GHS).
- 1 mg/L (Aq.Acute Cat.1, Aq.Chronic Cat.2/3, CLP & GHS).
- 0.1 mg/L (Aq.Chronic Cat.1/2, CLP & GHS).
- 0.01 mg/L (Aq.Chronic Cat.1, CLP & GHS).

A T/Dp test investigates whether or not the amount of ions released by a metal (massive, powder), metal compound or CIM at these various loadings is sufficient to cause an adverse effect (individual releases or combined via the Toxic Unit Approach in case of the release of multiple ions). This is tested under conservative conditions, ie conditions under which the transformation into metallic ion is maximised, within relevant environmental range.

The generic T/Dp approach that is followed for hazard classification purposes is shown in the overview below. Briefly, there are three T/Dp-guideline tests that can be performed:

- 24-hour screening T/Dp test.
- 7-day full T/Dp test.
- 28-day full T/Dp test.

The 24h-screening test assesses two properties of the test material: 1) to determine whether the material is a soluble or a sparingly soluble substance, and 2) to determine at what pH level the highest metal release takes place.



If the test material is found to be a sparingly soluble substance, the 7-day and 28-day full T/Dp tests can be conducted at the pH where the highest release was noted in the screening test. Results of the 7-day T/Dp test are used for the aquatic acute hazard assessment, whereas the results of the 28-day T/Dp test are used for the aquatic chronic hazard assessment. In theory the outcome of the 7-day T/Dp test can be used for the derivation of a chronic hazard classification (via extrapolation of the release data from 7–28 days, or application of the surrogate approach), but these methods are not recommended as they often result in a conservative, worst-case hazard classification.

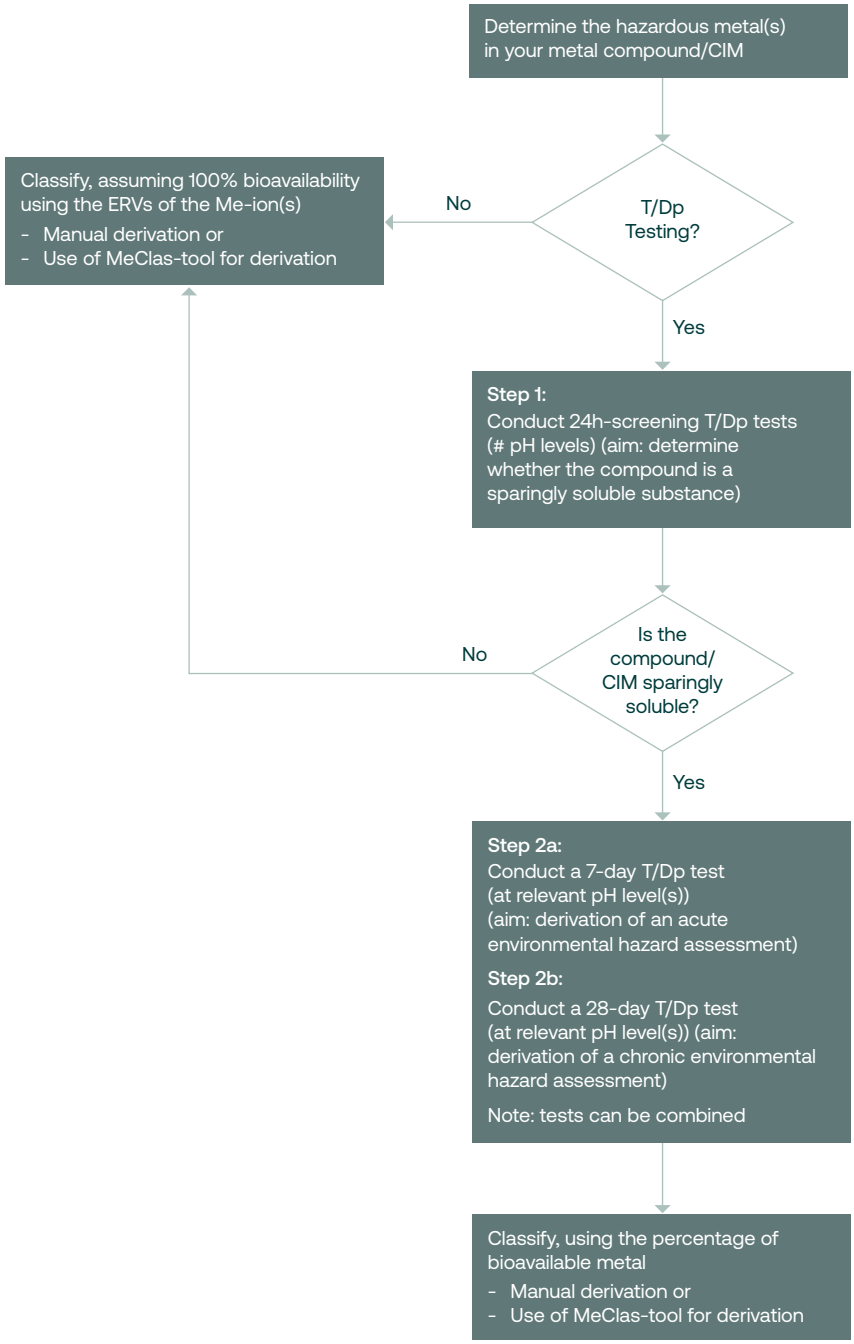


Figure 2. General decision tree for conducting Transformation/Dissolution testing with inorganic substances

Detailed information on how the outcome of the T/Dp test translates into specific environmental hazard categories, is explained in detail in **Annex 2** of this Fact Sheet. **Figures 3**, **4** and **5** provide a general overview of the three strategies that can be applied. Separate schemes for metals and metal compounds have been developed and presented in UN GHS (2025, Rev. 11) as well as in the ECHA Guidance on the Application of the CLP Criteria (2024, version 6), but the simplified schemes shown in Figures 3, 4 and 5 are applicable to both metals and metal compounds:

1. Determination of the acute hazard class based on a 7-day T/Dp test (**Figure 3**).
2. Determination of the chronic hazard class based on a 28-day T/Dp test (**Figure 4**).
3. Determination of the chronic hazard class based on a 7-day T/Dp test (surrogate approach; **Figure 5**).

It is important to know that for practical reasons (eg weighing of the material, detection limits, interference with natural background levels) it is not always possible to conduct T/Dp tests at the lowest loadings (typically at 0.01 and 0.1 mg/L) that are required for assessing the chronic aquatic hazard of metals and metal compounds. In those situations it is possible to extrapolate the releases from a higher loading to a lower one, assuming linearity between loading and release within the range of loadings considered.

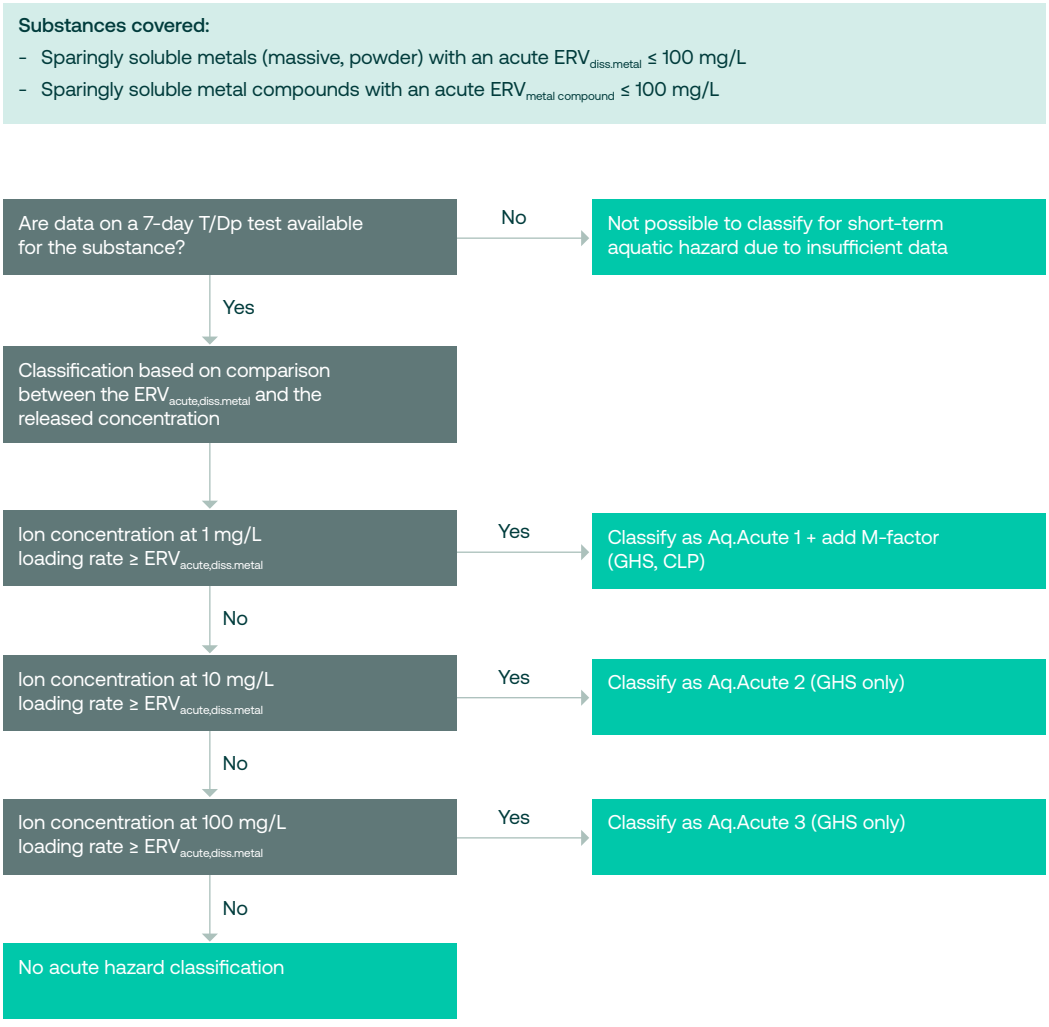


Figure 3. Classification strategy for determining acute aquatic hazard for sparingly soluble metals and metal compounds, using 7-day T/Dp data

Substances covered:

- Sparingly soluble metals (massive, powder) with a chronic $ERV_{diss\ metal} \leq 1$ mg/L
- Sparingly soluble metal compounds with a chronic $ERV_{metal\ compound} \leq 1$ mg/L



Figure 4. Classification strategy for determining the chronic aquatic hazard for sparingly soluble metals and metal compounds, using 28-day T/Dp data

Substances covered:

- Sparingly soluble metals (massive, powder) with an acute $ERV_{diss.metal}$ ≤ 1 mg/L
- Sparingly soluble metal compounds with an acute $ERV_{metal\ compound}$ ≤ 1 mg/L

and no 28-day T/Dp data available



Figure 5. Classification strategy for determining the chronic aquatic hazard for sparingly soluble metals and metal compounds, using 7-day T/Dp data (surrogate approach)

2.3. Direct Testing approach

Classification of a substance does not imply the generation of experimental data and should be performed using the relevant and reliable available dataset. However, in situations where information on the substance suggests that a calculated classification may be incorrect, confirmation of a determined classification can be achieved through direct testing. This approach is typically not recommended but can, for example, be applied in cases where significant uncertainties are associated with the existing toxicity data that were used in the calculation. This ecotoxicity validation should be conducted with the most sensitive species (trophic level) at dissolved ion concentrations equivalent to those measured in the T/Dp medium. However, there are valid arguments against performing ecotoxicity tests directly in the T/Dp medium because the composition of this medium[3] does not always meet some of the requirements for standard test media to ensure proper survival, growth and/or reproduction of the tested organism. For example, Ca- and Mg-levels in the medium for a T/Dp test at pH 6 are 10 and 20 times lower, respectively, than the recommended concentration levels in test medium for a 21-day chronic *Daphnia magna* test (OECD, 2012) and these reduced hardness levels may have a significant adverse effect on the overall health of daphnids, leading to reduced reproduction and survival. Also, algal test medium (OECD No.201) contains several essential elements and chelating agents (for keeping nutrients into solution) that are not present in the T/Dp test medium.

Therefore, ecotoxicity tests should be conducted in standardised test medium dosed at a metal concentration equivalent to the concentration level measured in the T/Dp medium. These tests can be initiated for metals and sparingly soluble metal compounds classified as Acute/Chronic 1, 2 or 3. When toxicity is found, the metal/metal compounds are classified accordingly (see **Figure 7**). If no acute/chronic toxicity is observed, then no classification is assigned.

Algae should be tested in a modified algal medium (excluding chelating agents) and deleting an essential element when this is the element of concern (eg cobalt). For daphnids, the different reconstituted ASTM-waters are recommended.

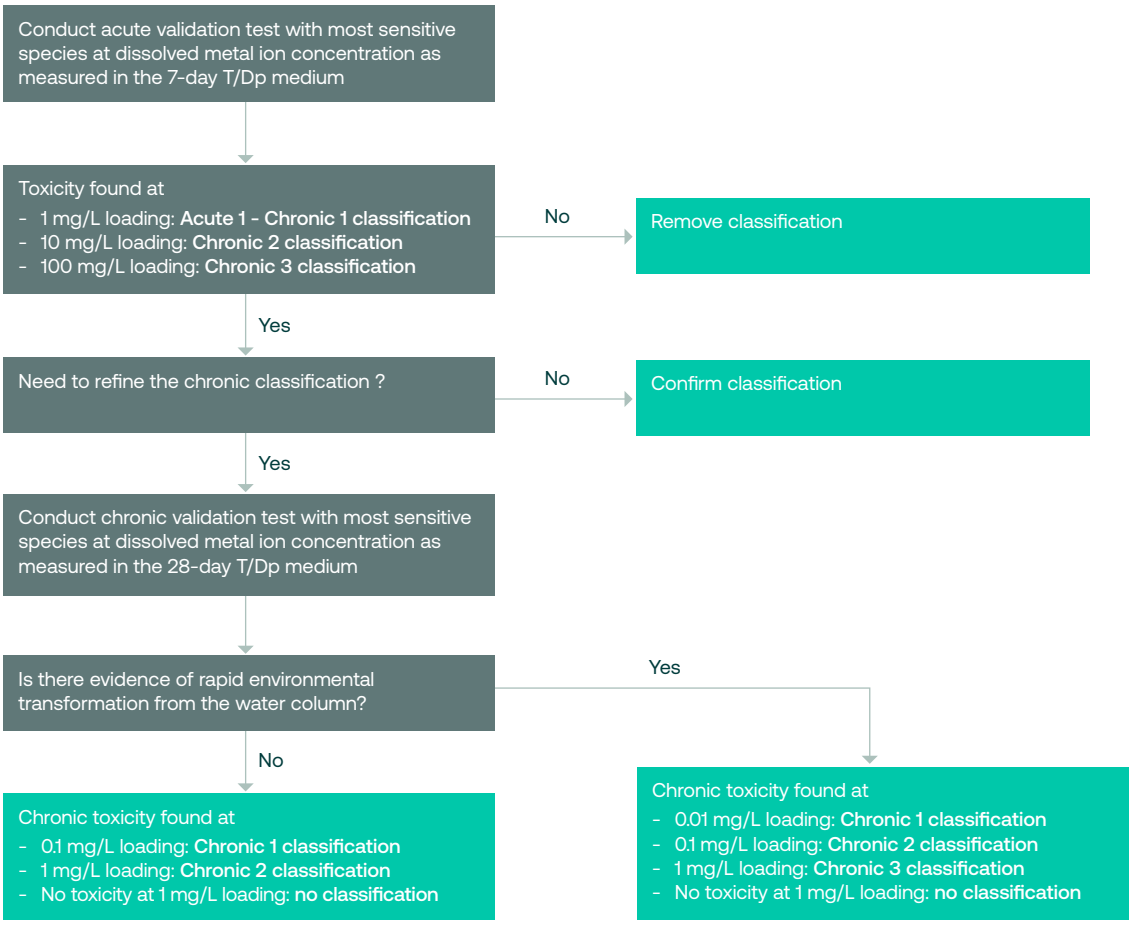


Figure 6. Direct testing approach

3. The exact composition of the T/Dp medium varies as a function of the required pH (6, 7 or 8).

Environmental Hazards Classification of CIMs

03



3.1. Introduction

The main classification principles for metals and metals compounds can be extended to simple (multi-)metallic compounds and complex metal-containing mixtures/materials, commonly referred to as Complex Inorganic Materials (CIMs) or More than One Constituent (MOC) substances/mixtures. Depending on the regulatory framework under which a specific CIM is assessed, the material is considered to be either a substance or a mixture.

When considering environmental hazards of CIMs, the classification should preferably be based on available information (including test data) on the CIM itself, if of sufficient quality. However, it is neither feasible nor recommendable (mainly from an animal welfare viewpoint) to perform (vertebrate) studies for each CIM separately. Insight into processes determining solubility is required as the foundation for a proper approach to estimate the environmental hazard profiles. The Transformation/Dissolution testing protocol (OECD, 2002) is the test described in the GHS that prevents the need for ecotoxicity testing of CIMs by basing the assessment on the soluble fraction of the ingredients or components. Using T/Dp data ensures that classification is based on the different metal ions that are released to environmental media with due consideration of their combined ecotoxicity. The T/Dp test measures the soluble fraction of each relevant metal that is present in the CIM, and this under testing conditions (pH, composition of the test medium, continuous stirring) that promote maximum solubility and bioavailability (worst-case scenario). Solubility is in this respect considered as a precautionary assessment of bioavailability.

For the purpose of this document, a distinction is made between two types of CIMs:

1. **A mixture of individual metals and/or compounds whose concentration and toxicity profiles are known**. This type of metal mixture contains several individual metals/metal compounds that have in most cases not interacted with other compounds in the mixture. This group of materials also includes alloys, which are metallic materials, homogeneous on a macroscopic scale, consisting of two or more elements that cannot be readily separated by mechanical means. They are therefore not simple compounds, but complex materials that have specific behaviours and intrinsic properties that may be different from those of the constituents (eg often reduced or increased toxicity due to changes in solubility). Under EU REACH and GHS, alloys are therefore considered to be special mixtures, acknowledging their specific nature and properties, and this should also be considered in their hazard assessment.
2. **Complex metal-containing materials, commonly referred to as UVCBs.** These materials are unique in their nature and composition, given their inherent heterogeneity and variability in composition and ecotoxicity profiles, and are identified under EU REACH and other chemical management systems as UVCB Substances. Typical inorganic examples of UVCBs are ores or ore concentrates.

It should be noted that the components of mixtures are commonly referred to as 'ingredients', whereas the components in a UVCB are defined as 'constituents'.

Having established the different types of CIMs considered in this Fact Sheet, the following section provides an overview of the classification approach. Briefly, the assessor starts with a characterisation of the CIM and then proceeds as far along the schemes as possible with the available data. Additional data may be gathered to proceed to a next stage or tier, and these extra steps typically allow for a refinement of the environmental hazard classification. This approach is in line with the general regulatory context in which ecotoxicity testing should only be considered in case no other existing data are available that provide for an adequate, reliable classification. It has been recognised, however, that particular CIMs may have unique metal release characteristics, and that in specific cases it may be relevant to develop more relevant ecotoxicity data sets to obtain a more appropriate classification. Consequently, some specific procedures may be in place for specific CIMs (eg use of T/Dp for the refinement of alloy classification). Each of these steps are further discussed in **Section 4** of this Fact Sheet, and where necessary the differences in guidance among specific CIMs are discussed in more detail. Generalised schematic overviews on how to classify a CIM are provided in **Figure 7** and **Figure 8** (a simplified version of Figure 7). The flow of Figure 8 reflects the calculation method that has been implemented in the MeClas tool, which is further discussed in **Section 4**.

More detailed background information on each step of Figure 8 is also provided in **Annexes 4** to **6** to this document. These Annexes allow the reader to gain more in-depth insights into the procedures and scientific principles behind the classification procedure. From a practical point of view, however, the environmental hazard classification of a CIM or MOC can be determined without requiring this detailed knowledge of the underlying scientific principles.

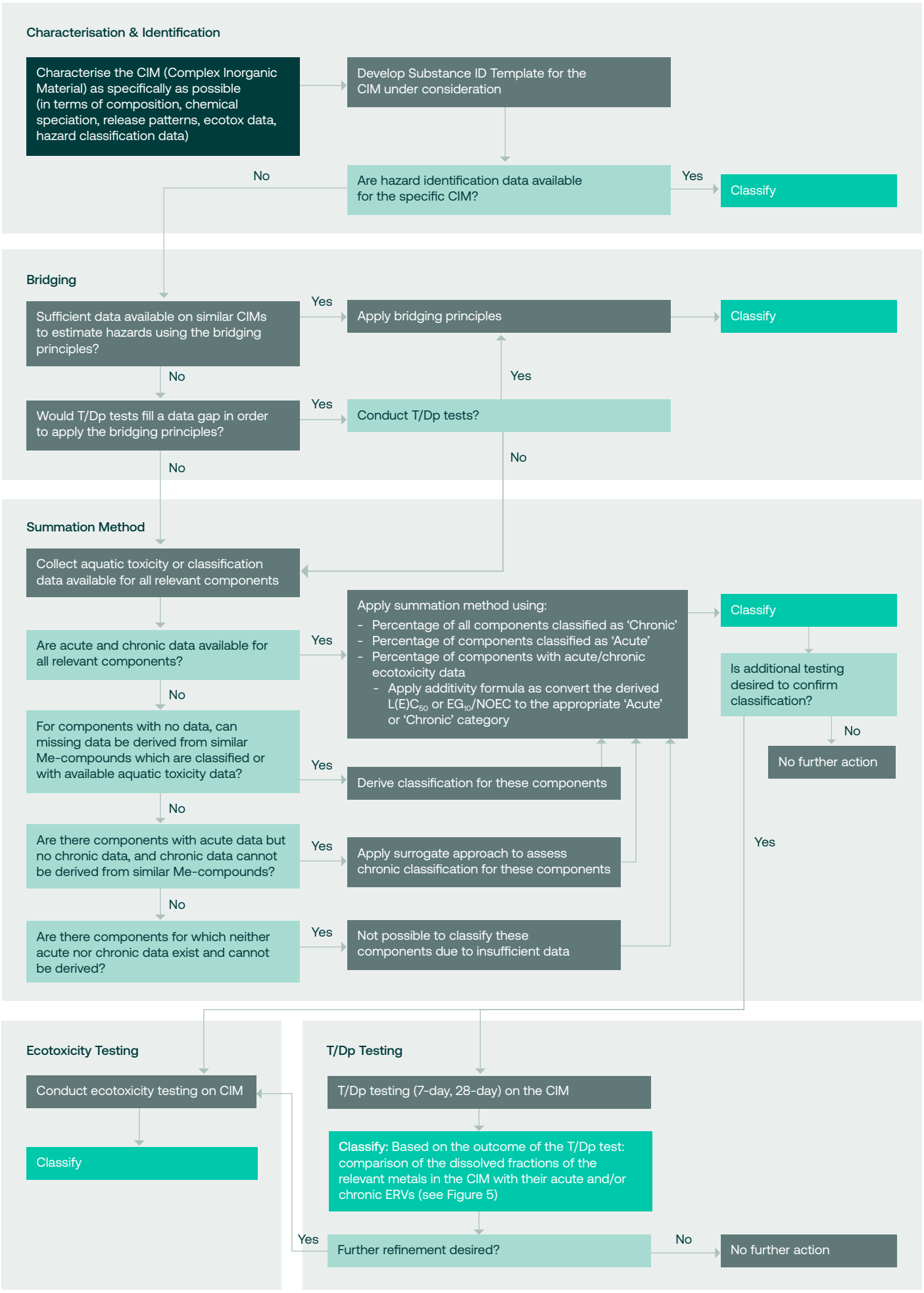


Figure 7. The conceptual outline of the classification strategy for complex inorganic materials

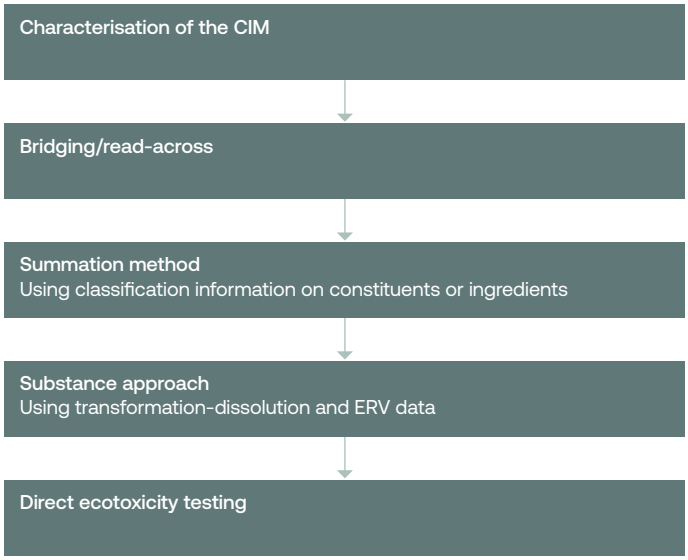


Figure 8. Generic scheme for the classification of CIMs

3.2. Read-across/bridging[4]

It is worth noting that the MeClas tool does not support the derivation of hazard classifications based on bridging or read-across. The bridging and read-across approaches refer to the possibility of assigning the existing classification of another substance (via 'read-across') or mixture (via 'bridging'), both used as 'source material' or 'chemical surrogate', to your specific CIM (which is the 'target material'). This approach needs the hazard assessor to demonstrate that both source and target material are sufficiently similar regarding their composition and/or physicochemical properties. This approach is typically applied when the environmental classification of the source material is based on T/Dp data, and the assessor would like to avoid T/Dp testing with one or more target material(s). Read-across of T/Dp data from one material to another can be justified if there is evidence to conclude that the relative release rate of the dissolved metals is the same between source and target material.

The two sub-sections below elaborate how to conduct the read-across and bridging approaches on UVCB substances, simple mixtures and alloys.

3.2.1. Read-across/bridging for Inorganic UVCB Substances

UVCBs with similar characteristics should be grouped together, and read-across the hazard classification when appropriate, eg based on the compositional information. The use of this methodology for classification processes, however, has to be done in such a way that within a specific group the displayed exposure behaviour results in the same environmental hazard conclusion.

Ideally, once data becomes available for a number of UVCBs within a particular peer group, it can be used to identify concentration 'envelopes' that correspond to different classification categories, such that defensible read-across of hazard classifications can be proposed for UVCBs whose composition clearly falls within those 'envelopes'. Expert judgement, supported by good experimental evidence is therefore required for the allocation of a UVCB to a specific peer group. In general, bridging principles for environmental endpoints include:

- Concentration of the constituent metal-bearing minerals or compounds.
- Physicochemical properties of the UVCB (eg ores and ore concentrates, refinables).
- Relevant ecotoxicological data on the metal(s) or the metal-bearing minerals or compounds.
- Metal release studies (T/Dp data).

3.2.2. Read-across/bridging for an alloy material (special mixture)

In many cases, the ecotoxicological information on the individual ingredients will form the basis for the classification of the alloy, considering the rate and extent to which metallic ions can be released from the alloy as determined in accordance with the Transformation/Dissolution protocol (OECD Guidance No. 29).

Existing grouping methodologies of alloys, as outlined in numerous national and international standards (AISI, ASTM, CEN, ISIJ, etc.), are mainly based on their chemical composition and/or specific properties, and not on their ecotoxicological potential. For example, metal alloys, by virtue of composition, are often grouped

4. When a mixture itself has not been tested to determine its hazardous properties, but there are sufficient data on similar tested mixtures and individual hazardous ingredient substances to adequately characterize the hazard of the mixture, these data should be used in accordance with a number of so-called bridging principles that are outlined in the GHS. The substance-specific approach entails that the mixture is treated/tested as if it were a substance, eg conducting T/Dp tests or direct toxicity tests with the mixture as test material.

into two classes: ferrous (incl. steels and cast irons) and non-ferrous alloys, with the latter group further subdivided according to base metal or some distinctive characteristic that is shared by a group of alloys (eg copper, aluminium, magnesium and titanium alloys, refractory metals, superalloys, etc.) (Callister 2007). For hazard classification purposes, however, such a grouping strategy is meaningless since it does not take the ecotoxicity and bioavailability of the different alloy ingredients into account.

Before classifying an alloy, assess whether structural relationships can be defined to classify the alloy based on comparison with alloys already classified for the environment. When a review of the available relevant information reveals that there is no evidence that the alloy under consideration would behave differently, it is suggested to classify accordingly. This bridging principle could include similar composition, similar surface and dissolution properties. For example: an alloy (I) containing the same alloying elements as alloy (II), for which hazard data are available for the alloying elements A and B and that has already been classified, could be assigned to the same hazard category if only the concentration of alloying metals A and B in alloy (I) are lower and/or Transformation/Dissolution test or other tests that provide information on release rates (eg corrosion test) results shows lower or equivalent metal A, B release in alloy (I) than alloy (II).

If there are no data of sufficient validity to show that the alloy can be allocated to a peer group, a simple solubility test such as the 24-hour Screening Dissolution Test (24-hour T/Dp) – as described in Annex 10 of the UN GHS Document (2017, Revision 7) – could be conducted on both the alloy under evaluation and the peer reference alloy as a relevancy check to apply bridging. The 24-hour T/Dp is chosen because of its high dose, rigid test conditions resulting in a high solubility and hence its better discriminatory power.

Results of the 24-hour T/Dp test can be used to assess the likelihood that the alloy under consideration will be releasing metal ions to a larger, smaller or similar extent than its alloying constituents. In addition, the 24-hour screening test results could also help in determining if the summation method can be used.



Classification of CIMs with the Metals Classification Tool (MeClas)

04



4.1. Background information on MeClas

The environmental hazard assessment of a CIM requires an extensive amount of information on each of its constituents or ingredients, and the required data are not always readily accessible. Also, correct interpretation and implementation of the data requires a thorough understanding of all the options, methodologies and approaches that can be used with the data available for a specific type of CIM.

In an effort to help the hazard assessors of CIMs with their hazard classification requirements, the Metals Classification Tool (MeClas; www.meclas.eu) (Verdonck et al., 2017) was developed in 2010. The MeClas tool (Metal Classification tool) is an IT web-based tool specifically developed to comply with the EU REACH, DSD/DPD and CLP requirements for the hazard identification and classification of complex inorganic materials like ores and concentrates, UVCB intermediates, alloys and slags. It was later expanded to cover the US HazMat legislation, UN GHS, IMO bulk transport legislation. Its original organisational and management structure, relying on the support and knowledge of various Metal Consortia, allowed the inclusion of the most recent database of Ecotoxicological/Toxicological Reference Values (ERV and TRV), but also correction factors for Transformation/ Dissolution, metal-specific concentration limits and M-factors, reference materials, etc. MeClas was originally developed by ARCHE Consulting and European Metals (previously Eurometaux) with input from various commodity associations and built on the metal-specific guidance in CLP and GHS. In other words, MeClas follows classification guidance and implements it accordingly to the legal ruling and provided technical guidance (ECHA, UN). For the EU, MeClas will not deviate from the proposed CLP guidance unless the proposed deviation has been agreed by ECHA. When needed, the MeClas model is adapted to ensure compliance with new/revised classification rulings.

The tool recognises the specific properties and assessment techniques for inorganics, using the most updated information on toxicity reference values and self-classifications available. MeClas includes a series of features that are crucial for metals and complex metal mixtures which – to date – are not included in the usual commercial hazard classification tools for substances and mixtures.

MeClas is built on a limited number of simple and basic principles:

— A tiered and inorganic-specific approach allowing refinement in accordance with the following (not necessarily sequential) steps: elemental concentrations speciation data – mineralogical evidence – correction based on time-dependent metal release (if relevant) and correction based on test data on the complex material. This multi-tiered approach allows for a progressive refinement of classification based on speciation, specific mineral content, and the availability of test data that are specific for the CIM being analysed.



— A core block including ERVs values and CLP and UN GHS hazard ID rulings.

— Enabling the inclusion of specific side modules if relevant (eg for Ores and Ore Concentrates, for Transport Classification, additional reference lists (eg Japan) and alloys,).

At the Tier 0 and Tier 1 level, MeClas considers the hazard of the speciation form in which each specific element is present in the CIM. In Tier 0, a compound with the most stringent environmental hazard classification is put forward as reference substance for each element, whereas Tier 1 considers the actual speciation form and associated environmental hazard profile. These environmental classifications (industry self-classification or the harmonised classification) are then used for the derivation of the aquatic hazard classes (acute, chronic) according to the summation method as defined in the CLP Regulation. Detailed background information on the summation method can be found in **Annex 5**.

— Tier 0 is a baseline hazard classification where the CIM is considered to be a mixture of 100% inorganic substances, and each element is represented by the most hazardous compound that has been identified for that element (= worst-case assumption).

— Tier 1 is a hazard calculation based on the specific hazard of the actual speciation form(s) in which each element is present in the CIM (eg compounds, minerals).

In summary, Tier 0 represents a worst-case situation whereas the outcome of Tier 1 is the more representative outcome for the assessed CIM.

In Tier 2 of the MeClas tool only the bioavailable fraction of each metal – as determined in a full T/Dp test – is considered for the calculations and derivation of appropriate hazard class. The following steps are implemented in MeClas:

1. Determination of the expected dissolved concentration of each relevant metal for each classification threshold concentration (0.01, 0.1, 1, 10 and 100 mg CIM/L) (soluble fraction as determined in T/Dp test).
2. Calculation of the contribution (= expected dissolved concentration/relevant $ERV_{acute/chronic}$) of each individual element to the theoretical expected acute and chronic ecotoxicity of the CIM for each classification threshold concentration.
3. Summation of all the individual toxic contributions for each classification threshold concentration (= additivity method).
4. When the sum exceeds the value of 1 for a specific classification threshold concentration, an adverse effect is expected at this concentration level, and the CIM is classified accordingly.

Tier 2 is the most representative outcome for the assessed CIM, and the calculation methodology is based on the additivity approach. More information on this approach is provided in **Annex 6**.

With the web-enabled MeClas tool it is possible for the hazard assessor of a CIM to determine the hazard classification of their complex materials (ores and ore concentrates, complex intermediates, alloys, UVCBs) by only using a relatively limited data set on elemental composition and – if available – speciation or solubility. The power of this tool lies in the fact that it recognises the specific properties and assessment techniques for such CIMs, hereby using the most updated information on, for example, toxicity reference values and harmonised/self-classifications. In other words, all required information on the hazard properties of relevant constituents and ingredients of CIMs is part of the MeClas database and calculations are executed automatically, hereby eliminating a major part of the workload for the hazard assessor.

It is worth noting that the MeClas database does not only contain the classification of metals and metal compounds but also includes the hazard classifications of a substantial number of minerals.

4.2. Practical Guidance on the use of MeClas for the environmental classification of a CIM

By following the different action steps that are described below, the hazard assessor of a CIM will be able to use the MeClas tool for the derivation of a reliable environmental hazard classification that is compliant with existing regulation on the hazard classification of CIMs. This classification procedure can be divided into several steps that need to be followed:

— Characterisation of the Complex Inorganic Material.

— Application of the bridging approach (mixtures) and the read-across approach (substances) (See Section 3.2).

— Application of the summation method based on information on the ingredients or constituents.

— Substance-specific approach[5] by assessing the classification based on T/Dp testing of the CIM.

— Direct ecotoxicity testing in the reconstituted test medium resulting from the T/Dp.

Figure 9 presents a schematic overview of the steps, analyses and experimental work required for the determination of an environmental hazard classification. The four steps identified herein are discussed further below.

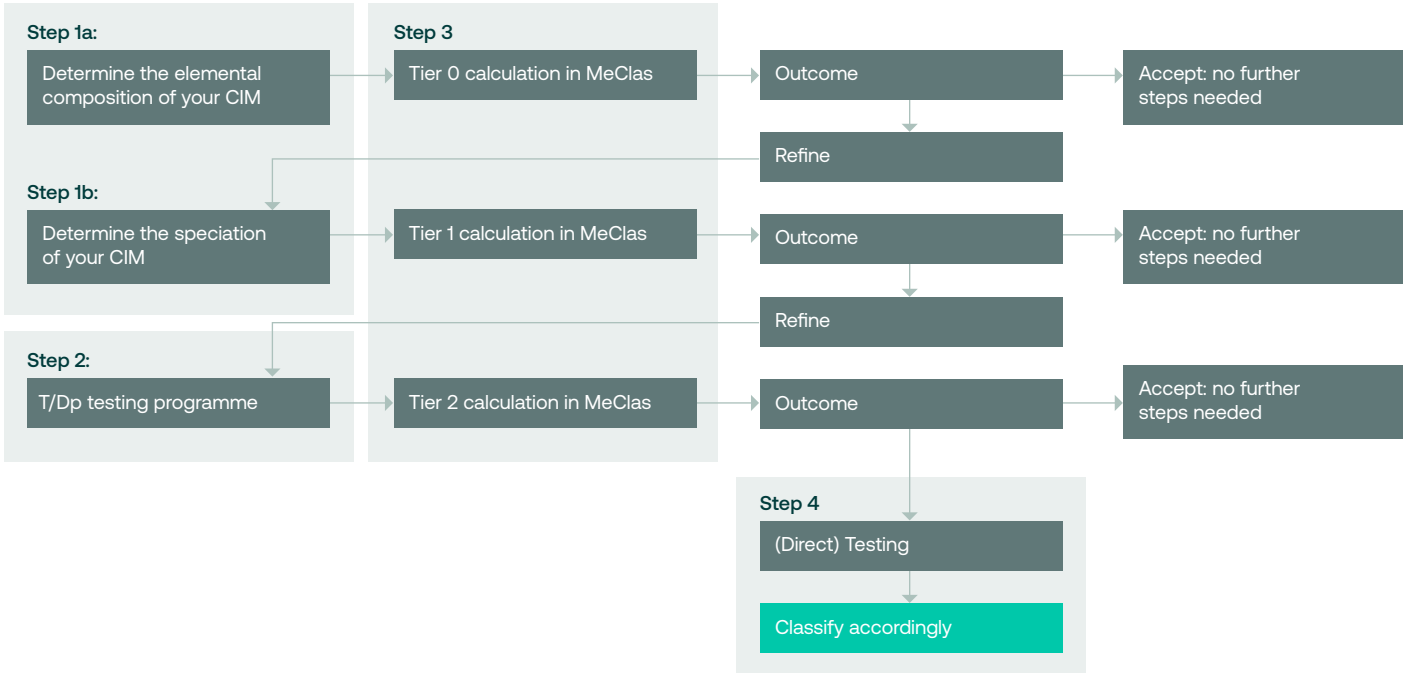


Figure 9. Stepwise classification approach for CIMs in MeClas

5. The substance-specific approach entails the mixture being treated/tested as if it were a substance, eg conducting T/Dp tests or direct toxicity tests with the mixture as test material.

4.2.1. Step 1a and 1b:

Characterisation of the CIM: chemical composition and regulatory context

The derivation of the environmental classification of a CIM requires that its composition is known in sufficient detail. As a minimum, the elemental composition (%w/w) is required for the derivation of a worst-case hazard classification. Additional information on the speciation profile (type of compounds, minerals) may allow for a refinement of the worst-case default outcome that is based on the elemental composition. An effective way of compiling all this information is the creation of a Substance ID.

More information on the required information as well as examples of Substance ID templates can be found in Annex 4.

Transferring the collected data in the MeClas data entry fields allows the hazard assessor to perform a Tier-0 and/or Tier-1 hazard classification calculation (ie classification based on the summation method, see Annex 5 for additional information on the summation method).

The collected information is filled into the MeClas data entry fields, after which the user selects which Tier to calculate. Figure 10 provides a layout of the MeClas data entry fields but also shows which fields that are relevant for specific tiers.

Relevant for TIER0-calculation

Relevant for TIER1-calculation

Relevant for TIER2-calculation: Acute classification, Chronic classification

Element	Concentration	Classification Entry	Source	Distribution % (relative to element)	Formula	TDP 7 days	TDP 28 days
Ni	5.60000					2.80000	5.40000
		Ni massive	1st ATP	0.00000	Ni		
		dinickel orthosilicate	1st ATP	0.00000	Ni_2SiO_4		
		Ni (other not classified compounds/species)	not classified	0.00000	Ni		
		Ni powder	1st ATP	0.00000	Ni		
		Ni silicate	1st ATP	45.00000	$NiSi_2O_4$		
		$Ni(OH)_2$	1st ATP	33.00000	$Ni(OH)_2$		
		Ni_2O_3	1st ATP	0.00000	Ni_2O_3		
		Ni_3S_2	self classification NiPERA	0.00000	Ni_3S_2		
		NiAs	Annex VI	0.00000	NiAs		
		$NiCO_3$	Annex VI	22.00000	$NiCO_3$		
		$NiK_2(SO_4)_2$	1st ATP	0.00000	$NiK_2(SO_4)_2$		

Figure 10. Generic outline of the MeClas data entry fields for CIMs

Apart from information on the chemical properties of the CIM, the regulatory framework under which the environmental hazard assessment of the CIM is conducted also determines the classification procedure (and input data) that are needed:

— For substances, (special) mixtures and UVCBs, the methods and principles that are outlined in the CLP Regulation need to be followed and applied.

— For articles (exempt under CLP) that require a hazard classification for transport purposes, the shape and weight can be taken into account, and the specific surface area (SA) approach is implemented.

— For inorganic waste, the hazard classification is typically in line with the CLP Regulation, but exemptions for eg massives are in place.

An extensive guidance document 'Guidance Note on the environmental classification of Complex Inorganic Materials (CIMs) containing Pb' was prepared in 2025 by European Metals (previously Eurometaux) and ARCHE Consulting (Belgium). This document clarifies when materials should be classified according to CLP/GHS (using MeClas) or when other tools or approaches are relevant (eg use of the transport classification tool for goods and articles when the CIM contains Pb).

4.2.2. Step 2:

Collection or generation of relevant T/Dp data

4.2.2.1. General approach

As previously pointed out, the MeClas Tier 0 assessment represents a worst-case outcome, but refinement is possible when full 7- and/or 28-day T/Dp data have been generated with the CIM. Background information on how T/Dp data are used for classification purposes can be found in **Annex 6**. Inclusion of T/Dp results in the designated MeClas data entry fields (**Figure 10**) allows the tool to perform the Tier-2 hazard calculation.

In some cases, the specific properties of the CIM make it impossible to conduct a relevant T/Dp test with the material; the 28d-T/Dp test is conducted at a maximum loading of 1 mg/L, but for some materials it is not possible to generate a homogenous 1 mg-sample with a composition that is representative for the CIM as a whole. For such materials it is recommended that information on speciation and/or mineralogy is collected or generated instead. Inclusion of the speciation data in MeClas allows the tool to perform a more refined Tier-1 hazard calculation.

4.2.2.2. Implementation of T/Dp test with alloys

T/Dp tests are conducted with CIMs for Tier 2 assessment purposes (eg MOCs such as UVCBs), whereas mixtures are assessed according to Tier 1 (no T/Dp testing; use of the summation method, based on classification if the mixture ingredients). Technically an alloy is a mixture of pure metals and therefore using the existing classification of the pure form in a summation method (powders, massive forms) seems logical.

However, alloys are referred to as special mixtures because the physicochemical properties of a metal in alloy configuration – including solubility – are often significantly different from those in the pure form. Therefore, the use of the summation method is only relevant and sufficiently conservative if there is no 'positive' alloy solubility effect, ie if the relative release of a metal in alloy form is not higher than the relative release in pure form. Hence, if there is evidence or relevant indication of a 'positive' alloy solubility effect, the Tier 0 method should be followed with potential Tier 2 refinement with relevant T/Dp data (if available).

It is worth noting that T/Dp testing for Tier 2 refinement can also be considered when a 'negative' alloy solubility effect is expected, ie the relative release of a metal in alloy form is lower than the relative release in pure form. This may be of particular interest for pure metals that have an environmental hazard classification, and for which a reduced release may result in a less stringent or no environmental hazard classification of the alloy in which they are present.

4.2.3. Step 3:

Calculation of the default classification with MeClas

Once all the required data on composition, speciation and solubility are entered into MeClas, the environmental classification can simply be calculated by selecting the appropriate tier. It should be noted that the MeClas tool will automatically use worst-case default values and assumptions for those data field for which no data have been provided.

The detailed User Manual on how to use the MeClas tool is available on the **MeClas website**.

4.2.4. Step 4:

Testing approach at levels equal to the metal release in T/Dp testing

The option to perform ecotoxicity tests has been embedded in the GHS and consequently also in the national and regional regulatory implementations of GHS as the EU CLP.

As a general recommendation, alternative approaches such as the bridging, summation and additivity methods should be considered, particularly where testing would involve the use of vertebrate animals such as fish before conducting ecotoxicity tests on CIMs.

If the use of alternative approaches is not possible or unreliable and no reliable ecotoxicity data is available for the CIM, ecotoxicity testing should be conducted with all three taxonomic groups that are used for the environmental hazard assessment (algae, invertebrates, fish) as the level of sensitivity among taxonomic groups is metal-dependent, and is also determined by the physicochemical properties of the test medium (eg pH). According to the EU CLP guidance, testing directly in the T/Dp medium may not be recommended when the composition of this medium is unlikely to meet the requirements for standard test media for given species to ensure proper survival and reproduction. Therefore, ecotoxicity tests should preferentially be conducted in standard media dosed at metal concentrations equivalent to the concentration level measured in the T/Dp medium.

Specific guidance exists on ecotoxicity testing for purposes such as classification refinement where it is stated that it may be appropriate to use the aqueous medium from a completed transformation test directly in OECD Guideline tests. The UN GHS Annex 10, for example, provides specific guidance for the modification of T/Dp media for use of the completed transformation medium in an OECD 201 algae ecotoxicity test. If the $CaCl_2.2H_2O$ and $MgSO_4.7H_2O$ concentrations of the transformation medium have been reduced to one-fifth of the ISO 6314 medium (ie to sustain lower pH levels), micronutrients can be added.

Both options have advantages and disadvantages, and expert judgement is needed on a case-by-case basis, which could include aspects related to the fate of chemical (eg the potential prevention of precipitation due to the changes in the composition of the medium). This is a very critical point to demonstrate, especially if a lower toxicity response would be measured from the mixture than expected from the additivity rule.

4.2.4.1. Toxicity testing with UVCB substances

In case hazard data are not available for all individual constituents, the approach taken could be to test the UVCB as it is – as a substance. Acute and chronic ecotoxicity tests should be conducted in standard media dosed at metal concentrations equivalent to the concentration level actually measured in the 7-day and/or 28-day T/Dp medium. In this case the most sensitive species approach can be used, but evidence will have to be collected for all three trophic level of organisms used in the classification scheme. The UVCB can then be classified directly on the outcome of the performed ecotoxicity tests.

The outcome of a testing approach may be significant for UVCBs where binding of the metal to abiotic and biological binding sites will be in many cases competitive.

When data from ecotoxicity tests indicate acute (>50% effect) or chronic (>10% effect) effects in test media that reflect the metal concentrations of the 7-day and 28-day T/Dp test loadings, the UVCBs should be classified accordingly. If no effects are observed, the UVCB should indeed not be classified.

4.2.4.2. Toxicity testing with a complex inorganic mixture – alloys

Conducting the direct testing approach with a mixture-CIM such as an alloy is recommended especially when existing information suggests potential antagonistic or synergistic effects, and when the composition of the CIM does not allow T/Dp testing or bridging. As stipulated before, these tests should be in line with the ECHA guidance on substances which are difficult to test (Guidance on the Application of the EU CLP Criteria – Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (EU CLP) of substances and mixtures (ECHA 2013) and OECD No. 23 Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals (OECD, 2019)).

When aquatic testing with an alloy is conducted for reasons of validation/refinement of a calculated classification, then the test should be carried out with the most sensitive aquatic standard species at dissolved ion concentrations for each of the metal elements, equivalent to those measured in the T/Dp medium. These tests can also be initiated for alloys classified as Aq.Acute 1/Aq.Chronic 1, 2 or 3 when antagonistic effects are expected. When toxicity is found, the alloy can then be classified directly on the outcome of the performed ecotoxicity tests.

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Annex 1: Acute and Chronic ERV Derivation in Accordance with the Principles of the CLP Regulation

A1.1. General considerations

When assessing the relevance and reliability of ecotoxicity data, one needs to keep in mind that the CLP Regulation represents a hazard-based assessment of substances, and not a risk-based approach. If applied correctly, all substances that have been assigned to the same environmental hazard category for a specific environmental endpoint (eg Aq.Acute Cat.1, Aq.Chronic Cat.1) will have comparable hazard/ toxicity profiles among them (within one order of magnitude). Correct grouping, however, can only be obtained when all substances are assessed against the same benchmarks. For environmental classification purposes these benchmarks should be acute and chronic adverse effects under standardised test conditions for several standard surrogate species representing a range of pre-defined trophic levels and taxa (algae, crustaceans, fish). However, when other potentially more sensitive taxonomic groups or other test conditions (different exposure periods, marine test media) are considered for the classification of a substance, the resulting hazard profile can no longer be compared with the hazard profile of substances which are only based on standard test species. A similar logic should be followed when considering the appropriate effect-parameters (survival, reproduction, growth and growth rate). Hence, from a strict category-based point of view, toxicological data for taxonomic groups or parameters whose sensitivity towards (specific groups of) chemicals may be significantly higher (eg insects, molluscs, rotifers) should not be considered for the hazard assessment of a substance. Ecotoxicological information on such species or parameters, however, remain part of the overall risk assessment, and should be included when setting safe, long-term environmental concentration levels (PNEC-derivation).

According to the second ATP (No 286/2011) of the CLP Regulation No 1727/2008, an acute/ chronic environmental classification of a substance can be derived from acute/chronic toxicity data when sufficiently available; in the absence of (adequate) chronic data, however, the chronic classification will be derived from acute data. The proper selection of the ecotoxicological information that can be used for the environmental hazard assessment, will define the overall quality and relevance of the derived environmental classification.

A1.2. Test species to be used for environmental hazard assessment

The CLP Regulation defines the taxonomic groups and testing protocols that should be considered for the hazard assessment (ie classification) of substances. The acute and chronic aquatic classification should be based on EC_{50}-values, NOECs or other equivalent EC_x (eg EC_{10}) that are generated according to the standardised test methods referred to in Article 8(3) of the CLP Regulation; results obtained from other validated and internationally accepted test methods can also be considered. The ECHA Guidance on the Application of CLP Criteria stipulates that 'Fish, crustacea and algae or other aquatic plants are tested as surrogate species representing a range of trophic levels and taxa, and the test methods are highly standardised. Valid data for short- and long-term tests on other organisms shall also be considered, provided they represent equivalent species and test endpoints.'

The species that are used for classification purposes cover a range of trophic levels and taxa and are considered as surrogate for all aquatic organisms. The ECHA Guidance on the Application of CLP Criteria further defines that 'Chronic toxicity data generated according to the OECD Test Guidelines 210 (Fish Early Life Stage), 211 (Daphnia Reproduction) and 201 (Algal Growth Inhibition) or equivalent can be accepted. Other validated and internationally accepted test methods could also be used. The NOECs or other equivalent ECx should be used.'

The different OECD Guidelines refer to the following species:



- Algae: *Pseudokirchneriella subcapitata* (syn: *Selenastrum capricornutum*; *Raphidocelis subcapitata*), *Desmodesmus subspicatus* (syn: *Scenedesmus subspicatus*), *Navicula pelliculosa*, *Anabaena flos-aquae*, *Synechococcus leopoliensis*;
- Fish: *Oncorhynchus mykiss*, *Pimephales promelas*, *Danio rerio*, *Oryzias latipes*, *Cyprinus carpio*;
- Crustaceans: *Daphnia species* (with specific reference to *Daphnia magna*).
- Apart from the organisms listed above, the OECD Guidelines also refer to several marine species, as well as several other well-documented freshwater/marine fish: *Cyprinodon variegatus*, *Menidia species*, *Carassius auratus*, *Lepomis macrochirus*, *Clupea harengus*, *Gadus morhua*. The guideline documents do refer to the possibility of using other species within each taxonomic group, but confirmation data should be available that those species can be maintained under the prescribed test conditions, ie that normal growth, development and reproduction is observed. This is in line with the ECHA Guidance on the Application of CLP Criteria which mentions that 'valid data for short- and long-term tests on other species at the same trophic level shall also be considered, provided they are equivalent in terms of species relevance, testing conditions and test endpoints'.

Regarding the use of algal data for hazard assessment purposes, the ECHA Guidance Document clarifies that the classification should be based on the algal growth rate reduction endpoint (E_rC_{50} [= EC_{50} (growth rate)] and NOE_rC [= NOEC (growth rate)] provided that the control growth is exponential (greater than a factor of 16). This endpoint is preferred because it is not dependent on the test design, whereas the endpoint, biomass (growth) inhibition (E_bC_{50}) depends on both, growth rate of the test species as well as test duration and other elements of test design. Thus, in circumstances where the basis of the EC_{50} is not specified and no E_rC_{50} is recorded, classification shall be based on the lowest EC_{50} available. Where the algal toxicity E_rC_{50} [= EC_{50} (growth rate)] falls more than 100 times below the next most sensitive species and results in a classification based solely on this effect, consideration should be given to whether this toxicity is representative of the toxicity to aquatic plants. Where it can be shown that this is not the case, professional judgement should be used in deciding if classification should be applied. The recommendation that growth rate is the preferred endpoint, is of great importance because the E_bC_{50} is typically more sensitive than the (ecologically more relevant) E_rC_{50}.

It should be noted that the Joint Research Centre (JRC) stated that the results of a 7-day reproduction study with the crustacean *Ceriodaphnia dubia* should not be considered for classification purposes when data for the standard species *Daphnia magna* are available (JRC-Report 'New criteria for environmental long-term aquatic hazard classification under the CLP Regulation (EC) N° 1272/2008 (2nd ATP) - Screening of Annex VI substances with harmonised classifications'). This restriction, however, is not outlined specifically in the CLP Regulation, and therefore there is no legal basis to omit available data for *C. dubia* for the derivation of Acute and Chronic ERVs.

The aim of the hazard assessment (ie classification), is not to protect all species from the potential adverse effects. The classification tries to place every substance in pre-defined hazard categories (for various physicochemical, human health and environmental endpoints), and all substances within a specific category are expected to share a similar (eco)toxicological or physicochemical hazard profile. A 'common' hazard profile within a category, however, can only be achieved when substances are evaluated against the same benchmarks, ie for the environment this means against the same set of standard test species, representing the three main taxonomic groups. When using additional taxonomic groups, the hazard profile may be determined by the inherent sensitivity of the evaluated test species from that additional taxonomic group, and not by the ecotoxicological profile that is derived from a standardised set of test organisms.

Consequently, test data for (non-standard) species that represent other taxonomic groups with a possible weaker/stronger toxic response when compared to standard species, should not be used for hazard classification purposes due to reasons of non-equivalence.

A1.3. Test methods to be used for environmental hazard assessment

A1.3.1. Acute classification

According to the general definition of 'acute aquatic toxicity' given in the regulatory criteria (CLP Regulation EU 1272/2008, Section 4.1.2.7.1) (EC Regulation, 2008; 2011) and ECHA CLP guidance (ECHA 2017, version 5) a fish 96h-LC_{50} (OECD 203 or equivalent), a crustacea species 48h-EC_{50} (OECD 202 or equivalent), and/or an algal species 72h- or 96h- EC_{50} (OECD 201 or equivalent), determine the acute toxicity classification.

These species are considered as surrogate for all aquatic organisms. Data on other species (such as duckweed *Lemna*) may also be considered if the test methodology is suitable. The EC_{50} values obtained from aquatic plant growth inhibition tests are normally treated as acute values for classification purposes. The standard species/endpoints for each of the three taxonomic groups are:

— 3(-4) days Algae EC_{50} growth rate (eg *P. subcapitata*, *C. vulgaris*, *C. reinhardtii*)

— 48 hours Invertebrates/Crustacea first instar juveniles L(E)C_{50} mortality or immobilisation (eg *D. magna*)

— 96 hours Fish – juveniles (0.1–5g) LC_{50} (eg *P. promelas*, *O. mykiss*, *S. fontinalis*, *D. rerio*, *C. carpio*)

— For vascular plants (eg *Lemna* sp), EC_{50} values obtained from tests consistent with OECD TG 221 and US EPA 850:4400 are retained for the database. The observational acute endpoint is the change (50% effect) in the number of fronds produced and the test duration is 7 days. It should be noted, however, that under the EU REACH Regulation algae are the preferred species regarding primary producers.

Standard endpoints that can be used for classification purposes have been defined for each taxonomic group. Mortality is the acute effect that is considered for crustaceans and fish (LC_{50}), whereas inhibition of growth rate is the relevant effect for algae (E_rC_{50}); effect on biomass can be used for algae when no data on growth rate are available.

In line with the definition of ECx and NOEC (provided in Section 4.1.1.1 of CLP Regulation), unbound L(E)C_{50} values should not be considered in the evaluation of the acute hazard.

A1.3.2. Chronic classification

According to the general definition of 'chronic aquatic toxicity' that is outlined in the CLP Regulation and in the 2nd ATP to the CLP (EC Regulation, 2008; EU Regulation, 2011), NOEC or other equivalent EC_x (eg EC_{10}) values should be used, and should be determined according to the following Standard Guidelines:

— For fish, chronic or long-term tests with fish that are initiated with fertilised eggs, embryos, juveniles, or reproductively active adults. Tests should be consistent with OECD Test Guideline 210 (Fish Early Life Stage), the fish life-cycle test (US EPA 850.1500), or equivalent. Observational endpoints may include hatching success, growth (length and weight changes of the surviving fish), spawning success, and survival.

— For daphnids, tests consistent with OECD TG 211 are recommended and retained.

— For algae, NOEC and EC_{10} values derived from 72- or 96-hours toxicity tests are generally considered as chronic data and used for classification (ECHA, 2015). E_rC_{10} is preferred over E_bC_{10} when available, as specified in the CLP Regulation EC 1272/2008 and 2nd ATP to the CLP).

— For vascular plants (eg *Lemna species*), NOEC/EC_{10} values obtained from tests consistent with OECD TG 221 and US EPA 850:4400 can be used for classification if no algal data are available. The observational endpoint in international protocols is the change in the number of fronds produced; test duration is 7 days.

In line with the definition of EC_x and NOEC (provided in section 4.1.1.1 of CLP Regulation), unbound NOEC/EC_{10} values should not be considered in the evaluation of the chronic hazard.

The ECHA Guidance on the Application of CLP Criteria (2017) also stipulates that 'valid data for short- and long-term tests on other species at the same trophic level shall also be considered, provided they are equivalent in terms of species relevance, testing conditions and test endpoints'.

A1.4. Data collection and quality assessment

Relevant ecotoxicological data can be drawn from relevant literature, published literature, available study reports, or internationally recognised databases that are used for regulatory purposes. Evaluation of data involves a review of how well each study was conducted, and how the results are interpreted to accept (or reject) a study in accordance with the purpose of the assessment. Criteria for assessing the reliability of test data have been proposed by eg Klimisch et al. (1997) and Moermond et al. (2016). Klimisch-categorisation (K1–K4) is based on the overall methodological quality of the study and completeness of reported, but does not necessarily make an explicit conclusion on the importance of the study as the latter may depend on the purpose for which the results are considered. A K1-classification requires that tests are performed in line with OECD Guidelines and that all key aspects are addressed with proper justification for any deviation from standard requirements. K4-studies (not assignable) typically refer to test data for which no information on testing procedures and conditions are available. In those cases where quality issues are identified for one or more of the criteria, the study will be qualified as K2 (reliable with restrictions) of K3 (unreliable), depending on the potential impact of the study limitations on the reported result. Discriminating between K2 and K3 does require a degree of expert judgement and understanding of the impact of test conditions on the observed ecotoxicological response.

Evaluation parameters include:

— Type of test.

— Description of test material and methods.

— Assessment of validity criteria.

— Description of physicochemical test conditions: temperature, oxygen, hardness, salinity, pH, dissolved organic carbon, light intensity and spectrum, photoperiod.

— Adequate chemical analysis, including measured concentration levels of test substances.

Other elements that determine the overall reliability of results include:

— Meeting minimal endpoint requirements in the control.

— A clear and consistent concentration-effect relationship (increasing effect with increasing dose).

— Hormesis effect should not be considered for EC_X derivation.

— $L(E)C_X$[6] and/or NOEC values that are estimated using appropriate statistical analysis; concentration-response modelling such as regression models to calculate $L(E)C_X$), however, are generally preferred over the classical hypothesis testing ($p< 0.05$) used to derive NOEC values.

— Availability of information concerning the statistics.

The CRED (Criteria for Reporting and Evaluating ecotoxicity data) guidelines that have been proposed by Moermond et al. (2016) represent a more detailed, transparent, and consistent alternative to the traditional Klimisch method. CRED guidelines have shown to be of particular use in the reliability assessment of non-standard guideline studies as the CRED-methodology enhances the overall transparency of (regulatory) decisions on the quality of the studies. Nevertheless there remains a need for expert judgement since the importance of some criteria will depend on the type of study.

6. A value of 10 for X (ie an effect of 10% in comparison to the control) is usually assumed for the derivation of an $L(E)C_X$ that is equivalent to the NOEC.

Extensive guidance on quality criteria in ecotoxicity testing is provided in the guidance documents that were developed by ECHA in their guidance on Information Requirements and Chemical Safety Assessment Documents (eg Chapter R.4: Evaluation of Available Information, 2001; Chapter R.10: Characterisation of Dose [Concentration]-Response for Environment, 2008, 2012).

After qualifying a report as reliable, confirmation should also be made about the relevance of the data for hazard/classification purpose. This is a step that is particularly important for sparingly soluble metals/metal compounds to check for. For example, the pH-boundaries of the full Transformation/Dissolution protocol range from 5.5 to 8.5, whereas the acceptable pH in the various OECD test media is situated from 6 to 9 (see **Table A1.1)**. This discrepancy can lead to significant hazard data gaps for metals whose toxicity is significantly determined by pH; at the lowest pH levels (<6) no reliable ecotoxicity data are available for assessing the hazard at pH 5.5, whereas the lack of T/Dp information at higher pH levels (>8.5) does not allow for a hazard assessment that is based on reliable ecotoxicological information for the 8.5–9 pH range (see **Annex 2** for more information on the T/Dp test). Such relevancy issues related to the acceptable/recommended physicochemical property ranges of test media should be considered carefully. The main attention points when assessing the relevance of a data point include:

- Ecological relevance of the endpoint used.
- Relevance of the test substance.
- Relevance of the species other than the standard species that are specified under UN GHS (2015, Rev.6) and EU CLP (2008).
- Relevance and adequacy of exposure duration.
- Acclimatisation/adaptation.
- Relevance and adequacy of the test medium for hazard classification purposes.

More descriptive information and conditions on these critical aspects for metals can be found in the MERAG Fact Sheet on data reliability and relevance (MERAG, 2016a Fact Sheet 03: Effects Assessment[7]).

Regarding the relevance of the test medium, the various OECD Testing Guidelines for algae, fish and crustaceans provide detailed information on test media that can be used for acute and chronic ecotoxicity testing, as well as specific physicochemical criteria to be met to consider test results as reliable/relevant. **Table A1.1** presents an overview of the relevant test media quality criteria that are reported in these guidelines.

With exception of the algal media, all waters (natural, artificial) that are considered relevant for short-term and long-term tests with invertebrates and fish, should have a total organic carbon content not exceeding 2 mg/L. Acceptable ranges on pH and hardness are similar for fish and crustaceans, and are in line with typical environmental conditions in EU-surface waters (eg typical hardness of 125 mg/L as $CaCO_3$, based on median Ca- and Mg -levels in FOREGS[8]). Reported ranges for hardness and pH are notably narrower in the recommended algal media, but this is because only artificial media are considered for this taxonomic group. These media are no more than a solution of various salts in deionised water, and the pH obtained in the media is determined by the equilibrium between CO_2 concentration in the medium and in the overlying air. The hardness, on the other hand, is solely determined by the added amount of Ca and Mg. Natural waters are typically not used for algal testing due to the presence of natural algal communities in natural waters, making the use of natural waters as test medium more challenging.

Table A1.1 Physicochemical properties of various OECD test media

Taxonomic group and Guideline	Information on test media	Acceptable/ Recommended range		
		pH	Hardness (mg $CaCO_3$/L	C-content (mg/L)
Algae **OECD 201**	Artificial media are defined. No reference to natural waters.	7.5–8.1 (depending on medium); variation <1.5	15–60	Not specified
Crustaceans **OECD 202, 211**	Artificial media are defined. Natural waters are considered suitable.	6–9	140–250 (for *D. magna*)	< 2
Fish **OECD 203, 210, 212, 215, 229**	Artificial media are defined. Clean natural waters or dechlorinated tap water are considered suitable.	6–8.5	40–250 (preferably < 180)	< 2

7. https://www.icmm.com/website/publications/pdfs/mining-metals/merag/merag-fs3-2016.pdf
8. http://weppi.gtk.fi/publ/foregsatlas/

A1.5. Data treatment, interpretation and ERV derivation

When a limited number of data are available for a substance, the lowest reliable and relevant value for each taxonomic group is determined, resulting in an Ecotoxicity Reference Value (ERV) for each of the three taxonomic groups and for each species. The lowest of the three acute ERVs is the final ERV_{acute} that is used for defining the acute hazard profile, whereas the lowest of the three chronic ERVs is the final $ERV_{chronic}$ that is used for defining the chronic hazard profile.

Unlike organic substances, metal salts often have several data points for one single endpoint. The most straightforward way to handle situations when there are multiple reliable data points available for a given test species/endpoint is to use the lowest value, eg the lowest NOEC or $L(E)C_x$.

ECHA Guidance Document Guidance on the Application of CLP Criteria states that the most sensitive (the one with the lowest $L(E)C_{50}$ or $NOEC/EC_{10}$) is generally used for classification, as this approach is a conservative approach, especially when a wide range occurs between the lowest and highest data points for a given species. However, this must be dealt with on a case-by-case basis. When larger data sets (four or more values) are available for the same species, same endpoint and same parameter, the geometric mean of toxicity values may be used as the representative toxicity value for that species. Indeed, according to the guidance for substances, 'where four or more ecotoxicity data on the same species and endpoint are available, the data should be grouped, and the geometric mean used as a representative toxicity value for that species'. In estimating a mean value, it is not advisable to combine tests of different species within a taxonomic group or in different life stages or tested under different conditions or duration. Also, if acclimation/adaptation is important then test results could be grouped, based on the similarity of the background in the culture medium with the background found typically in the environment.

It should be noted that the guidance on grouping does not specifically refer to differences in test medium properties but rather uses the generic terminology 'different conditions'. The latter could refer to differences in light intensity, testing temperature, feeding regime, medium renewal, etc, but could also cover variation in test medium properties such as pH, hardness and dissolved organic carbon content. These properties may be of limited importance for many (organic) substances but typically have a significant effect on the bioavailability and toxicity of metals through various mechanisms (speciation, competition for binding, complexation). Since most ecotoxicity tests differ among each other for one or more of these physicochemical parameters, the derivation of a geometric mean would only be possible in specific situations where all these parameters were monitored frequently during the exposure period and proven to be virtually identical.

For some metals a possible solution to this problem would be the normalisation of the data to identical physicochemical conditions using bioavailability modelling approaches. Bioavailability models consider the interaction of metals with organic and inorganic ligands in test media and natural environments, using metal speciation models for example WHAM, Visual Minteq, PHREEQ, etc. Such models calculate the non-complexed and complexed fractions of the metal ions. More advanced bioavailability models have also been developed such as the Biotic Ligand Model (BLM) allowing for the calculation of the concentration of metal ion responsible for the toxic effect at the level of the organism. BLM integrates data from speciation models with the interactions between metal ions and other competing ions at binding sites on the organism-water interface (eg epithelial cells of gill tissue). The BLM model has at present been developed and validated for a limited number of metals, organisms, and endpoints. An extensive review of the concepts of the several existing BLM models and the model parameters can be found, for example, in Niyogi and Wood (2004)[9] and Adams and Garman (2024).[10]

The tools mentioned above can be used for the normalisation of toxicity data towards the hardness/DOC or to the pH conditions dictated by the Transformation/Dissolution protocol, but are not yet recognised as official standard method. If used, the models and formulae used for the characterisation of metal bioavailability in the test media should always be

9. Niyogi S., Wood C. M., 2004. Biotic ligand model, a flexible tool for developing site-specific water quality guidelines for metals. *Environ.Sci.Technol.* 38(23): 6177–6192.
10. Adams W. J., Garman E. R., 2024. Recommended updates to the USEPA Framework for Metals Risk Assessment: Aquatic Ecosystems. *Integr.Environ.Assess.Manag.* 20(4): 924–951.

clearly documented and/or reported, allowing for their translation back to natural environments, and interpretation of the results within a regulatory context should be done with caution.

Translating the data for all species to a generic medium would allow to determine specific geometric mean values if sufficient data (n=4) are available. The main requirement for such an approach, however, is to define the composition of a generic medium that is relevant for all test species. Taking into account the information provided in **Table A1**, a common hardness level for all three species cannot be defined as algae prefer low hardness whereas both fish and crustaceans prefer a significantly higher hardness. Regarding the pH, algae should be tested in a slightly basic medium. This pH level is acceptable for crustaceans and fish, but for some metals the highest toxicity is observed at more acidic conditions (eg pH 6). For sparingly soluble metals, this pH-dependent toxic response is managed by the derivation of pH-specific ERVs that are then compared with the T/Dp results conducted at these respective pH levels. The pH-banding methodology, however, is in principle not applicable for soluble compounds where only one ERV value is used.

From the data provided in **Table A1**, it can be concluded that tests conducted in media with an organic carbon content that exceeds 2 mg/L, should not be used for classification purposes. Dissolved organic carbon (DOC) forms complexes with metals, thereby reducing their bioavailability and toxicity. Various studies have demonstrated the reduction of metal toxicity in natural waters with high dissolved carbon content. Excluding test data obtained in high-DOC media when assessing the hazard properties of metals is therefore justified. With the existing normalisation tools, however, it is possible to translate EC_{10}s/NOECs that were generated in high-DOC media (>2 mg/L) to values that represent the expected response in low DOC-medium (0–2 mg/L). Such an approach would significantly expand the size of the data set that is available for ERV derivation, providing that the normalisation models have been properly validated and have been accepted for regulatory purposes, and if it can be demonstrated that the deviation from the physicochemical parameters as defined in the OECD Guidelines did not act as a confounding factor on the outcome of the test.

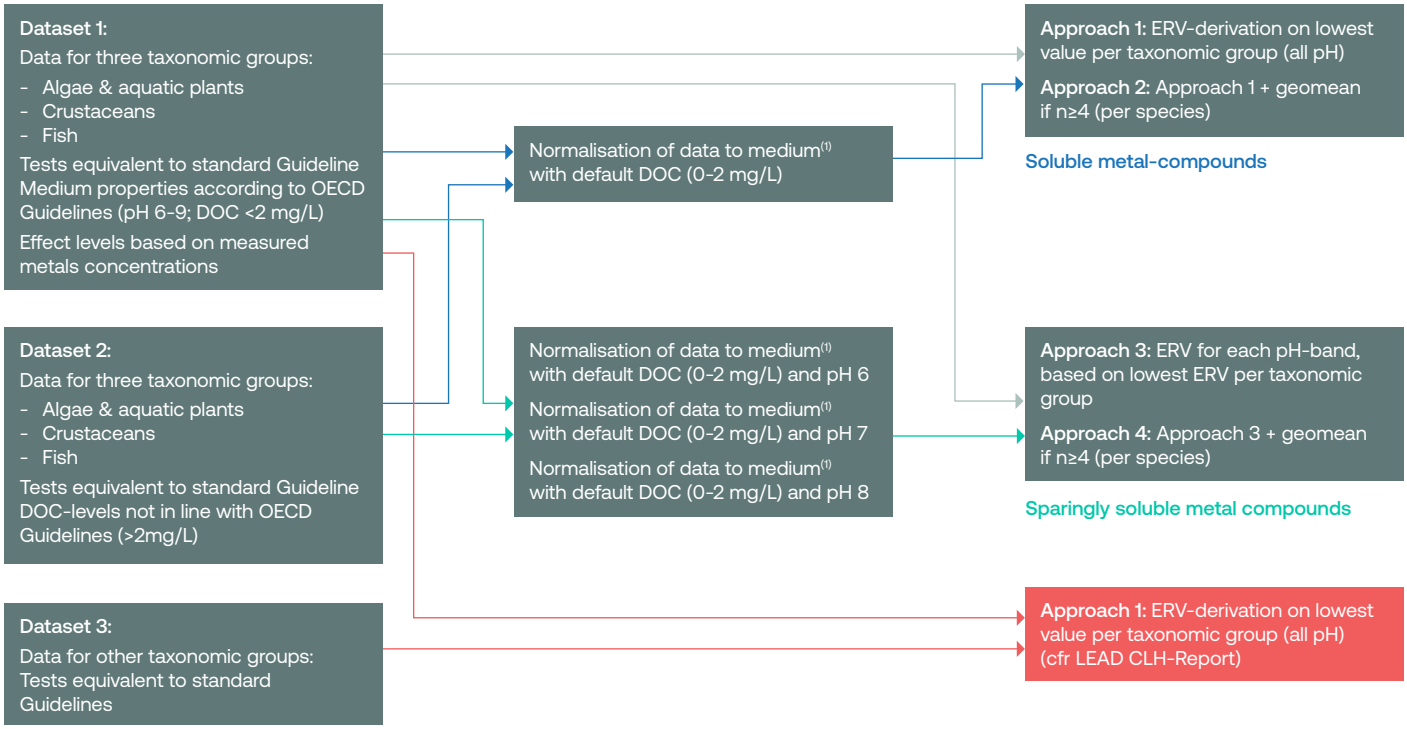
Data treatment regarding sparingly soluble metal compounds

The methodology for the classification of sparingly soluble metals and inorganic metal compounds is discussed in Annex IV of the Guidance Document on the Application of the CLP Criteria. According to this Annex, a decision on whether the substance is classified will be made by comparing aquatic toxicity data and solubility data. Depending on the available data two approaches can be followed:

— Limited dataset is available: existing data should be taken together irrespective of whether the toxicity and dissolution data are at the same pH and the lowest data point should give the basis for classification. This default approach may lead to the lowest toxicity data point being compared with the highest transformation dissolution result, but with each parameter not necessarily determined for the same pH levels. This approach is not environmentally relevant since dissolution at eg pH 6 would not occur (see **Annex 2** of this document) simultaneously with exposure at pH 8. Thus, additional dissolution testing is recommended to avoid making comparisons that are not ecologically relevant.

— More extensive toxicity/dissolution dataset is available: a split of the Acute and Chronic ERVs can be performed according to their pH used during T/D test. The worst-case classification entry across pHs should be used based on comparing T/Dp data with relevant ecotoxicity data across the pH range. Meaning that toxicity data and transformation data are in this case always compared at the same pH.

This split of the effects data into pH classes would apply in an equal way to the acute and the long-term effects data sets.



(1) the same for all organisms, or specific for each taxonomic group (algae, crustaceans, fish)

Figure A1.1. Chronic ERV derivation method – overview of the proposed data treatment strategy

Conclusion

The generic wording on how to perform the data treatment and ERV derivation – as found in the CLP Regulation and associated ECHA Guidance Document Guidance on the Application of CLP Criteria – in combination with the overall complexity of metal ecotoxicity, has resulted in different ways to derive appropriate Acute and Chronic ERVs for soluble and sparingly soluble metal compounds. This ambiguity – even on a regulatory level – is clearly reflected in various metal CLH proposals for a harmonised environmental classification, where rapporteur Member States used methodologies for the derivation of chronic ERVs that significantly deviated from some of the principles that are described in the CLP Regulation.

The general scheme that is outlined in **Figure 1** can be followed for the derivation of chronic ERVs for Metals and Metal Compounds. A comparable methodology can be followed for the revision of the acute ERVs, but any methodology that includes a normalisation step can infrequently be applied as the required normalisation tools sometimes lack acute data and only available for a few metals.

Step 1: Division of the data into three groups:

— **Dataset 1** contains all reliable and relevant data on algae/aquatic plants, crustaceans and fish that were generated in test media that meet the OECD criteria on DOC and pH (6–9). Hardness for eg crustaceans may not be considered to be an exclusion criterion for the following reasons:

- The reported hardness in the OECD 202/211 guidelines is specific for *Daphnia species* but not necessarily for other crustaceans.
- All data have been assessed to be reliable; hence it is assumed that all test validity criteria were met (eg on reproduction) and therefore the hardness of the test medium was sufficiently suitable.

— **Dataset 2** contains any remaining reliable and relevant data on algae/aquatic plants, crustaceans and fish that were generated in test media that meet the OECD criterion on pH (6–9), but not on DOC.

— **Dataset 3** contains reliable data on other taxonomic groups that are used for risk assessment purposes, and that were generated in test media that meet the OECD criterion on DOC.

Step 2: Application of various data treatment approaches (used when considered appropriate and relevant):

- **Approach 1** is the most generic approach where the ERV is based on the lowest value per species ($ERV_{species}$), and all data within a taxonomic group are pooled together (no differentiation based on test medium composition).
- **Approach 2** is a refinement of Approach 1, where the $ERV_{species}$ is a geometric mean if four or more values are available for that species.
- **Approach 3** generates ERVs that are in principle only used for the environmental classification of sparingly soluble compounds: the datasets are further divided into 3 pH-bands, and the pH-specific ERV for each taxonomic group (ERV_{pH6}, ERV_{pH7}, ERV_{pH8}) is based on the lowest value per species ($ERV_{species,pHx}$).
- **Approach 4** is a refinement of Approach 3, where the $ERV_{species,pHx}$ is a geometric mean if four or more values are available for that species.

Regarding the proposed bioavailability corrections (ie normalisation of ecotoxicological information covered by Dataset #2), this type of refinement is only possible for metals for which validated normalisation models are available (eg MERAG, 2016a).

A1.6. Statistical extrapolation method for ERV derivation

According to the ECHA Guidance (ECHA, 2017), statistical techniques (eg HC_X derivation) can be considered to estimate the aquatic toxicity reference value for classification in a weight of evidence (WoE) approach when the available data set meets the criteria for applying the Species Sensitivity Distribution (SSD) approach (number of species to ensure statistical relevance, representation of required taxonomic groups):

'In case of very large data sets meeting the criteria for applying the Species Sensitivity Distribution (SSD) approach or other statistical and data combination techniques (eg HC5 derivation, use of 10^{th} or 90^{th} percentiles, etc.) can be considered in order to estimate the aquatic toxicity reference value for classification (equivalent to using the lowest EC_{50} or NOEC), within the WoE.'

In the statistical extrapolation method, the susceptibility of a set of species for a given toxicant can be described by some statistical distribution. Such an SSD can be visualised as a cumulative distribution function. The cumulative distribution function curve follows the distribution of the sensitivity data obtained from ecotoxicological testing, plotting effect concentrations derived from acute or chronic toxicity tests, ie $L(E)C_{50}$ and $NOEC/EC_{10}$-values, respectively.

Detailed information on how to apply the SSD-approach for environmental classification purposes is provided in the MERAG Fact Sheet 08 (MERAG, 2016c). Some of the key elements of this approach, however, are given below:

- **Size of the data set:** an appropriate question to consider while evaluating the data set as a candidate for the statistical extrapolation approach is 'how many data are needed?' to fit a SSD model with sufficient confidence using all available acute/chronic NOEC values as input. The larger the sample size, the greater one's confidence in the choice of a probability distribution and the corresponding estimates. Conversely, for small sample sizes, goodness-of-fit statistics will often fail to reject any of the hypothesised probability distribution function. In general, there is no rule of thumb for the minimum sample size needed to specify an SSD. Increasing sample size may, however, be an important consideration when making decisions about uncertainty related to the use and relevance of the SSD.
- **Choice of the appropriate distribution model:** both parametric (eg Log-normal, Weibull distributions, etc.) and non-parametric distributions can be used to characterise the SSD, but it is critical to recognise that the choice of distribution model can influence the resulting SSD and the derived hazardous concentration. Although it is often impossible to exclude *a priori* any distribution, there may be mechanistic reasons that dictate the shape of the 'real' distribution may be determined by mechanistic reasons, eg due to (homeostatic) regulation of essential and non-essential metals. For this reason, it has been suggested that a threshold model for

SSD development may be more appropriate for metals in general, and essential elements in particular (Brix et al. 2001; Van Straalen 2002; Van Sprang et al. 2005).

- **Incorporation of bioavailability in the SSD:** the importance of bioavailability and physicochemical parameters on metal toxicity has been explained in Section A1.5., and these concepts are also relevant for data points that are part of a SSD.
- **Selection of an appropriate HC_X for classification purposes:** the 5th percentile of an SSD is used as the reference value for PNEC-setting. For hazard ranking purposes, however, the choice of the 5th percentile as an ecotoxicity reference value could be too stringent in comparison with the lowest value method when the SSD data set is small. The 20th percentile value of an SSD (HC_{20}) as a reference value typically corresponds to the lowest ecotoxicity value of three available ecotoxicity values. This percentile is based on a comparison between different plotting positions (ie methods to determine percentiles of data points). The 20th percentile is the average of the most common plotting system (mean) and the scientifically recommended most accurate method. Therefore, a cut-off value of HC_{20} values is recommended for deriving an ecotoxicity reference value for classification purposes (MERAG, 2016c).

A1.7. Derivation of the M-factor (multiplying factor)

The derivation of an appropriate classification of (complex) metal-containing materials using the summation method requires the classification of each relevant constituent in this material. However, when a material contains one or more components that are classified as Aq.Acute 1 or Aq.Chronic 1, attention must be paid to the fact that such components may contribute to the ecotoxicity of the material even at a very low concentration. This is the case when the acute and/or chronic ERV is/are well below the threshold concentration that defines the Aq.Acute 1/Aq. Chronic 1 classification: 1 mg/L (acute), 0.1 mg/L (chronic without evidence of environmental transformation of the dissolved ion), or 0.01 mg/L (chronic with evidence of environmental transformation of the dissolved ion). Under these circumstances, the generic application of the mixture rules as outlined in the summation method can lead to an 'under-classification' of the material. Therefore, a multiplying factor (M-factor) is assigned to each component that is classified as Aq.Acute 1 and/or Aq.Chronic 1:

- Substances belonging to the classification category 'Aq.Acute 1, M=10' are on average 10 times more toxic than those belonging to 'Aq.Acute 1, M=1'.
- Substances belonging to the classification category 'Aq.Acute 1, M=100' are on average 10 times more toxic than those belonging to 'Aq.Acute 1, M=10'.
- Higher M-factor values follow the same principle.

Table A1.2. Acute and chronic M-factors

ERV_{acute} (mg/L)	Multiplying factors (M)	
$0.1 < ERV_{acute} \leq 1$	1	
$0.01 < ERV_{acute} \leq 0.1$	10	
$0.001 < ERV_{acute} \leq 0.01$	100	
$0.0001 < ERV_{acute} \leq 0.001$	1,000	
Continue in factor 10 intervals	...	
$ERV_{chronic}$ (mg/L)	Multiplying factors (M)	
	No environmental transformation	Environmental transformation
$0.01 < ERV_{chronic} \leq 0.1$	1	Not applicable (Aq.Chr.Cat.2/3)
$0.001 < ERV_{chronic} \leq 0.01$	10	1
$0.0001 < ERV_{chronic} \leq 0.001$	100	10
$0.00001 < ERV_{chronic} \leq 0.0001$	1,000	100
Continue in factor 10 intervals	...	...

Annex 2: Transformation/Dissolution Test Protocol and Implementation for Setting Acute and Chronic Hazard Classes for Metals and Metal Compounds

A2.1. Introduction

Metals, sparingly soluble metal compounds (SSMC) and complex metal-containing substances/mixtures undergo interactions with their surrounding media that affect the release and fate of the metal ion, partitioning from the water column and the species of the metal ion(s) that exist there. It is therefore necessary to consider whether metal ions are likely to be formed and if so whether they are likely to be formed rapidly enough to cause a hazard concern, ie whether the concentrations reached within a given timeframe exceed the Ecotoxicity Reference Values (ERVs, See Annex 1) (UN GHS 2025, Rev.11).

The rate and the associated magnitude of the metal ion concentration, which is known as 'Transformation/ Dissolution (T/D)', can vary extensively between the metal, metal compounds, and metal-containing materials, and is an important factor in determining the appropriate hazard class. It is also important to realise that metal dissolution is affected by several physico-chemical factors, not least of which are the properties of the media with respect to pH, ionic concentrations, temperature, O_2 concentration and CO_2 concentration. In addition to these properties, other factors such as the exposure time to the test media, the size and specific surface area of the particles that have been tested, and the mass or surface area loading of the metal in the media will play a part in determining the concentration of total dissolved metal in the water.

In summary, the level of the metal ions that may be released to an aqueous solution following the addition of metal-containing substances is largely be determined by the following processes/conditions:

- The loading and particle size of the metal
- The corrosion rate
- The extent to which it can react with the media to transform to water soluble forms, and
- The pH and ionic composition of the media

As various parameters are known to have a significant impact on the release rate of metal ions, transformation data can generally only be considered as reliable for the purposes of classification if conducted according to the standard Transformation/Dissolution Protocol (T/Dp). Guidance on how to conduct a T/Dp test is given in OECD Guideline No. 29 which was further incorporated into Annex 10 of the UN GHS Document (2025, Rev.11). Further details on the composition of the T/D artificial media are also given in this Annex, ie the concentration of total organic carbon in the medium should not exceed 2.0 mg/L.

It is worth noting that case-by-case adaptations to the testing protocol may be required for so-called 'difficult to test substances', and any changes to the protocol requires proper motivation and justification. An example of such a complex substance is nanomaterials where, for example, separation of the nanomaterial from the T/D medium for analytical purposes, proper characterisation of the exposed surface area and understanding of dissolution/release mechanisms all represent challenging obstacles when conducting a T/Dp test.

Different types of T/D tests have been described in OECD No. 29 and Annex 10 of the UN GHS (2025, Rev.11):

- A 24-hour 'screening' test
- A 'full' 7-day T/Dp test
- A 'full' 28-day T/Dp test

The function of the screening test is to identify those metal compounds or metal-containing materials that undergo dissolution and transformation rapidly, such that they are expected to elicit an ecotoxicological response at an exposure concentration that equals the hazard thresholds (and therefore comparable/ indistinguishable from soluble forms). Metal compounds and metal-containing materials that do not behave in this way are then subjected to 'full' T/Dp tests. For metals and complex inorganic materials (eg inorganic UVCBs, ores and ore concentrates, alloys), the screening test is not required and only the full test is relevant. Full T/Dp tests can be performed with massives and powders, different loading rates, and different pH levels.

Because pH has a significant influence on T/D, both the screening test and the full tests should in principle be carried out at a pH that maximises the concentration of the dissolved metal ions in solution. If no relevant literature data exist, a preliminary screening test may help defining this. In the absence of screening data that would allow the determination of the most appropriate pH level, the full range of environmental relevant pH levels (6 to 8.5) must be considered in full T/Dp testing. In addition, to take into consideration possible long-term effects on acidic lakes, an expanded pH range of 5.5 to 8.5 should be used for the 28-day full test. However, the OECD Transformation/Dissolution Validation Management Group recommended restricting the pH range for the 28-day full test to the pH range of 6.0-8.5 for the present time, because no suitable system could be recommended that could maintain the pH constant at the lower range (pH = 5.5) of the test, without influencing the transformation dissolution or ecotoxicity properties of the metal, alloy or the SSMC (Helsinki meeting June 2003). It should be further noted that complex substances and mixtures of different metals may have different pH-release behaviour requiring the full T/Dp to be conducted at multiple pH levels (eg 6 or 8, or even 7).

A2.1.1. The 24-hour screening Transformation/ Dissolution test – SSMC

The function of the screening test is to identify those metal compounds that undergo either dissolution or Transformation/Dissolution such that their rate of dissolution is like that of soluble forms. Under UN GHS (2025, Rev.11), metal compounds, having the smallest representative particle size on the market, are introduced into the aqueous medium at a single loading of 100 mg/L. Agitation is maintained at a standard rate during a 24-hour period. After 24 hours of agitation, the dissolved metal ion concentration is measured.

The 24-hour screening T/Dp test can also be used as pre-testing phase before conducting full 7 and 28-day T/Dp tests. The purpose of the pre-testing phase is to ensure accuracy and precision of the results obtained from the T/D protocol. This pre-test may help laboratories that are not familiar with the protocol to successfully perform a T/Dp test and it can include the following checks: the efficiency of the filtration method, the efficiency of the shaking conditions, issue of potential abrasion during agitation of the sample, the measuring technique and mass balance, the relevant pH for the full test and the most relevant loadings to start the 'full test' with.

This pre-testing should be done with a reference material that has been well studied, is stable/ representative in composition.



A2.1.2. The 7-day full Transformation/Dissolution test – SSMCs and CIMs/MOCs

The 7-day full T/Dp test is intended to determine the rate and extent of Transformation/Dissolution of sparingly soluble metal compounds, metals and complex multi-metallic materials at different loadings of metal in the aqueous phase. Generally, massive forms and powders are introduced into the aqueous medium at three different loadings: 1, 10 and 100 mg/L. These loadings correspond to the different acute classification categories under GHS (2025, Rev.11). A single loading of 100 mg/L may be used if a significant release of dissolved metal species is not anticipated or alternatively 1 mg/L if a release that would classify as acute 1 is expected. Transformation/Dissolution is accomplished by standardised agitation, without causing abrasion of the particles and maintaining the integrity of the surface of the test substance and any solid reaction product coatings formed during the test. The 7-day T/Dp results used are the dissolved metal ion concentrations obtained after the 7-day T/Dp testing period.

A2.1.3. The 28-day full Transformation/Dissolution test – sparingly soluble metals, metal compounds, and CIMs/MOCs

The long-term T/D endpoint is obtained during a 28-day T/Dp test at different pH levels, using a single load of 1 mg/L (UN 2025, Rev.11; Annex 10: Guidance on Transformation/Dissolution of metals and metal compounds in aqueous media). This loading corresponds to the chronic toxicity threshold that differentiates between a classification and no classification for the long-term environmental endpoint. Lower loadings that correspond with the threshold levels for the different chronic classification categories (0.1 mg/L, 0.01 mg/L) are not assessed due to practical reasons (accurate dosing, heterogeneity of some testing materials, analytical limitations regarding detection limits). The intent of these studies is to determine whether sufficient metal ions will go into solution across a pH range of 6–8.5 that would result in chronic effects. The test conditions of the 28-day test are like those of the 7-day study (ie it is recommended to continue the 7-day study using 1 mg/L loading for 28 days to evaluate the potential for long-term or chronic effects and to remain consistent with the conditions and results of the 7-day test). When specific criteria are met (ie the metal release for a specific surface area is known), the 28-day T/Dp data that are generated at 1 mg/L loading can be used for extrapolating releases at lower loadings, as is also foreseen in the CLP guidance on metals.

Annex 3: Critical Surface Area Approach

Surface area is an important parameter to consider in the classification of metals for aquatic hazard because any variation in surface area tested may significantly change the concentration of dissolved metal ions released within a given time-window for a specific mass loading. This is especially relevant for poorly or sparingly soluble metals, where dissolution is limited by surface area (Skeaff et al., 2000). Thus, particle size or surface area is fixed for the purposes of a Transformation/ Dissolution protocol (T/Dp) test, allowing the comparative classifications to be based solely on the loading level.

When generating classification data in a T/Dp test the massive form of a metal is represented by particles with a diameter of 1mm, whereas for powders the smallest particle size marketed is used to determine the extent of the transformation. There may be cases where data generated for a particular metal powder are not considered to be suitable for classification of the massive forms. For example, where it can be shown that the tested powder is structurally a different material (eg different crystallographic structure) and/or it has been produced by a special process and is not usually generated from the massive metal, classification of the massive can be based on testing of a more representative particle size or surface area, if such data are available. The powder may be classified separately based on the data generated on that material. However, in normal circumstances it is not anticipated that more than two classification proposals would be made for the same metal. As stated above, metal massives are tested at a particle size of 1mm diameter, but this default value could be altered if justifiable.

Metals with a particle size smaller than the default diameter value of 1mm can be tested on a case-by-case basis. One example of this is where metal powders are produced by a different production technique or where the powders give rise to a higher dissolution (or reaction) rate than the massive form leading to a more stringent classification.

The particle sizes tested and used for classification and labelling depend on the substance being assessed and are shown in the following table.

Table A3.1. Typical particle sizes tested and used for classification and labelling

Type	Particle size	Comments
Metal compounds	Smallest representative size sold	Never larger than 1mm
Metals – powders	Smallest representative size sold	May need to consider different sources if yielding different crystallographic/ morphologic properties
Metals – massive	1mm	Default value may be altered if sufficient justification

As described in Annex 10 of the UN GHS (2025, Rev.11) it is possible, using the T/Dp, to obtain a correlation between the concentration of the metal ion after a specified time interval as a function of the surface area loadings of the forms tested. Such correlations should be established for the relevant pH ranges as specified in the protocol. In such cases, it could then be possible to estimate the level of dissolved metal ion concentration at a given pH of the metal with different particles, using the CSA approach (Skeaff et al. (2000)). From this correlation and a linkage to the appropriate toxicity data at corresponding pH level, it is possible to determine a CSA of the substance that delivers the L(E)C_x/NOEC to the dissolution medium and then to convert the CSA to a Critical Particle Diameter (CPD) (see **Example Box A3.1**). This CPD at appropriate mass loadings for acute and long-term hazard assessment can then be used to determine the classification category of powders based on the finest representative powder on the market and determine an accurate classification of the massive metal by applying a 1mm (default) diameter.

While the concept of deriving a CSA and CPD from T/Dp correlations is scientifically interesting, this approach is not yet standardised or formally recognised in regulatory frameworks. The robustness and reproducibility of such correlations strongly depend on the quality of dissolution and toxicity data, and their practical application for classification purposes should therefore be treated with caution.

A schematic overview of the different steps of the CSA concept is given in **Figure A3.1**.

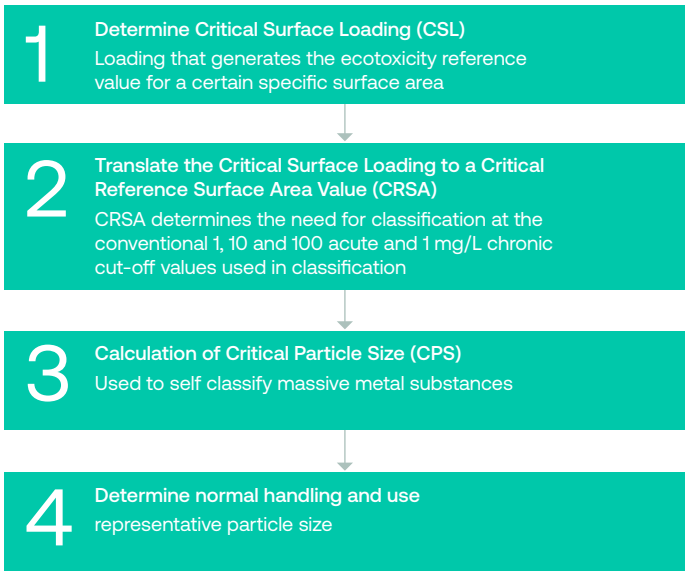


Figure A3.1. General overview of the various steps involved in the Critical Surface Approach

Within the CSA approach, an equation is developed to predict metal ion release (based on the measured metal ion release from multiple loadings of the metal), which is correlated to measured surface area, and a corresponding calculated equivalent particle diameter (**Figure A3.2**). The basis of the CSA method is that the release of metal ions is dependent on the surface area of the substance, with this release being predictable once the relationship has been established. The CSA is defined as the surface area loading (mm^2/L) to a medium that delivers a *concentration of ions in solution that exceeds the ecotoxicity reference value for the metal*. The term SA is the measured specific surface area (m^2/g) of the metal sample. The measured specific CSA ($SA_{critical}$) (m^2/g) is the measured specific surface areas for the corresponding low, medium and high loadings which are associated with the respective acute and long-term aquatic toxicity classification categories in the classification scheme for metals and metal compounds.

A typical equation for this relationship for a given substance, aquatic medium, pH and retention time is:

$$\log (C_{Me(aq)}, \text{mg/L}) = a + b \log(SL_a)$$

With:

- $C_{Me(aq)}$ = total dissolved concentration of metal ion (mg/l) at a particular length of test time (ie 168 hours for acute toxicity transformation testing) under certain conditions (ie pH, specified medium, etc.), as determined by Transformation/Dissolution testing of different surface area loadings.
- a, b = regression coefficients.
- SL_a = initial surface area loading (mm^2/L) [equals (measured specific surface area, SA, in m^2/g) X (substance mass loading in g/L) X 10^6], where SA was measured with the BET nitrogen adsorption-desorption technique.

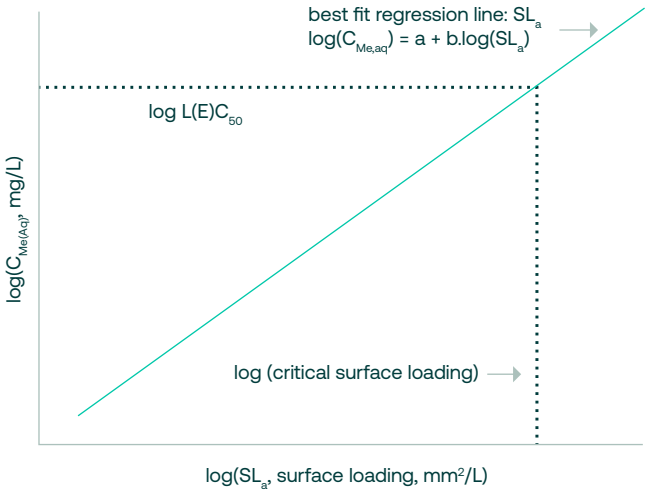


Figure A3.2. Determination of critical surface loading from regression line of log concentration of dissolved metal versus log surface loading (adapted from Skeaff et al. 2000)

Recent investigations of T/Dp data for massives and powders demonstrated that the Transformation/ Dissolution function was often linear and could hence be described as:

$C_{Me(aq)} = a + b(SL_a)$

Given the surface area is such a crucial parameter to determine the intrinsic dissolution release/surface to facilitate reading any variation in the particle size or surface area tested would cause a significant change in the levels of metals ions released over a specific period. Hence, the development of the critical particle size defines the potential for a given substance under a given set of experimental conditions. For the purposes of the T/Dp test, the particle size or surface area for a given metal substance is fixed (ie it is a property of that substance). This allows for classification to be based solely on the loading levels of the tested metal substance that delivers the metal in solution in excess of the 1, 10 and 100 mg/L cut-off values.

Therefore, the critical surface loading can be converted into a Critical Reference Surface Area that corresponds to the conventional 100, 10 and 1 mg/L cut-off points used in acute and chronic hazard identification. In general, the following equation can be used to calculate the Critical Reference Surface Area (CRSA):

$CRSA = (10 \times CSL_a) / CP$

With:

— CRSA = Critical Reference Surface Area (cm^2/g) that triggers classification

— CSLa = Critical Surface Loading (mm^2/L)

— CP = classification cut-off point (1, 10, 100 mg/L)

The Critical Reference Surface Area of a particle can be further translated into a Critical Particle Size (CPS), ie the size of a particle (massive, powder or alloy) above which an insufficient amount of ions is produced in an aqueous medium at the highest loading of the metal (ie is 100 mg/L for acute and 1 mg/L for chronic) to reach the ecotoxicity reference value (ie above which a downgrading in classification or a no classification result is obtained).

For standardisation, it is assumed that the particle size is spherical so that the CPS can be expressed as a diameter. The benefit of this approach is that it allows for comparison on an equal basis between different metals and particle sizes of the same metal or metal substances.

Hence, the CPS corresponds with a Critical Diameter (CD) according to the following equation:

$(SA_{sphere} / V) = CSRA \times \rho Me = 6 / CD$

With:

— SA_{sphere} = surface area sphere ($\pi \times d^2$, cm^2)

— V = volume sphere ($(\pi/6) \times d^3$, cm^3)

— CRSA = Critical Reference Surface Area (cm^2/g) that triggers classification

— ρMe = density metal (g/cm^3)

— CD = critical diameter (cm)

Figure A3.3 shows how the different classification cut-off values are transformed to critical diameters. This transformation allows a classification of a metal-containing powder to be conducted based on particle size and the outcome of the T/Dp test.

For chronic classification, the surface area or diameter should be compared with the respective chronic critical reference surface areas or the chronic critical diameters.

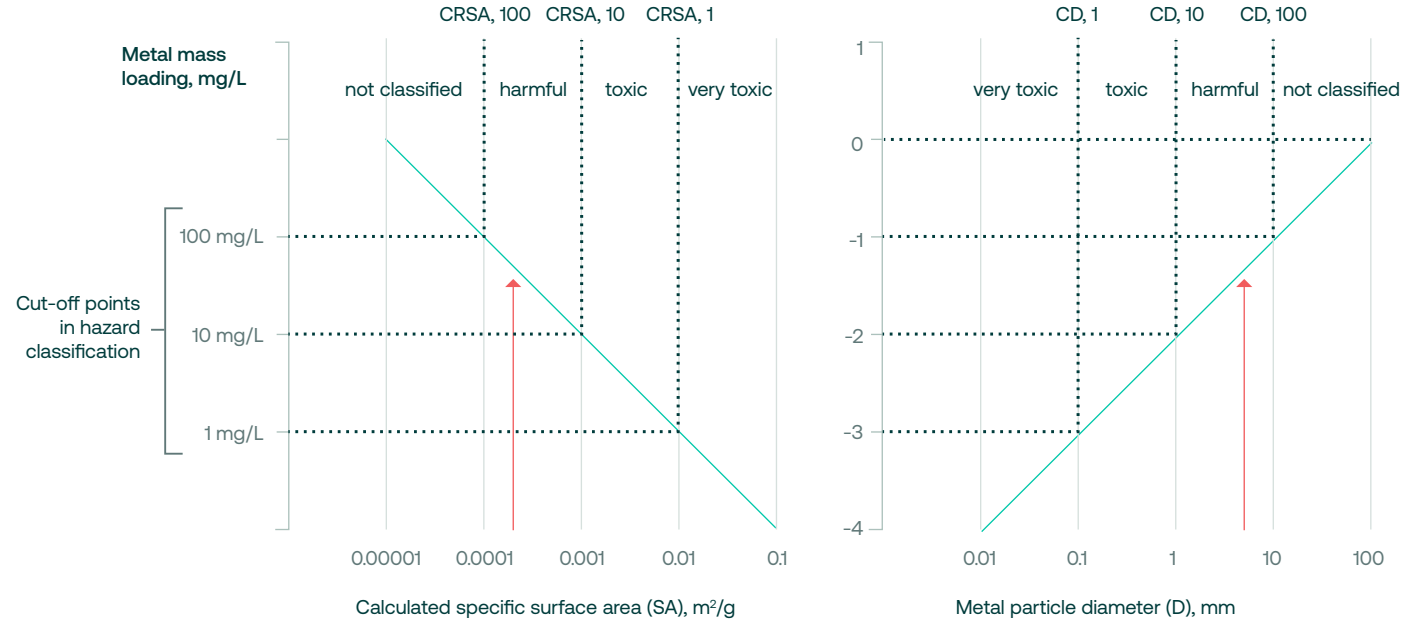


Figure A3.3. Illustration of acute hazard identification line and resulting self-classification levels for a metal with (a) various calculated Critical Reference Surface Area values and (b) Critical Diameters (CD) (adapted from Skeaff et al. 2000)



Example Box A3.1. Derivation of the acute and chronic environmental classification for a pure metal powder using the CSA Concept

To use the CSA method to determine the environmental hazard classification, the following data are required:

— Specific Surface Area usually expressed in m^2/g measured by the N-BET method (ISO 2003, 2010; ASTM 2010).
— The specific gravity (density) in g/L.
— The ERVs for acute and chronic ecotoxicity usually expressed as µg/L.
— The metal release values of the T/Dp at the acute and chronic cut-off loading in µg/L.

As an example we will use the metal X with the following properties:

Properties	
Specific Surface Area	10,000 mm^2/mg
Specific gravity	9 Kg/L
Acute ERV	50 µg/L
Chronic ERV	25 µg/L

And with the following results for the standard T/Dp (the values were chosen to illustrate the linearity of the metal released as a function of the loading).

Loading, mg/L	7 days' release of X, µg/L	28 days' release of X, µg/L
100	250	-
10	25	-
1	2.5	10

Classifying using the Critical Surface Loading Approach

The first step is to determine the amount of metal released per surface area unit (as $\mu g/mm^2$) at the different loadings, and divide these by the amounts released:

Initial Surface loading (SL_a), mm^2/L	7 days' release of X, $\mu g/mm^2$	28 days' release of X, $\mu g/mm^2$
1,000,000	0.00025	-
100,000	0.00025	-
10,000	0.00025	0.001

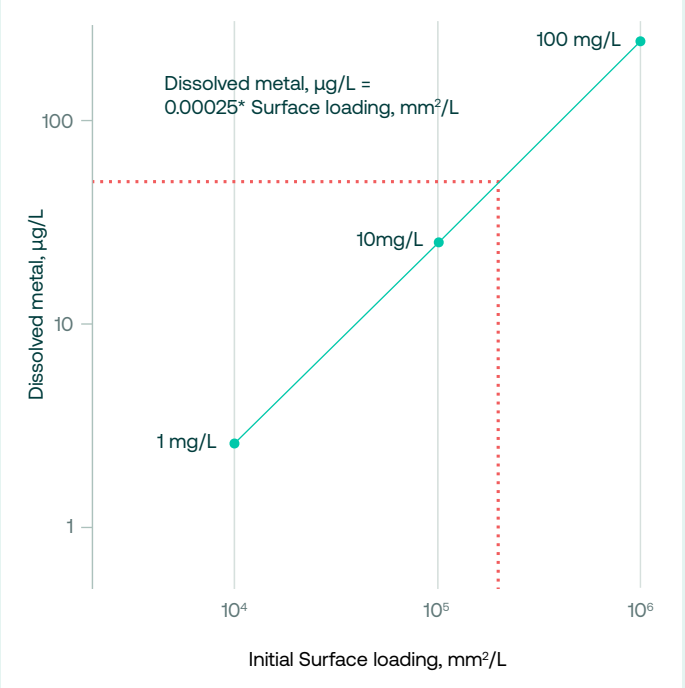
With these data, the Critical Surface Loading can be derived, ie the surface loading necessary in mm^2/L that can release an equivalent number of ions to reach the acute or chronic ERV.

	ERV, µg/L,	Critical Surface Loading, mm^2/L
Acute	50	200,000
Chronic	25	25,000

Then, an acute 3 classification will be triggered for this substance, because the surface loading of 200,000 mm^2/L is greater than 100,000 mm^2/L (10 mg/L) and lower than 1,000,000 (100 mg/L).

For chronic toxicity this metal powder will not classify, because at the maximum loading of 10,000 mm^2/L for 1 mg/L (Chronic 3), the surface loading does not exceed the Critical Surface Loading of 25,000 mm^2/L.

This is shown in the following figure (acute classification only):



Classifying using the Critical Diameter (CD) Approach

Using the values of Critical Surface Loading (CSL), the Critical Reference Surface Area (CRSA) can be derived for each loading.

For acute toxicity:

Loading, mg/L	CSL, mm^2/L	CRSA, in cm^2/g
100	200,000	2
10	200,000	20
1	200,000	200

To get classified for a specific acute hazard category (1, 2 or 3), the specific surface of the sample should be equal to or greater than the CRSA at that loading.

Also, using the specific gravity value of the sample, it is possible to calculate the Critical Diameter (CD) that a particle of this particular type of metal powder should have to classify in a given acute category (assuming the particles are perfect spheres). In this case:

CD (mm) = 6 / [CSRA (cm^2/g) x ρMe (g/cm^3)]

The corresponding CD values are then:

Loading, mg/L	CRSA, in cm^2/g	CD, in mm
100	2	0.33
10	20	0.033
1	200	0.0033

The procedure is homologous for chronic classification.

Annex 4: Characterisation and Identification of Complex Inorganic Materials (CIM)

A4.1. Introduction

The most straightforward characterisation of a CIM is to determine the percentage of each metal that is present in the material, without considering the chemical structures that embed these metals. The relevant components of a CIM are those which are classified 'Acute 1' or 'Chronic 1' and present in a concentration of 0.1 % (w/w) or greater, and those which are classified 'Chronic 2', 'Chronic 3' or 'Chronic 4' and present in a concentration of 1% (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components (those with an M-factor) that a component present in a lower concentration can still be relevant for classifying the CIM for aquatic environmental hazards. Generally, for components classified as 'Acute 1' or 'Chronic 1' the concentration to be considered is (0.1/M-factor)% (w/w) (CLP Regulation, EC1272/2008; Annex 1, Section 4.1.3.1).

A generic classification could then be derived following the mixture rules under GHS and EU CLP, using the classification of a soluble metal form. It is expected, however, that such an approach, would result in an overly conservative outcome that overestimates the solubility and availability of the metal ions in aqueous medium.

Hence, a proper characterisation of a metal-containing CIM should address the different properties of the material that may affect the release and availability of metal ions. The most critical parameters for different types of complex materials are given in the following sections.

A4.2. Characterisation of inorganic UVCB (iUVCB) substances

An accurate and precise analytical characterisation of inorganic UVCBs (eg ore concentrates, recyclables) is critical to ensure a UN GHS/EU CLP classification that is as accurate as possible.

The high variability of iUVCB constituent concentrations complicates fulfilling the toxicity and ecotoxicity testing requirements because a 'worst-case' or representative sample cannot be selected or generated. Instead, there is less uncertainty in relying on the ecotoxicity information of the data-rich constituents and their concentration. In contrast, the lower variability of the speciation/mineralogy of the main iUVCB constituents enables the identification of representative samples for the purpose of analytical speciation/mineralogy analysis and testing physicochemical properties.

Therefore, for iUVCBs:

— The substance testing approach is mainly relevant for the physical hazards. Sometimes, in those cases where minor constituents do not significantly contribute to the substance hazard, a substance testing approach can also be used for human health and environmental hazards.

— The constituents' testing approach is usually relevant for the human health and environmental hazards.

Considering the high number and data richness of iUVCB constituents, a constituents-based approach (ie based on constituents testing data) is applied to estimate the effects for relevant ecotoxicological endpoints of the entire iUVCB. The principles of the method are:

1. Calculation of the classification of the UVCB substance applying the rules for mixtures as set up in EU CLP Section 4.1.4.
2. Derivation of the hazardous concentration of the UVCB corresponding to the calculated classification category using the adequate EU CLP Guidance Annex I table.

This approach provides conservative hazard estimates and furthermore considers the variability in elemental (chemical) composition of the UVCB.

In summary, the iUVCB characterisation is based on information collected from representative samples, with composition uncertainty and variability addressed as follows:

— Firstly, report the full composition as elemental composition, as this is the most accurate information:
  - Each constituent is listed as element
  - Each element is assigned with min, max and typical concentration
— Secondly, assign each element with its expected speciation (mineralogical species) in order to classify based on CLP mixture rules. When the speciation of the elemental constituent is unknown or if different species co-exist (eg intermetallic and metal sulphides), the speciation with the reasonable worst-case classification is assigned.

Variability in composition is further assessed by checking elemental concentrations and ensuring that the reasonably higher concentration is considered, ie the maximum of the typical concentrations reported.

Based on the data and reasonable worst-case assumption, iUVCB is derived by applying the CLP mixture rules.

Where relevant, documenting the geological interpretation of the results as well as the effects of production processes, regular transport, handling and use on chemical speciation and physicochemical properties can be added to the composition reporting, to support reasonable worst-case assumptions. Furthermore, the full overview can be complemented by collecting the current (self- and harmonised) classification(s) of all constituents above the cut-off of 0.1%/M (CLP Regulation, EC1272/2008; Annex 1, Section 4.1.3.1) and the best available ecotoxicological hazard data set that exists for the inorganic UVCB and its constituents.

It is worth noting – though outside the scope of an environmental hazard assessment – that the regular substance testing approach remains the relevant one when assessing physico-chemical hazard properties since variability in composition or unknown species is not expected to not affect the physico-chemical hazard classification.

In practice, classifications and hazard information is included and regularly updated in the MeClas classification tool; a manufacturer (or importer) of a CIM who wishes to determine an environmental classification of their material can therefore simply use the tool without having to document or collect this type of information.

At the end of the characterisation process, a quick ‘summation-check’ could be performed to evaluate whether the typical concentration is close to 100% and not exceeding it. This can also help with identifying any relevant data gap and/or the potential presence of unidentified constituents.

A typical example of a substance identification (SID) template for an UVCB is given below. This Example Box also reports existing conventional classifications for each constituent (where applicable). Information on hazard classification of metal compounds can be found in, for example, regional and national inventories of classified substances such as the European Chemicals Agency Classification and Labelling Inventory. This kind of information, however, is already present in MeClas and this is therefore only useful when the hazard calculations are conducted manually.

A simple Excel template has been developed for iUVCB assessment reporting in EU REACH and helps gathering and documenting data and expert assumption as showed in the **Figure A4.1** below. The Excel table supports gathering elemental composition, concentration details and speciation for each constituents in the first columns A to E. Typically listing all elements in alphabetical order, it simplifies reporting and allows direct input of information in the MeClas tool and further completes the classification summary columns F and G with details on the species assigned in MeClas and the rationale supporting the choice (ie analytical knowledge, reasonable worst case, worst case, as explained in **Figure A4.2**) .

	Composition				Classification	
	Concentration (%)			SID	MeClas - Classification Assessed according to CLP Mixture Rule	
Element	Min	Max	Typical	Species	ENV & HH species	Species allocation rationale
Ag	0.001	0.2	0.008	Ag metal (alloy)	Ag massive (>1 mm)	analytical knowledge
Al	0.36	2.8	1.33	oxide	Al massive/Al compounds	reasonable worst case
As	0.01	0.9	0.2	multimetalic alloys	As powder (<1 mm)	reasonable worst case
Au	0.04	0.002	0.39	metallic	Au	worst case
Bi	0.115	6	2.2	metallic/oxides	Bi (other not classified compounds/species, e.g. Bi_2S_3	worst case
Ca	0.2	2.5	0.9	oxides, silicates	CaO	worst case
Cd	0	0.025	0.2	unknown	CdS	reasonable worst case
Co	0.02	0.9	0.15	multimetalic alloys and CoS sulphides	Co powder (< 1mm and non-respirab	reasonable worst case
Cu	25	77	58	Cu-Fe sulphides	xx% Chalcocite, xxxx% Copper (I) oxide, xxx 1% Cu massive	analytical knowledge
Fe	0.2	20	15	Cu-Fe sulphides	Fe/Fe compounds (eg FeS_2)	worst case
K	0	0.15	2	unknown	K/K compounds	worst case
Mg	0.01	0.04	3	unknown	Mg/Mg compounds	worst case
Mn	0	0.08	2.5	unknown	MnO_2	reasonable worst case
Mo	0	0.01	1	unknown	MoS_2	reasonable worst case
Na	0	0.2	1	unknown	Na (other not classified compounds/:	worst case
Ni	0	8	1.2	multimetallic alloys	Ni massive	reasonable worst case
Pb	0.01	5	0.4	Pb metal (and below 20% of total is as PbO)	Lead compounds with the exception of those specified elsewhere in Annex VI	reasonable worst case
S	9.2	33	18	sulphides	Metal sulfides/sulphates	analytical knowledge
Sb	0.1	0.34	3	unknown	Sb compounds, with the exception of the tetroxide (Sb_2O_4), pentoxide (Sb_2O_5), trisulphide (Sb_2S_3), pentasulphide (Sb_2S_5) and those specified elsewhere in Annex VI	reasonable worst case
Se	0	0.58	2	unknown	Selenium compounds except cadmium sulphoselenide	reasonable worst case
Si	0.5	0.78	4	non-crystaline	SiO_2 non-crystalline	reasonable worst case
Sn	0	0.36	2	metallic	Sn	analytical knowledge
Te	0	0.23	3	unknown	Cu_2Te	reasonable worst case
Zn	0.2	5	1	sulphides	ZnS	reasonable worst case

Figure A4.1. How composition and species allocation appears in MeClas: CIM/iUVCB composition reporting

Classification: Constituents Species Allocation	Definition	Clarification
Worst case	When constituent species is unknown and process information is not sufficient to support analytical information, the species selection is based on hazardous classification information class only (precautionary principle).	Without certainty on SID &/or process, we select the species leading to worst case HH and for worst case ENVI classification. Two different columns are reported in the summary to clarify when they diverge.
Reasonable worst case	When constituent species is unknown, but expert knowledge is available on analytic information (SID)/ process/ bioavailability, the species selection can be refined identifying the reasonable worst case mineralogical form.	Analytical results and process information can clarify which forms are to be expected in a substance, for instance when it's mainly oxidic and no S is present, than a SO4/S worst case species will not be considered.
Analytical knowledge	When constituents species are known from analytical information (SID), these are directly assigned.	The availability of SID information/analytical results allow overcoming the uncertainty which can be typical of UVCBs.

Figure A4.2. Classification constituents species allocation rationale

Input values:			
Element	Concentration % (user input)	Distribution %	Species/Classification entry
Ag	12	100	Ag_2O
As	3.5	100	As_2O_3/AsO_3
Au	3	100	Au compounds
B	2.8	100	$Na_2B_4O_7$
Ba	16	100	BaO_2
Bi	6	100	Bi
Ca	0.27	100	CaO
Cr	0.1	100	Cr_2O_3
Cu	37.5	100	Copper (I) oxide
Fe	19	100	Fe/Fe compounds (e.g. FeS_2)
Ir	0.002	100	Ir/Ir compounds
Mg	0.1	100	Magnesium powder (pyrophoric)
N	3.7	100	NH_3
Na	11	100	Na_2CO_3
O	25	100	O
Pb	44.4	100	Lead compounds with the exception of those specified elsewhere in Annex VI
Pd	0.0014	100	Pd compounds (e.g. $[Pd(NH_3)_4](OH)_2$)
Pt	0.0002	100	Pt compounds with the exception of Pt compounds specified in Annex VI
Rh	0.0057	100	Rh compounds
Ru	0.002	100	Ru compounds
S	5.4372633	100	Metal sulfides/sulphates
Sb	7	100	Sb_2O_3
Se	0.97	100	Selenium compounds except cadmium sulphoselenide
Si	11.2	100	SiO_2 crystalline & respirable
Sn	8.68	100	Sn compounds
Te	3	100	TeO_2
Zn	5.12	100	ZnO

Figure A4.3. Example of the appearance of composition and species allocation in MeClas

A.4.3. Characterisation of inorganic mixtures/ special mixtures

Unlike inorganic UVCBs or multi-constituent substances, simple mixtures contain substances that have not interacted with each other. The behaviour and properties of a simple mixture are generally driven by those of its ingredients. The only information required to assess the environmental classification of a simple mixture are the list of the ingredients, their concentration and classifications.

Alloys, however, are a special type of mixtures. An alloy is not a simple 'mixture' of two or more metals, but a material that has specific behaviours and intrinsic properties that are usually very different from those of its constituents, hence the term 'special mixtures'. Alloys can be found in many forms (eg massive forms like: wires, rods, strips), as well as powders and pastes.

Hazard classification of alloys simply based on the hazardous properties of its constituents may be incorrect and mean that an alloy is classified on the

basis of the intrinsic properties of its constituents rather than on the properties of the alloy itself. In addition, as is the case for pure metals, the physical form of the alloy (eg massive or powder) influences the release, hence its environmental classification.

The degree of refinement that can be applied to a worst-case, hazard classification of an alloy is determined by the availability of information on (some of) the following physico-chemical characteristics and properties. If relevant and available, the characterisation of alloys should include the relevant data to support classification (see main guidance, Annex 6 on T/Dp, etc.):

- Physico-chemical properties of the alloy and constituents.
- Physical/Crystal structure of the alloy.
- Relevant ecotoxicological data on the alloy.
- Measured data on dissolution properties (measured by the TDP (OECD 29)). Data from other simple solubility tests may be indicative but are not always accepted for the purpose of hazard self-classification.
- Particle size or particle size distribution (PSD) and specific surface area of the alloy measured by eg BET method.
- Electrochemistry evidence.
- Available information (incl. classification) of comparable alloys (for bridging).

Specific attention should also be given to assess whether differences in minor ingredient or impurities content in the alloy could (significantly) affect physico-chemical properties that could lead to a change in release rate resulting in a different environmental classification category.

This characterisation and the further classification combine the collection of reliable available analytical information on the alloy with the judgement of experienced experts.

Like the approach followed for UVCBs, the collected information on the alloy could be summarised in a Mixture ID Template as shown in Example Box A4.1.

Example Box A4.1. Simple Mixtures ID template (further characterisation data to be added as necessary)

Copper alloy mixture ID profile, contains mostly relevant data for Environmental Classification	
Name:	Free Cutting Brass in massive form
Source:	From the melting of three or more pure metals while they are in liquid phase.
Process: Melting	Designation: ASTM C38500, CEN: CW614N (CuZn36Pb3)
Physical Properties	— Specific Gravity: 8.5g/cm^3 — Melting Point: 880–895°C — Particle size: not applicable (massive alloy)

Elemental Composition

IUPAC (or other) Name of constituents	EC-N°	CAS N°	Content %	Classification for the environment
Copper	231-159-6	7440-50-8	57.0–59.0	Not classified
Lead	231-100-4	7439-92-1	2.5–3.5	Aq.Chron.1, M=10
Zinc	231-175-3	7440-66-6	37.5–40.5	Not classified

Release information if available:

- T/D release at pH 6 after 7 days at 1 mg/L loading: < 0.6 µg Cu/L, < 5 µg Zn/L, < 0.4 µg Pb/L
- T/D release at pH 6 after 28 days at 1 mg/L loading: 1.6 µg Cu/L, < 5 µg Zn/L, < 0.4 µg Pb/L

Annex 5: Classification of Complex Inorganic Materials – Summation Method

A5.1. Introduction

When no relevant toxicological data are available for a CIM, or read-across/bridging is not feasible, the next step in the environmental hazard of the CIM will be based on the environmental hazard profile of its individual components. Briefly, the general rules of the summation method as outlined in the UN GHS and its regional and national implementation legislations is not only applicable for mixtures of multiple metallic components, but can also be used for the classification of inorganic complex substances (like UVCBs).

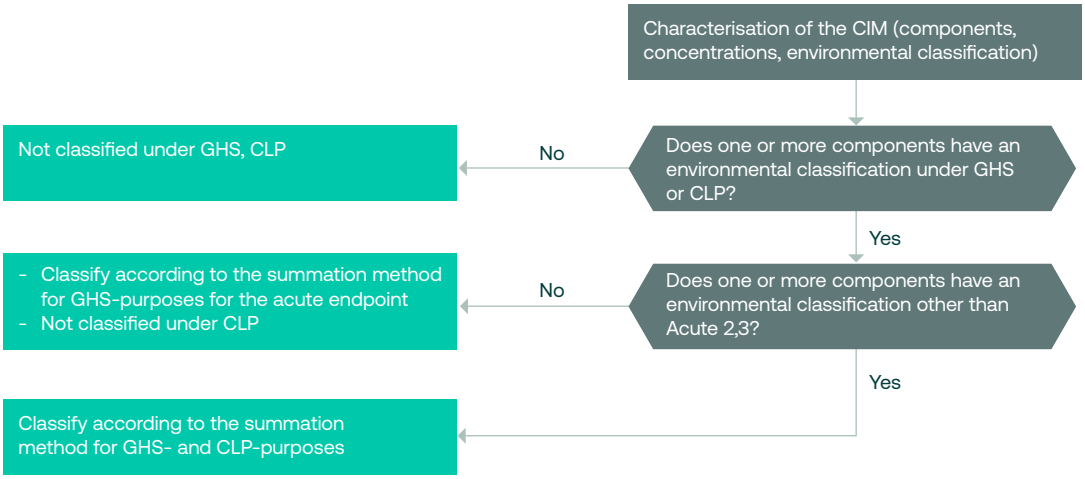


Figure A5.1. The conceptual outline of the classification strategy for a CIM, using the summation method

The **relevant components** of CIMs for environmental hazard classification are those which are classified:

— as 'Aq.Acute 1' or 'Aq.Chronic 1' and present in a concentration of 0.1/M% (w/w) or greater (with 'M' being the M-factor associated with the Aq.Acute 1 and Aq.Chronic 1 classification), and

— 'Aq.Acute 2', 'Aq.Acute 3', 'Aq.Chronic 2', 'Aq.Chronic 3' and 'Aq.Chronic 4' and present in a concentration of 1% (w/w) or greater.[11]

A detailed explanation of how to conduct the summation method for determining the classification of a mixture is given in the UN GHS (UN GHS Rev.11, 2025) and in the EU CLP-Directive No 1272/2008. The principles of this approach are used for the classification of complex multi-metallic materials. A concise summary of the summation method is given below.

— **Aq.Acute 1 classification of a CIM:** If the sum of the concentrations (in w/w%) of all Aq.Acute1 classified components of the CIM – multiplied by their corresponding acute M-factor where applicable – is higher than 25%, the whole CIM is classified as Aq.Acute 1.

— **Aq.Acute 2[12] classification of a CIM:** When the CIM is not classified as Aq.Acute 1, classification of the CIM as Aq.Acute 2 should be considered. A CIM is classified as Aq.Acute 2 if ten times the Aq.Acute 1 fraction (see the previous step) plus the sum of the concentrations (in w/w%) of all components classified as Aq.Acute 2 is equal to or greater than 25%. No further classification calculation steps are required for a CIM classified as Aq.Acute 2.

11. Aq.Acute 2 and 3 are not applicable in some jurisdictions eg the EU.
12. Not relevant in jurisdictions that haven't implemented Aq.Acute 2, like EU-CL.

— **Aq.Acute 3[13] classification of a CIM:** When the CIM is not classified as Aq.Acute 1 or 2, classification of the CIM as Aq.Acute 3 should be considered. A CIM is classified as Aq.Acute 3 if ten times the % that was calculated for the Aq.Acute 2 assessment plus the sum of the concentrations (in w/w%) of all components classified as Aq.Acute 3 is equal to or greater than 25%. No further classification calculation steps are required for a CIM classified as Aq.Acute 3.

— **Aq.Chronic 1 classification of a CIM:** If the sum of the concentrations (in w/w%) of all Aq.Chronic 1 classified components in the CIM – multiplied by their corresponding chronic M-factor where applicable – is equal to or greater than 25%, the CIM is classified as Aq.Chronic 1. No further classification calculation steps are required for a CIM classified as Aq.Chronic 1.

— **Aq.Chronic 2 classification of a CIM:** When the CIM is not classified as Aq.Chronic 1, classification of the CIM as Aq.Chronic 2 should be considered. A CIM is classified as Aq.Chronic 2 if ten times the Aq.Chronic 1 fraction (see the previous step) plus the sum of the concentrations (in w/W%) of all components classified as Aq.Chronic 2 is equal to or greater than 25%. No further classification calculation steps are required for a CIM classified as Aq.Chronic 2.

— **Aq.Chronic 3 classification of a CIM:** When the CIM is not classified as Aq.Chronic 1 or 2, classification of the CIM as Aq.Chronic 3 should be considered. A CIM is classified as Aq.Chronic 3 if ten times the % that was calculated for the Aq.Chronic 2 assessment plus the sum of the concentrations (in w/w%) of all components classified as Aq.Chronic 3 is equal to or greater than 25%. No further classification calculation steps are required for a CIM classified as Aq.Chronic 3.

— **Aq.Chronic 4 classification of a CIM:** For a CIM that contains classified components, but which is not classified as Aq.Chronic 1, 2 or 3, a Chronic 4 classification must be considered. A CIM is classified as Aq.Chronic 4 if the sum of the concentrations (in w/w%) of components classified as Aq.Chronic 1, 2, 3 and 4 is equal to or greater than 25%.

The application of the M-factor for Aq.Acute 1 and Aq.Chronic 1 components of a CIM ensures that contributions of very ecotoxic components (ie substances that show toxic effects at very low concentration levels) is adequately taken into account.

Table A5.1. Aquatic classifications with M-factors

Σ Aq.Acute 1 x M ≥ 25%	Aq.Acute 1
10 x Σ (M x Aq.Acute 1) + Σ Aq.Acute 2 ≥ 25%	Aq.Acute 2
100 x Σ (M x Aq.Acute 1) + 10 x Σ Aq.Acute 2 + Σ Aq.Acute 3 ≥ 25%	Aq.Acute 3
Σ Aq.Chronic 1 x M ≥ 25%	Aq.Chronic 1
10 x Σ (M x Aq.Chronic 1) + Σ Aq.Chronic 2 ≥ 25%	Aq.Chronic 2
100 x Σ (M x Aq.Chronic 1) + 10 x Σ Aq.Chronic 2) + Aq.Chronic 3 ≥ 25%	Aq.Chronic 3
Σ Aq.Chronic 1 + ΣAq.Chronic 2 + Σ Aq.Chronic 3 + Σ Aq.Chronic 4 ≥ 25%	Aq.Chronic 4

A5.2. Summation method for an UVCB substance

The composition and consequently the classification of UVCB substances, such as ores or ore concentrates and refinables can be defined in the following ways:

UVCB composition information	Which classification of constituents to use?
Elemental data only	Worst-case classification of the metal as a soluble metal compound
Speciation of the relevant metals present in the UVCB is available	Classification of the identified constituents
	For constituents for which no classification data is available, the classification can be derived as described in Section 2
Combination of elemental and speciation data	For metals for which the speciation is unknown, use the worst-case classification of the metal as a soluble metal compound
	For metals for which the speciation is known, use the classification of the constituent present in the UVCB

13. Not relevant in jurisdictions that haven't implemented Aq.Acute 3, like EU-CLP.

For those UVCBs where classification information is lacking for certain constituents, the percentage of constituents with missing information should be mentioned.

The Substance ID Template that is generated during the UVCB characterisation should contain the existing classification (Aq.Acute/Chronic classifications, or no classification) for each relevant element and/or mineral/compound that has to be considered when deriving the final classification. With this information, the general summation method can be conducted on an elemental or mineralogical/compound basis.

The different classification strategies are demonstrated in Example Box A5.1 using the Substance ID Template that was given in Example Box A4.1 for an ore concentrate.

Example Box A5.1. Classification of an ore concentrate, based on the SID Template for an UVCB given in Example Box A4.1 using the MeClas tool

Considering the hypothetical copper concentrate with the following hazard profile, where environmental classification for most components is available

Name of constituents	Typical % w/w	Aquatic classification (CLP)
Chalcopyrite ($CuFeS_2$)	63.5	None
Enargite (Cu_3AsS_4)	0.8	None
Pyrite (FeS_2)	18.5	None
Chalcocite (Cu_2S)	2.8	Aq.Acute 1, M=1 Aq.Chronic 2
Covellite (CuS)	1.1	Aq.Chronic 3
Sphalerite Zn(Fe)S mixture of cadmium sulphide with zinc sulphide (xCdS.yZnS)	1.1	None
Galena (PbS)	0.08	Aq.Acute 1, M = 10 Aq.Chronic 1, M = 1
Bornite (Cu_5FeS_4)	1.0	Aq.Acute 1 M=1 Aq.Chronic 3
Quartz (SiO_2)	2.1	None
Pentlandite $(Ni, Fe)_9S_8$	0.1	Unknown
Arsenopyrite (AsFeS)	0.02	Aq.Acute 1, M = 1 Aq.Chronic 1, M = 1
Water (H_2O)	8	None

Summation method

According to the table in Section 3.4

Σ M x Aq.Acute 1 ≥ 25%	Aq.Acute 1
Σ M x Aq.Chronic 1 ≥ 25%	Aq.Chronic 1
10 x Σ (M x Aq.Chronic 1) + Σ Aq.Chronic 2 ≥ 25%	Aq.Chronic 2
100 x Σ (M x Aq.Chronic 1) + (10 x Σ Aq.Chronic 2) + Σ Aq.Chronic 3 ≥ 25%	Aq.Chronic 3
Σ Aq.Chronic 1 + Σ Aq.Chronic 2 + Σ Aq.Chronic 3 + Σ Aq.Chronic 4 ≥ 25%	Aq.Chronic 4

Acute classification

Name of constituents	Typical % w/w	Aquatic classification	M, factor
Bornite (Cu_5FeS_4)	1.0	Aq.Acute 1	M = 1
Chalcocite (Cu_2S)	2.8	Aq.Acute 1	M = 1
Galena (PbS)	0.08	Aq.Acute 1	M = 10
Arsenopyrite (AsFeS)	0.02	Aq.Acute 1	M = 1

Assessment for Aq.Acute 1 – CLP and GHS

Resulting summation % for the UVCB = $(1.0\% \times 1)_{Bornite} + (2.8\% \times 1)_{Chalcocite} + (0.08\% \times 10)_{Galena} + (0.02\% \times 1)_{Arsenopyrite} = 4.62\ \%$

4.62 < 25%, therefore the UVCB does not classify as Aq.Acute Cat.1

Assessment for Aq.Acute 2 – GHS only

Resulting summation % for the UVCB = $(10 \times 1.0\% \times 1)_{Bornite} + (10 \times 2.8\% \times 1)_{Chalcocite} + (10 \times 0.08\% \times 10)_{Galena} + (10 \times 0.02\% \times 1)_{Arsenopyrite} = 46.2\ \%$

4.62 > 25%, therefore the UVCB classifies as Aq.Acute Cat.2

Chronic Classification

Name of constituents	Typical % w/w	Aquatic classification
Covellite (CuS)	1.1	Aq.Chronic 3
Chalcocite (Cu_2S)	2.8	Aq.Chronic 2
Galena (PbS)	0.08	Aq.Chronic 1, M = 1
Bornite (Cu_5FeS_4)	1.0	Aq.Chronic 3
Arsenopyrite (AsFeS)	0.02	Aq.Chronic 1, M = 1

Assessment for Aq.Chronic 1

Resulting summation % for the UVCB = $(0.08 \times 1)_{Galena} + (0.02 \times 1)_{Arsenopyrite} = 0.1\%$,

0.1% ≤ 25%, therefore no Aq.Chronic Cat.1 classification for the UVCB is obtained

Assessment for Aq.Chronic 2

Resulting summation % for the UVCB = $(2.8\% \times 1)_{Chalcocite} + (0.08 \times 1 \times 10)_{Galena} + (0.02 \times 1 \times 10)_{Arsenopyrite} = 3.8\%$,

3.8% ≤ 25%, therefore no Aq.Chronic Cat.2 classification for the UVCB is obtained

Assessment for Aq.Chronic 3

Resulting summation % for the UVCB = $(1.1\%)_{Covellite} + (0.08\% \times 1 \times 100)_{Galena} + (0.02\% \times 1 \times 100)_{Arsenopyrite} + (2.8\% \times 10)_{Chalcocite} + (1.0\%)_{Bornite} = 40.1\%$,

40.1% ≥ 25%, therefore the UVCB classifies as **Aq.Chronic Cat.3**

Conclusion

The aquatic hazard classification under CLP for this concentrate, using the summation method, should be reported as:

— Aq.Chronic Cat.3 (H412)

The aquatic hazard classification under GHS for this concentrate, using the summation method, should be reported as:

— Aq.Acute Cat.2 (H401)
— Aq.Chronic Cat.3 (H412)

A5.3. Summation method for an inorganic mixture and special mixtures like alloys

These general summation rules also apply on CIMs that are considered to be mixtures and the starting point for these calculations are the concentration and the classification of each ingredient that is part of the mixture. An example of such a CIM could be a mixture of different metal oxides, each with their own environmental classification.

The schemes in current legislation consider alloys to be treated as mixtures. Each ingredient of the alloy is considered as the metallic form, and the classification that is assigned to each fraction of the metal in the alloy corresponds to the existing classification of the pure massive/powder metal (depending whether the alloy exists in a massive or powder form). This approach, however, is only meaningful when the solubility and dissolution rate of the metal in the alloy-structure are similar (or lower) than in the pure metal form. If this is not the case, the application of the summation method – using the classification of the pure form – may underestimate the actual environmental hazard of the alloy.

The summation method should therefore not be used for alloys or other special mixtures when available data from, eg a T/Dp test indicate that the properties of one (or more) of their ingredients would result in a classification that is more stringent than that of the pure form. The recommended classification strategy for such an alloy is provided in Annex 6.

Annex 6: Classification of Complex Inorganic Materials – Substance Approach Based on Transformation/ Dissolution Data

A6.1. Introduction

A classification approach that is based on Transformation/Dissolution (T/D) data (substance-specific approach) is warranted for Complex Inorganic Materials (CIMs like inorganic UVCBs (iUVCBs), alloys or other complex inorganic materials like frits). In this approach, the classification is based on the additivity method applied on the soluble fraction of metals in the CIM. Figure A6.1 presents the generic classification scheme for CIMs.

Note on alloys (also discussed in Annex 4 and Annex 5): Alloys are defined by the UN GHS and CLP Regulation as a metallic material (homogenous on a macroscopic scale) that consists of at least two metallic elements which are combined in such a way that they cannot be readily separated by mechanical means. UN GHS, however, does consider alloys as mixtures for the purpose of classification. It is relevant to note, however, that neither the definition of a substance or a mixture is applicable on metallic alloys, and this has been recognised by the European Chemicals Agency. Alloys typically possess properties that are different from those of their pure constituents. These properties are intentionally searched for throughout alloy manufacturing processes (eg increased resistance to corrosion). Alloying also influences the solubility and release of the metal ions included in the alloy matrix (decreased or occasionally increased solubility). The EU REACH and CLP Guidance recognise this and mention that alloys are considered to be 'special mixtures'. In some alloys like steel, the concentration of alloying elements may be very low but nevertheless modify

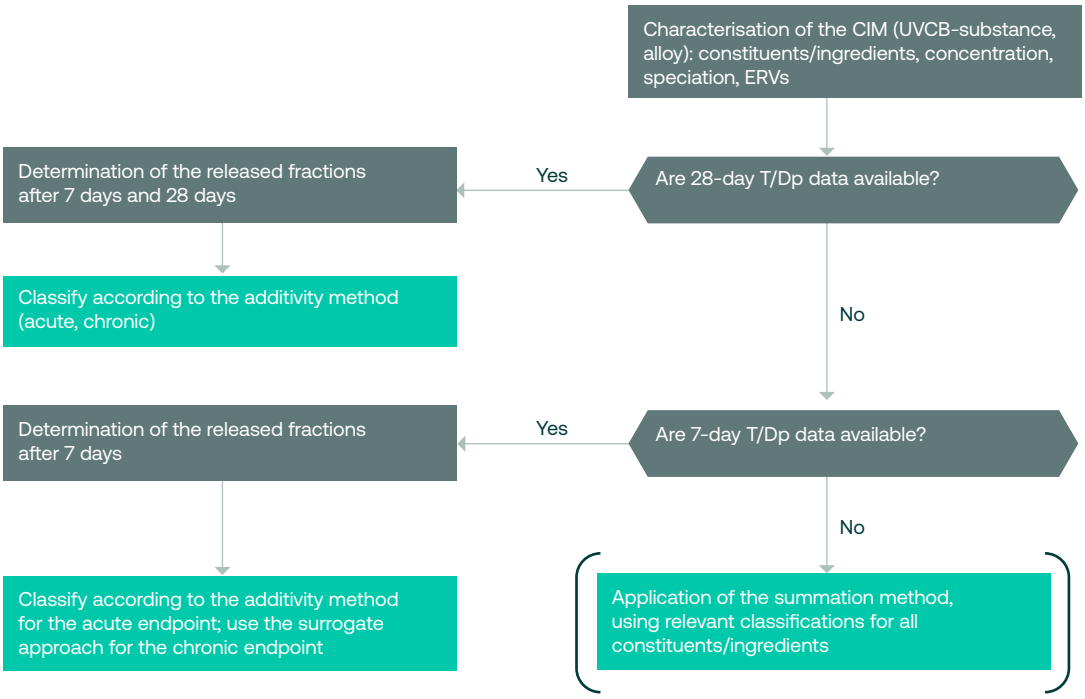


Figure A6.1. The conceptual outline of the classification strategy for a CIM, using the substance-based approach with T/Dp data and additivity rules

specific properties of the alloy extremely. For classification purposes, all ingredients (intentionally and non-intentionally added) need to be considered if their individual concentration is exceeding the cut-off value of 0.1%.

The solubility and dissolution rate of each constituent can be adequately quantified with the Transformation/ Dissolution protocol (T/Dp) test. Results of a T/Dp test will therefore play a key role in the assessment of the environmental hazard classification of an alloy.

It is worth noting that the constituents in other special mixtures like frits may also exhibit different relative release rates when compared to their pure forms.

A6.2. Determination of the soluble fraction

Transformation/Dissolution protocol (T/Dp) tests help determine the fraction of each metal that is released (cationic, anionic) and that needs to be considered in environmental hazard assessment. T/Dp tests should be carried out at the pH level (6, 7 or 8) that maximises the release.[14] This pH level is typically determined in 24-hour T/Dp screening tests at 100 mg/L loading at pH 6, 7, 8. The screening test provides also useful information to optimise the design of the 7- and 28-day test (eg loading rate).

Based on the chemical composition of the material and the measured dissolved metal concentrations in the 7-day and 28-day T/Dp tests, it is possible to derive an acute and a chronic release factor.

— Acute release factor for an element = amount released after 7 days at 1 mg/L loading (= amount added to the T/Dp test).

— Chronic release factor for an element = amount released after 28 days at 1 mg/L loading (=amount added to the T/Dp test).

If only acute T/Dp release data are available for a complex multi-metallic material, an extrapolation from a 7-day (1 mg/L) release factor to a 28-day release factor could be made by multiplying the known release factor by a correction value. This value depends on the curve fitting of the 7d T/Dp data whereby multiple concentrations should be measured between 0 and 7 days to allow a best extrapolation of the expected 28d release rate. For most CIMs a direct, linear extrapolation from 7 to 28 days is a conservative approach (ie four times the release after 7 days equals the release after 28 days).

When only one loading has been tested (eg 1 mg/L – 'source' loading), then extrapolation to another loading ('target' loading) – whether or not in combination with this correction factor for a longer/shorter dissolution period – could be applied by multiplying (in case of upscaling the loading) or dividing (in case of downscaling the loading) the observed release by the factor of difference between the 'source' and 'target' loading. This approach assumes that both 'source' and 'target' loading are situated within a concentration range where the relationship between release and loading is linear. If the one or both loadings, however, are in the range where a non-linear relationship exists, ie close to steady-state conditions and/or saturation, this approach may result in a significant underestimation or overestimation of the dissolved fraction. Supporting information on eg comparable CIMs may therefore be required to justify the application of the up/downscaling approach. Only those metal fractions that are released from the complex material are considered when assessing the environmental hazard classification.

The methodology for deriving the classification of a CIM based on T/Dp data is explained in more detail in the following paragraphs. The levels of the metal ions that are released into the medium during T/Dp testing are the starting point for these calculations.

In theory, the acute T/Dp test is conducted at a loading of 1 mg/L (in the EU and Turkey where only Aq Acute 1 is implemented), plus 10 and 100 mg/L (only in jurisdictions which have implemented Aq Acute 2 and 3 (as cut-off values for acute aquatic classification)). The loadings for chronic T/Dp tests are 1, 0.1 and 0.01 mg/L (cut-off values for chronic aquatic classification). In practice, obtaining small, representative samples of an UVCB substance may often be challenging due to varying composition and spatial heterogeneity of samples, and a 1 mg/L loading is often the lowest loading at which tests at the chronic level can be reliably performed. As stated previously, lower loadings are required for the chronic aquatic hazard endpoint, but the relevance of conducting a test at these lower loadings needs to be assessed upfront. The heterogeneity of the samples is relevant in this respect, but also for example, there is no added value of conducting T/Dp tests with loadings where even 100% dissolution of the metal under consideration would give rise to a concentration below the detection limit.

14. For CIMs where the maximum release of hazardous constituents is observed at different pH levels, full T/Dp tests are required at different pH levels. The hazard assessment for a specific pH will be based on the various metal ERVs and release rates that have been determined for that pH.

The individual metal concentrations in the T/Dp medium are then compared with the individual Ecotoxicity Reference Values (ERVs) per metal. Results from the 7-day T/Dp tests are compared with the acute $ERV_{diss.metal}$, and the results of the 28-day T/Dp tests are compared with the chronic $ERV_{diss.metal}$. Exceeding the acute and/or chronic ERVs leads to the respective acute and/or chronic classification of the CIM.

In those cases where the released concentration of each metal in the T/Dp medium remains below their respective individual ERVs, the potential for toxicity of the material still has to be evaluated to account for possible cumulative effects. As a starting and reasonably conservative assumption, it has been assumed that the metals exhibit a similar joint (additive) action. As such, the toxicity of the material can be calculated on a theoretical basis using the concentration addition model proposed by Anderson and Weber (1975).

In this model, the 7d and 28d T/Dp dissolution data for the individual metals are compared with respectively the acute and chronic ERV of each single metal and expressed as a fraction (ie toxic units (T.U.s)) of the acute and chronic ERV. The expected toxicity of the complex material (based on the additivity hypothesis and expressed as T.U.s is given by Eq-A1, ie the sum of the ratios of actual dissolved metal concentration to their ERV:

$$Mixture\ toxicity = \Sigma \frac{C_{mi,a\ dissolved}}{ERV_{mi}} \qquad \text{Eq-A1}$$

Where:

— $C_{mi,a\ dissolved}$ = actual dissolved metal concentration metal i

— ERV_{mi} = ERV of metal i

This exercise has to be carried out for the acute and chronic environmental aquatic classification.

In case of the use of acute ERV values, and assuming complete concentration addition, the 50% response of a mixture of chemicals is obtained when the sum of T.U. of all individual components equals unity. Therefore, if Σ(T.U.) ≥ 1 at a specific loading, the complex metal-containing material should be classified accordingly.

Depending on the type of T/Dp data that are available for a CIM, two different classification strategies are applicable: the first method is used when both 7-day and 28-day T/Dp data are available, whereas the second method (surrogate approach) is applicable when only information on the acute toxicity (ERV_{acute}, 7-day T/Dp data) is available (ie no $ERV_{chronic}$, no 28 T/Dp data). It is worth noting that prior to the introduction of EU REACH there were various hazardous metals for which no (or insufficient) data were available to determine a reliable chronic ERV. However, with the EU REACH Regulation coming into force, there was an obligation for many of these metals to generate chronic ecotoxicological data that could also be used for the derivation of a chronic ERV. The relevance of the surrogate approach as described in this Annex has therefore decreased over time but has been added here for reference.

It should also be pointed out that all of the calculations outlined in this section are performed automatically in the MeClas classification tool; the sections below only explain and provide more detailed background information on the principles and calculation procedures that are followed in the MeClas classification, but in practice there is no need to conduct these calculations manually when using MeClas.

A6.3. Classification based on 7-day and 28-day T/Dp data

If the ∑ T.U. after a period of 7 days and/or 28 days is at or higher than one (Acute and Chronic ERVs available for all relevant metals in the CIM), then the CIM is classified as follows:

A6.3.1. Acute classification

(a) Classify Aq.Acute 1:

— If the summation of the acute T.U.s of the different compounds of the CIM at the low loading rate (1 mg/L in a 7-day T/Dp test) is ≥ 1, then classify Aq. Acute 1.

(b) Classify Aq.Acute 2 (GHS only):

— If the summation of the acute T.U.s of the different compounds of the CIM at the medium loading rate (10 mg/L in a 7-day T/Dp test) is ≥ 1, then classify Aq.Acute 2. (GHS only)

(c) Classify Aq.Acute 3 (GHS only):

— If the summation of the acute T.U.s of the different compounds of the CIM at the high loading rate (100 mg/L in a 7-day T/Dp test) is ≥ 1, then classify Aq.Acute 3 (GHS only).

The CIM is not classified for the acute environmental endpoint when the summation of the T.U.s obtained from the 7-day T/Dp test at a loading rate of 1, 10 and 100 mg/L, respectively, is less than 1.

A6.3.2. Chronic classification under a non-rapid removal scenario

This classification strategy is applicable when all relevant metallic elements in the CIM are considered as inorganics that are not rapidly removable.[15]

a) Classify as Aq.Chronic 1:

— If the summation of the chronic T.U.s of the different compounds of the CIM at a loading rate of 0.1 mg/L (in a 28-day T/Dp test) is ≥ 1, then classify Aq.Chronic 1.

b) Classify as Aq.Chronic 2:

— If the summation of the chronic T.U.s of the different compounds of the CIM at a loading rate of 1 mg/L (in a 28-day T/Dp test) is ≥ 1, then classify Aq.Chronic 2.

The CIM is not classified for the chronic environmental endpoint if the summation of the T.U.s obtained from the 28-day Transformation/Dissolution test at a loading rate of 1 mg/L is less than 1.

A6.3.3. Chronic classification under an environmental transformation scenario

This classification strategy is applicable when all relevant metallic elements with a chronic ERV in the CIM are considered as 'environmentally transformed' (ie equivalent to biodegradation for organic compounds).

a) Classify as Aq.Chronic 1:

— If the summation of the chronic T.U.s of the different compounds of the CIM at a loading rate of 0.01 mg/L (in a 28-day T/Dp test) is ≥ 1, then classify Aq.Chronic 1.

b) Classify as Aq.Chronic 2:

— If the summation of the chronic T.U.s of the different compounds of the CIM at a loading rate of 0.1 mg/L (in a 28-day T/Dp test) is ≥ 1, then classify Aq.Chronic 2.

c) Classify as Aq.Chronic 3:

— If the summation of the chronic T.U.s of the different compounds of the CIM at a loading rate of 1 mg/L (in a 28-day T/Dp test) is ≥ 1, then classify Aq.Chronic 3.

The CIM is not classified for the chronic environmental endpoint if the summation of the T.U.s obtained from the 28-day Transformation/Dissolution test at a loading rate of 1 mg/L is less than 1.

A6.3.4. Chronic classification under a mixed scenario (environmental transformed and non-transformed inorganics)

This classification strategy is applicable when both environmentally transformed and non-transformed elements are present in the CIM. **The $ERV_{metal\ ion}$ of each metal that does not undergo significant environmental transformation (ie not rapidly removable) is divided by 10** and used for T.U. derivation;

a) Classify as Aq.Chronic 1:

— If the summation of the chronic T.U.s of the different compounds of the CIM at a loading rate of 0.01 mg/L (in a 28-day T/Dp test) is ≥ 1, then classify Aq.Chronic 1.

b) Classify as Aq.Chronic 2:

— If the summation of the chronic T.U.s of the different compounds of the CIM at a loading rate of 0.1 mg/L (in a 28-day T/Dp test) is ≥ 1, then classify Aq.Chronic 2.

c) Classify as Aq.Chronic 3:

— if the summation of the chronic T.U.s of the different compounds of the CIM at a loading rate of 1 mg/L (in a 28-day T/Dp test) is ≥ 1, then classify Aq.Chronic 3.

The CIM is not classified for the chronic environmental endpoint if the summation of the T.U.s obtained from the 28-day Transformation/Dissolution test at a loading rate of 1 mg/L is less than 1. When 28-day T/Dp test data are not available, the release rates can be estimated from the 7-day T/Dp test data; extensive experience with the T/D protocol has demonstrated that reliable predictions can be made for other loading rates and exposure periods in order to make maximal use of existing T/D data. For example, the values of the released concentrations from a 7d-T/Dp test, multiplied by a factor of four, can be used as a conservative estimate for the release after 28 days (assumption of constant release rate over a 28-day period) if the dissolution curve up to 7 days contains several measuring points allowing predictable curve fitting. In addition, the 28-day results for the lower chronic loading rates (0.1 and 0.01 mg/L) can be safely derived by extrapolation from T/Dp evidence from higher loading rates.

This extrapolation approach from day 7 to day 28 assumes that the release rate of the metal(s) from the CIM remains constant between day 7 and day 28. In reality the dissolution of an inorganic compound from a CIM is not a linear process, but diminishes over time.

15. The concept of environmental transformation (=alternative concept for inorganics to biodegradation for organics) has been defined in the main section of this Guidance document.

Hence, the extrapolated value after 28 days is expected to be higher than the concentration that would have been determined in a 28-day T/D test. As such, this approach is considered to be conservative and underestimation of the chronic hazard is unlikely.

A6.4. Classification based on 7-day T/Dp data and Acute ERV data (surrogate approach in the absence of chronic ERV)

If only acute ERV data and 7-day T/Dp data are available, the chronic classification can be assessed using a surrogate approach.

If the ∑ T.U. after a period of 7 days exceeds the value of one, then the CIM is classified as follows:

(a) Classify Aq.Acute 1 and Aq.Chronic 1:

— If the summation of the acute T.U.s of the different compounds of the CIM at the low loading rate (1 mg/L in a 7-day T/Dp test) is ≥ 1, then classify Aq.Acute 1. Classify also as Aq.Chronic 1, unless the compound(s) do not meet the CLP criteria on bioaccumulation and rapid removal (cfr. inorganic alternative to 'degradation') that warrant such classification.

(b) Classify Aq.Acute 2 (GHS only) and Aq.Chronic 2:

— If the summation of the acute T.U.s of the different compounds of the CIM at the medium loading rate (10 mg/L in a 7-day T/Dp test) is ≥ 1, then classify Aq.Acute 2. Classify also as Aq.Chronic 2, unless the compound(s) do not meet the CLP criteria on bioaccumulation and rapid removal (cfr. inorganic alternative to 'degradation') that warrant such classification.

(c) Classify Aq.Acute 3 (GHS only) and Aq.Chronic 3:

— If the summation of the acute T.U.s of the different compounds of the CIM at the high loading rate (100 mg/L in a 7-day T/Dp) is ≥ 1, then classify Aq.Acute 3. Classify also as Aq.Chronic 3 classification, unless the compound(s) do not meet the CLP criteria on bioaccumulation and rapid removal (cfr. inorganic alternative to 'degradation') that warrant such classification.

Solubility measured as T/D data can only be considered as reliable for the purpose of classification if conducted according to the standard protocol in Annex 10 to UN GHS. Other dissolution techniques or Water Accommodated Fractions as used for organics are not considered relevant[16]

A6.5. Solubility correction for UVCB substances

When T/Dp tests are considered for a UVCB substance, sufficient attention should be given to the selection of the sample to be tested. It is critical that the composition and physicochemical properties of the selected sample are representative for the UVCB substance that is assessed, and that the concentration levels of the constituents that are most critical for the classification, represent a worst-case composition. These aspects are discussed in detail in Van Assche et al. (2019).

Due to the complexity of UVCB substances, it is not possible to give specific guidance for each type of CIM. A more generic classification strategy has therefore been developed (**Figure A6.2**).

— The CIM is not releasing measurable amounts of the soluble ions under the conditions of the 28-day T/Dp (soluble metal compounds are not present in the aqueous medium above the detection limit). In that case, a null classification (no classification) is justified.

— Results that are available from a 28-day T/Dp test show that concentration in the aqueous medium of the metals in the UVCB are less than the chronic ERVs of the dissolved metals and the sum of the T.U.s is below 1. In that case, the UVCB is not classified for the chronic endpoint.

— The CIM does release significant amounts of the soluble metal ions under the condition of the T/Dp, and several metals can be identified as contributing T.U.s. In this case, the classification can be assessed following the T.U. approach.

16. When debating the environmental classification strategy for metals and metal compounds both the OECD and the EU decided that WAF testing should not be allowed for metals and its compounds or mixtures for Hazard classification. Main arguments why the WAF should not be used for inorganics include the facts that the particle size and surface area determine the release rate, dissolution waters differ from the waters for testing and the impact of pH on dissolution.

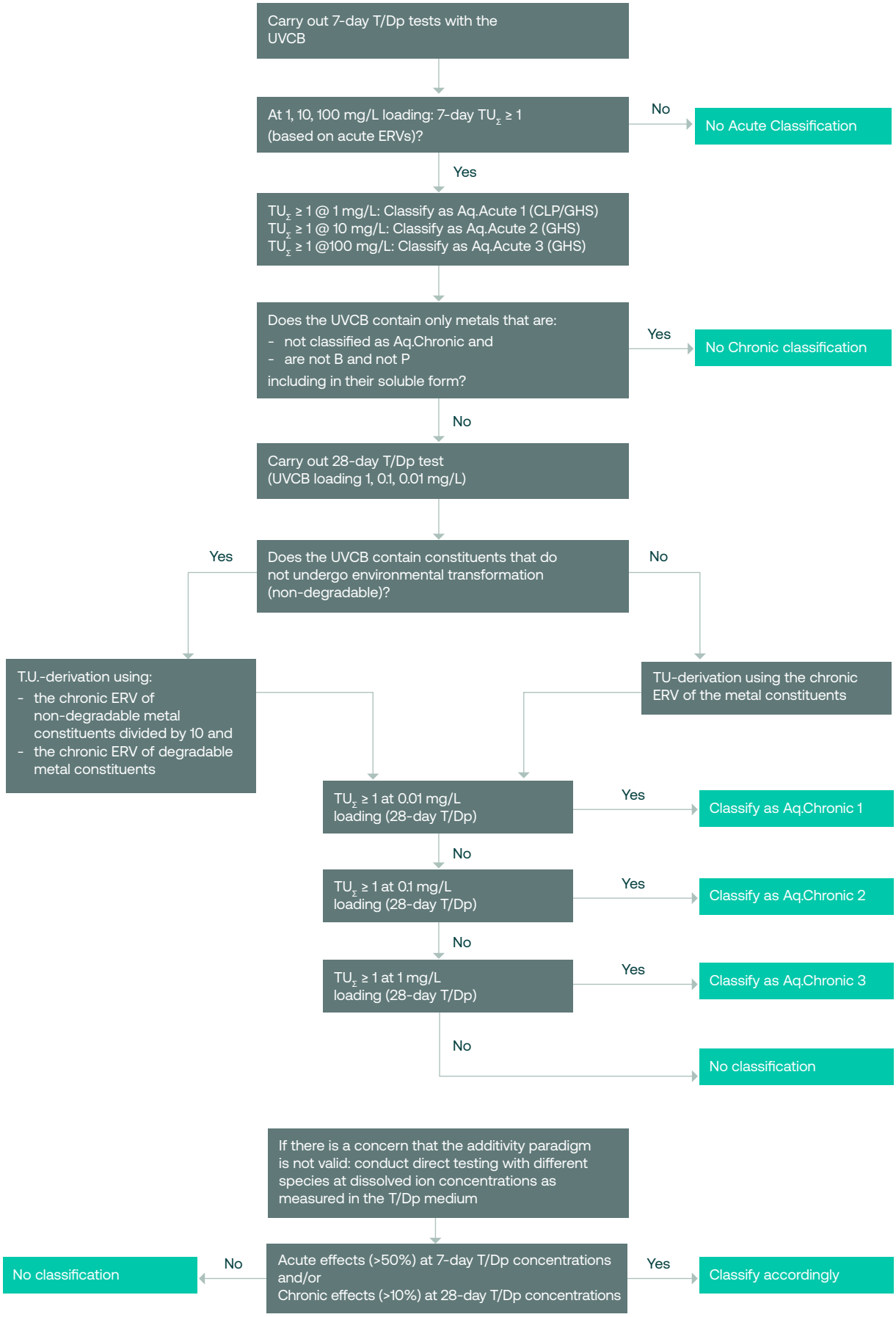


Figure A6.2. Classification strategy for UVCB substances based on chronic data

In Example Box A6.1 the classification of a complex metal-containing material is derived from available T/Dp data.

Example Box A6.1. Classification of a UVCB material using T/Dp data

A CIM is composed of different metal compounds, maybe even different compounds of the same metal. The chemical composition of these materials is typically expressed in ranges of the metal content (expressed in w/w percentage). An example is given in the table below, together with the classification of the relevant metal speciation form. The highest concentration for each element is taken into account for the hazard assessment calculations.

Element	Concentration in the material (w/w%)	Environmental classification of relevant metal compound
Copper (as CuO)	25–29%	Aq.Acute 1, M=10 ; Aq.Chronic 1
Iron (Fe_2O_3)	22.5–26.5%	Not classified
Arsenic (As_2O_3)	0.010–0.015%	Aq.Acute 1 ; Aq.Chronic 1
Cadmium (CdO)	0.001–0.002%	Aq.Acute 1, M=10 ; Aq.Chronic 1, M=10
Aluminium (Al_2O_3)	0.25–0.30%	Not classified
Other	44.18–52.24%	Not classified

According to the summation rules, this material will be classified as Aq.Acute 1 and Aq.Chronic 1 (since the fractions of the ingredients with Aq.Acute 1 and Aq.Chronic 1 classification exceed 25%). This classification is entirely driven by the presence of copper, and the amount of CdO and As_2O_3 is below the concentration cut-off that determines whether a constituent needs to be taken into account for detemining the environmental hazard (0.1%/M).

Refinement of the classification can be achieved by taking the copper release data from 7-day and 28-day T/Dp tests into account (loading: 1 mg/L)

Element	Release after day 7 (T/Dp test @ 1 mg/L)	Release after day 28 (T/Dp test @ 1 mg/L)
Copper	0.98%	1.50%

For copper, the released amounts of metal after 7 days and 28 days are compared with the Acute and Chronic ERV, respectively, and for the different loadings the following applies:

Loading	Cu-content in material	Released amount after 7 days (release factor of 0.98%)(1)	Released amount after 28 days (release factor of 1.50%)
100 mg/L (Acute 3)	29.0 mg/L	284.2 µg Cu/L	–
10 mg/L (Acute 2)	2.90 mg/L	28.4 µg/L	–
1 mg/L (Acute 1)	0.29 mg/L	2.84 µg/L	4.35 µg/L

(1) release factor at 1 mg/L is also used for higher loadings

The current ERV_{acute} for copper is exceeded at a loading of 10 mg/L; therefore the material will be classified as Aq.Acute 2 under UN GHS. The $ERV_{chronic}$ for copper is not exceeded at a loading of 1 mg/L (28-day release of 4.35 µg/L); therefore the material has no chronic classification.

A6.5. Solubility correction for alloys

As already indicated in the **Introduction** of this Guidance Document, the physico-chemical properties of a metal in pure form may differ significantly from the properties of that metal present in an alloy configuration. The following criteria are considered when making the distinction between the pure metal form and the metal in alloy form:

— Differences in dissolution.

— Differences in classification (as a result of different solubility).

— Differences in manufacturing processes/methods.

— Normal handling/use of alloys does not lead to the formation of powders that could trigger a different classification.

When considering T/Dp testing, alloys that are only used in the massive form and that do not give rise to fine particles during their normal handling and use could be tested for transformation dissolution kinetics at the default particle size of 1mm (diameter of a spherical particle). A summarised overview of the alloy classification methodology is given in **Figure A6.3**

The classification procedure uses the composition of the alloy as the starting point. When none of the soluble ionic forms of the metals in the alloy are considered as classifiable (ie $ERV_{acute,ion}$ and $ERV_{chronic,ion}$ are higher than 100[17] and 1 mg/L, respectively), then the alloy will not be classified for the environment. This stipulation implies that relevant and reliable ecotoxicity data are available for the soluble (ionic) form of each metal in the alloy.

When it comes to the classification of an alloy that contains one or more classifiable ingredients, the generic approach should be that alloys can be considered to be simple mixtures where the release of metals from the massive/powder alloy is similar to the release of the metals from their pure massive/powder form. It is recommended, however, to collect evidence to demonstrate that this hypothesis is justified, eg via grouping approach, solubility (screening) tests. Under these circumstances, existing classifications of the pure metal forms (massive or powder) are used as proxy for the classifications of the metals in alloy configuration, and the summation method is used for calculating the classification of the alloy.

If there are indications that the metal solubilities in the alloy may be significantly different from the solubilities of the pure forms (as demonstrated by 24-hour T/Dp data, evidence from similar alloys, evidence from other test methods), the classification of the alloy should be based on the soluble fraction of the metals in the alloy. Currently available 24-hour T/Dp data indicate that soluble metal ion concentrations after 24 hours are a reliable indicator for assessing whether the long-term release pattern of the alloy is similar to that of the pure metal, or whether an increased release or decreased release (alloy effect) can be expected.

If evidence is available, from 24-hour T/Dp data or other information, that metal solubility in the alloy may be significantly higher from the solubilities of the pure forms, then worst-case classifications for soluble compounds are used for each metal, and the summation method is applied (assuming 100% release).

Three generic classification procedures can be followed if 24-hour T/Dp screening is available:

— **Scenario 1:** Metal releases from the alloy are equivalent to those of the pure massive/powder forms of the constituents: Classification of the pure metal form can be used, and classification for the alloy is based on the summation method.

— **Scenario 2:** Metal releases from the alloy are significantly lower than than the releases from the pure metal massive/powder forms of the constituents: Classification of the pure metal form can be used as a worst-case, and classification for the alloy is based on the summation method. Refinement of the classification, however, is possible by conducting 7-day/28-day T/Dp tests.

— **Scenario 3:** Metal releases from the alloy are significantly higher than than the releases from the pure metal massive/powder forms of the constituents: classification of the pure metal from cannot be used as a worst-case classification. The worst-case classification associated with the metal ion is used for each metal, and the summation method is applied (assumption: present as the most environmentally hazardous soluble compound). Refinement of the classification, however, is possible by conducting 7-day/28-day T/Dp tests.

17. Under EU CLP, the acute threshold for classification is 1 mg/L.

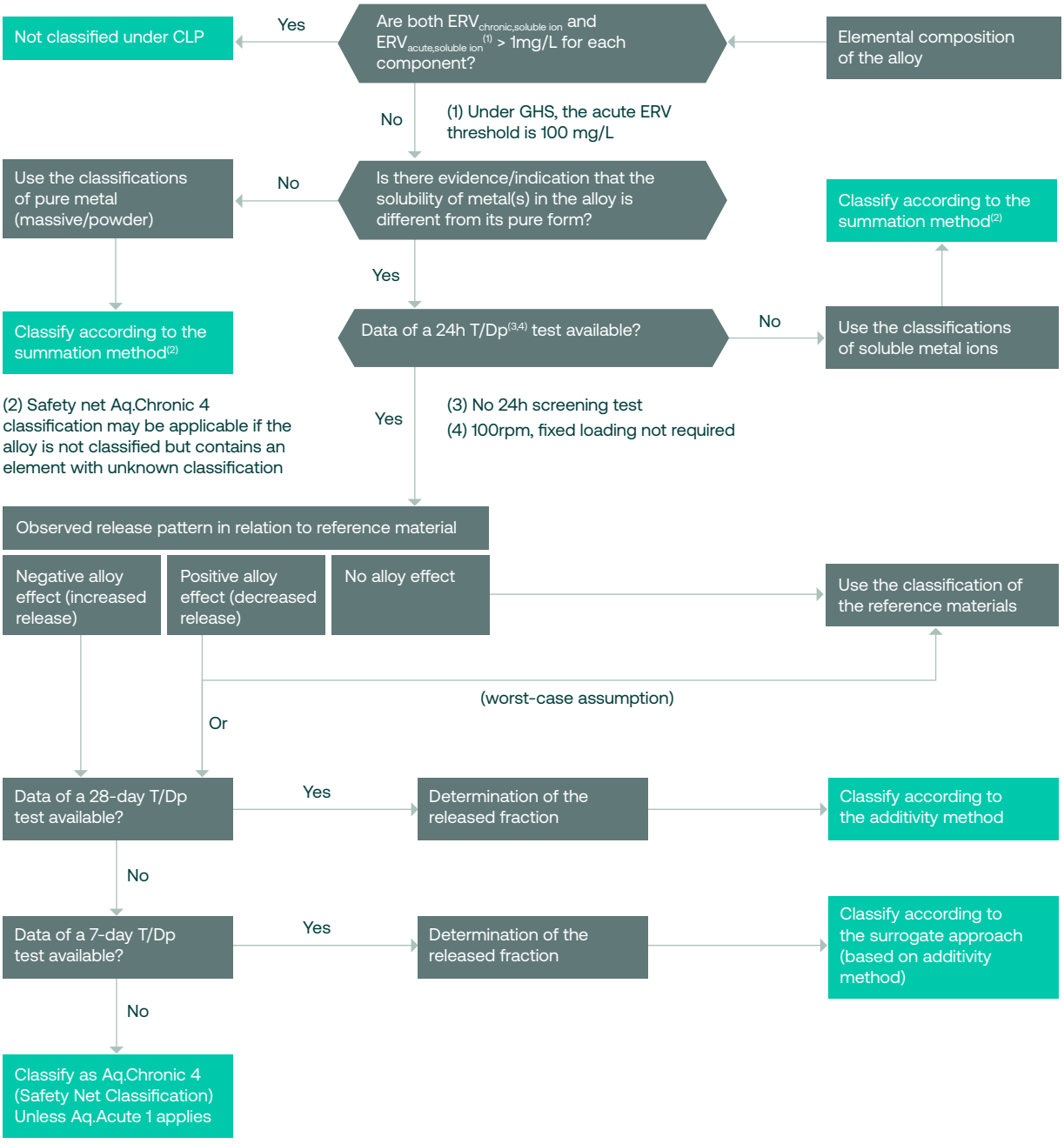


Figure A6.3. General classification scheme for alloys[18]

The classification under Scenario 2 and Scenario 3 can be refined if 28-day and/or 7-day T/Dp data are available. If both 28-day and 7-day data are available, both acute and chronic classification will be determined in accordance with the additivity method, taking into account the T/Dp data. If only 7-day T/Dp data are available, the chronic classification would be based on extrapolation of the release data from 7-day T/Dp data to 28 days, or based on the surrogate approach if no $ERV_{chronic}$ is available for one or more relevant metals. As long as T/Dp data are not available, and the alloy contains metals classified in their soluble form, the Aq.Chronic 4 safety net classification is applied (unless Aq.Acute 1 applies, based on the hazard of the soluble ion).

It is noteworthy that comparing the release rate from the alloy with the release rate from the pure metal should include a concentration adjustment step: an alloy only contains a specific percentage of a metal, whereas the pure metal contains 100% of the metal. This difference should be taken into account when comparing both release rates to assess the alloy effect.

18. While the ecotoxic properties of an alloy are usually less than the combined toxicity of the components, there are cases for alloys with increased release, higher ecotoxicity as the summation of the individual contribution. This is accounted for in the system when the classification is based on T/Dp data.

Secondly, for some alloys it has been demonstrated that the ratios between different constituents in the (thin) surface layer of an alloy can be significantly different from the overall composition; an alloy containing 2% of metal X may actually have a significant higher or lower percentage in the surface layer than in the body of the alloy. Such differences in distribution should also be recognised when interpreting the T/Dp data, or when 'grouping' alloys for read-across purposes. Available information on such differences within an alloy particle may help to understand and explain positive/negative alloy-effects. This knowledge is often available with alloy manufacturing companies.

A step-wise example of the classification of an alloy – taking into account more information on the alloy in each step – is presented in Example Box A6.2.

Example Box A6.2: Classification of an alloy, based on elemental composition and on T/Dp data

An alloy (massive) has three different ingredients (Me_A, Me_B, Me_C) and the following properties are known:

— Composition of the alloy, and acute/chronic ERV for the soluble ion of each metal in the alloy;

— Me_A-ion in soluble forms is classified as Aq.Acute1/Chronic1, M-factor 1;

— Me_B-ion in soluble forms is classified as Aq.Acute1/Chronic1, acute M-factor = 1 ; chronic M-factor = 10;

— Me_C-ion in soluble forms is not classified under CLP, but is Aq.Acute 3 under GHS;

— Pure metal forms are not classified (based on 28-day T/Dp testing with the massive pure metals);

— All three metals are not rapidly removed;

— 24-hour release rate (in %) for each metal in the massive form;

— 24-hour release rate (in %) for each metal in an alloy configuration (outcome of 24-hour T/Dp test);

— 28-day release rate (in %) for each metal in an alloy configuration (outcome of 28-day T/Dp test).

The physicochemical and ecotoxicological properties of the alloy constituents are as given in the following table:

Table B8.1: Physicochemical and exotoxicological properties of alloy constituents

	Me_A	Me_B	Me_C
Percentage in alloy	12%	8%	80%
Classification of pure massive metal[(1)]	Not classified	Not classified	
Ion-based ERV_{acute}	400 µg Me_A/L Aq.Acute 1, M=1	110 µg/Me_B/L Aq.Acute 1, M=1	10,500 µg Me_C/L Aq.Acute 3 (GHS)
Ion-based $ERV_{chronic}$	32 µg Me_A/L Aq.Chronic 1, M=1	3 µg/Me_B/L Aq.Chronic 1, M=10	2,200 µg Me_C/L Not classified
Release rate of the pure massive (24h T/Dp)	0.042%	0.028%	0.02%
Release rate of metal in alloy (24h T/Dp) after concentration adjustment	0.041% No alloy effect	0.21% Negative alloy effect	0.02% No alloy effect
Release rate of metal in alloy (7d T/Dp) after concentration adjustment	0.28%	1.42%	0.03%
Release rate of metal in alloy (28d T/Dp) after concentration adjustment	0.89%	3.9%	0.06

(1) Based on 28d T/Dp data (not reported)

Step 1: Classification based on composition (summation method)

Assumption: all metal in the alloy is soluble

Is the alloy Aq.Acute 1? Summation of all Aq.Acute 1 fractions, corrected with M-factor:

12% + 8% = 20% < 25% (cut-off for Aq.Acute 1): **Alloy is not classified for the acute hazard under EU CLP**. Under GHS, however, the alloy will be classified: Assessing whether the alloy is classified as Aq.Acute 2 requires that all Aq.Acute 1 fractions are multiplied by 10, and the sum is compared with the threshold value of 25%:

(12% * 10) + (8% * 10) = 200%; this exceeds the value of 25% and therefore **the Alloy is classified as Aq.Acute 2 under GHS**.

Is the alloy Aq.Chronic 1? Summation of all Aq.Chronic 1 fractions, corrected for M-factor:

12% + (10 * 8%) = 92% > 25% (cut-off for Aq.Chronic 1): **Alloy is classified as Aq.Chronic 1**.

Step 2: T/Dp-based refinement of the classification, using 24-hour data

Evaluation of an alloy effect requires the comparison of 24-hour T/Dp results of the pure metals with those of the metals in alloy configuration. If no alloy effect (or a positive alloy) is observed for each hazardous metal ion, then the standard summation method according to GHS can be used. As the massive form of each of the three metals is not classified, the alloy would also not be classified:

24-hour T/Dp for Me_A and Me_C: metal release from massive metal and metal in alloy configuration are similar: no alloy effect;

24-hour T/Dp for Me_B: metal release in alloy configuration is almost one order of magnitude higher than the release from the massive form: negative alloy effect.

Due to the negative alloy effect for Me_B, read-across from the massive form in the summation method is not allowed for this metal. Instead the classification of the soluble Me_B-compound should be used in the summation method.

Step 3: Acute classification based on 7-day T/Dp test (T.U. approach)

at loading of 100 mg/L:

— $Me_{A,released}$ = loading * fraction of $Me_{A,alloy}$ * 7-day release rate = 100000 µg/L * 0.12 * 0.0028 = 0.0336 mg/L = 33.6 µg/L

— $Me_{B,released}$ = loading * fraction of $Me_{B,alloy}$ * 7-day release rate = 100000 µg/L * 0.08 * 0.0142 = 0.114 mg/L = 113.6 µg/L

— $Me_{C,released}$ = loading * fraction of $Me_{C,alloy}$ * 7-day release rate = 100000 µg/L * 0.80 * 0.0003 = 0.024 mg/L = 24 µg/L

The alloy will be classified as Aq.Acute 3 if the sum of toxic units (ie concentration at 100 mg/L loading/ERV_{acute}) exceeds 1 T.U.

Σ T.U. = ($Conc.Me_A$ / $ERV_{acute;MeA}$) + ($Conc.Me_B$ / $ERV_{acute;MeB}$) + ($Conc.Me_C$ / $ERV_{acute;MeC}$)

Σ T.U. = (33.6 µg/L / 400 µg/L) + (113.6 µg/L / 110 µg/L) + (24 µg/L / 10500 µg/L) = 0.084 + 1.03 + 0.0023 = 1.121

This value is higher than 1.0, and therefore the alloy is classified as Aq.Acute 3 (GHS only).

A comparable analysis with loadings of 1 and 10 mg/L (classification cut-off values for Aq.Acute 1 and 2, respectively) resulted in T.U. values below 1.0. Hence, there was no need to classify the alloy as Aq.Acute 2 (GHS) or Aq.Acute 2 (CLP and GHS).

Step 4: Classification based on 28-day T/Dp test (T.U. approach)

at loading of 1 mg/L (classification cut-off for Aq.Chronic 2):

— $Me_{A,released}$ = loading * fraction of $Me_{A,alloy}$ * 28-day release rate = 1000 µg/L * 0.12 * 0.0089 = 1.07 µg/L

— $Me_{B,released}$ = loading * fraction of $Me_{B,alloy}$ * 28-day release rate = 1000 µg/L * 0.08 * 0.039 = 3.12 µg/L

— $Me_{C,released}$ = loading * fraction of $Me_{C,alloy}$ * 28-day release rate = 1000 µg/L * 0.80 * 0.0006 = 0.52 µg/L

The alloy will be classified as Aq.Chronic 2 if the sum of toxic units (ie concentration at 1 mg/L loading/$ERV_{chronic}$) exceeds 1 T.U.

Σ T.U. = ($Conc.Me_A$ / $ERV_{chronic;MeA}$) + ($Conc.Me_B$ / $ERV_{chronic;MeB}$) + ($Conc.Me_C$ / $ERV_{chronic;MeC}$)

Σ T.U. = (1.07 µg/L / 32) + (3.12 µg/L / 3 µg/L) + (0.52 µg/L / 2200 µg/L) = 0.03 + 1.04 + 0.0002 = 1.07

This value is higher than 1.0, and therefore the alloy is classified as Aq.Chronic 2.

A comparable analysis with a loading of 0.1 mg/L (classification cut-off for Aq.Chronic 1) results in a T.U. of 0.10; this is well below 1.0, and therefore there is no need to classify the alloy as Aq.Chronic 1.

Classification of the alloy, based on elemental composition: **Aq.Acute 2 and Chronic 1**.

Refinement: Classification of the alloy, based on 24-hour and 28-day T/Dp data: **Aq.Acute 3 and Aq.Chronic 2**.

Glossary of Terms

A–D	Anderson–Darling test
AISI	American Iron and Steel Institute
ASTM	Advancing Standards Transforming Markets International (formerly known as American Society for Testing and Materials)
ATP	Adaptation to Technical Progress
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BET	Brunauer–Emmett–Teller theory
BLM	Biotic Ligand Model
CD	Critical Diameter
CLP	Classification, Labelling and Packaging of substances and mixtures (Regulation (EC) No 1272/2008)
CP	Classification cut-off Point
CPD	Critical Particle Diameter
CPS	Critical Particle Size
CRSA	Critical Reference Surface Area value
CSA	Critical Surface Area
CSL	Critical Surface Loading
CSR	Chemical Safety Report
DIN	Deutsches Institut für Normung
DOC	Dissolved Organic Carbon
DPD	Dangerous Preparations Directive (1999/45/EC)
ECHA	European Chemicals Agency
EC_x	Effect Concentration
ERV	Ecotoxicity Reference Value
EU	European Union
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
HC_x	Hazardous Concentration that is expected to affect x% of the species in the evaluated ecosystem
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
ISIJ	The Iron and Steel Institute of Japan
KOW	Octanol-water partition coefficient
K-S	Kolmogorov–Smirnov test
L(E)C_x	Lethal (Effect) Concentration that affects x% of the test species for a particular parameter (eg mortality, growth rate…)
Me	Metal
M-factor	Multiplication factor
MW	Molecular weight
NOEC	No Observed Effect Concentration
O&C	Ores and Ore Concentrates
OECD	Organisation for Economic Co-operation and Development
PHREEQ	A computer program for speciation, batch-reaction, one-dimensional transport, and inverse geochemical calculations
EU REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (EC 1907/2006)
SA	Specific Surface Area
SLa	(Initial) Surface Area Loading
SSD	Species Sensitivity Distribution
SSMC	Sparingly Soluble Metal Compounds
T/D	Transformation/Dissolution
T/Dp	Transformation/Dissolution protocol
TU	Toxic Unit
UN	United Nations
US EPA	The United States Environmental Protection Agency
UVCB	Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials
WHAM	Windermere Humic Aqueous Model
WoE	Weight of Evidence approach

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