Fact Sheet

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MERAG

FAQ Toolkit

Metals Environmental Risk Assessment Guidance



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

ICMM Mining with Principles

EUROPEAN METALS

With ARCHE Consulting



Introduction

This toolkit is a supporting resource to the Metals Environmental Risk Assessment Guidance (MERAG) Fact Sheet 8: Classification, which forms part of the MERAG framework[1] for the environmental classification of metals and metal compounds. It is designed to assist practitioners in the practical application of the principles set out in the Fact Sheet.

The toolkit is intended for use by practitioners responsible for environmental classification under the United Nations Globally Harmonised System (UN GHS) and the EU Classification, Labelling and Packaging (CLP) Regulation. It supports classification of substances and mixtures prior to market placement, including complex metal-containing materials such as ores and concentrates, alloys, and inorganic substances of unknown or variable composition, complex reaction products and biological materials (UVCBs).

Under both the UN GHS and CLP, environmental classification is based on hazard. The objective, as defined by the United Nations, is to communicate intrinsic physical and (eco)toxicological properties of chemicals through standardised labelling and safety data sheets, thereby supporting the protection of human health and the environment during manufacture, handling, transport, and use.

While these frameworks provide detailed classification criteria, they remain largely generic and do not explicitly address the specific behaviour of metals and metal-containing materials. For such substances, classification for aquatic toxicity requires consideration of metal-specific properties, including solubility, speciation, complexation, environmental transformation, and matrix effects. These properties also influence appropriate testing approaches, in particular the Transformation/Dissolution protocol (T/Dp; OECD Guideline No. 29), which is central to the classification of poorly soluble and complex inorganic materials.

To address these limitations, the MERAG framework was developed in 2007 through collaboration between industry, scientific experts, and regulators, facilitated by ICMM and European Metals (formerly 'Eurometaux'), with technical input from ARCHE Consulting. MERAG consolidated the available scientific evidence and established consistent approaches for the environmental classification of metals and metal compounds.

Since then, scientific advances and regulatory experience have driven further development of this framework, particularly to address complex metal-containing materials. In parallel, the Metals Classification Tool (MeClas) was developed to operationalise this guidance and support transparent, consistent, and efficient classification workflows.

It is important to note that the UN GHS is limited to the harmonisation of hazard identification and communication and does not extend to harmonised approaches for risk assessment or risk management. In contrast, under EU legislation, the outcome of hazard classification under CLP may trigger additional regulatory obligations related to risk management. Nevertheless, classification under UN GHS and CLP may have implications beyond hazard communication and can influence downstream regulatory frameworks, including transport regulations, waste classification, and Seveso requirements.

How to use this document

The 'Quick Start Classification Workflow' in the next section summarises the classification procedure outlined in detail in MERAG Fact Sheet 8. Additional information can be found in the Annexes of that Fact Sheet or in the FAQ section of this toolkit.

1. https://www.icmm.com/en-gb/guidance/mining-metals/merag

Quick Start Classification Workflow

How do I classify my material?

Step 1
Identify whether your material represents

- A single substance (mono-constituent)
- A 'simple or special' mixture of substances (including multi-constituents, alloys, etc.)
- A complex inorganic material (eg pigments, inorganic UVCBs)

Step 2
Determine the regulatory status of your material in your jurisdiction

- Substance or mixture
- Article
- Materials/goods for transport purposes
- Waste material

Step 3
Characterise your material

- Mandatory:
  - Composition (elemental, speciation if possible)
- Optional (may support potential refinement of the environmental classification):
  - Particle Size Distribution (PSD)
  - Specific Surface Area (SSA)
  - Density (g/cm^3)

Step 4
Conduct a Tier 0–1 classification

- Calculate the environmental classification of your material with the MeClas tool, using the information collected in Steps 1–3

Step 5a
Conduct a Tier 2 calculation in MeClas (ie potential refinement of the classification)

- Please identify if you have the following information to include in the next tier of the MeClas Tool:
  - Transformation Dissolution Protocol (OECD 29) data
- If you do not have such information, please consider:
  - conducting screening T/Dp, and/or;
  - conducting full T/Dp

Step 5b
Calculate the environmental classification of your material with the MeClas tool, using the information collected or generated in Step 5a

FAQ

A. Regulatory and Scope

What is the difference between a massive and a powder?

Under REACH, powders are particles with a diameter < 1mm, whereas massives exceed this size. For classification purposes under CLP and GHS, the hazard of a massive is based on spherical particles with a diameter of 1 mm.

Why is the regulatory status of my material relevant for its hazard classification?

Differences in the procedures and methodologies to determine the environmental hazard exist among national/regional/global regulations that cover specific types of materials and goods. The EU-waste regulation, for instance, defines several materials that are exempt from hazard classification (cft. List of Waste), whereas these exemptions are not considered under GHS or CLP. A second example is the hazard classification of materials for transport purposes where some hazard categories that exist under GHS and CLP are not included in the transport regulations – eg ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road), IATA (International Air Transport Association), and IMDG (International Maritime Dangerous Goods Code). Determination of the applicable regulatory status is therefore required to ensure that a correct environmental hazard for your material is calculated and always communicated.

Is there a difference between an environmental hazard classification under transport regulations and under GHS/CLP rules?

A hazard classification for transport (eg ADR, IATA, IMDG) must be determined for all goods (substances, mixtures, articles) that are transported, whereas GHS and CLP only apply to substances and mixtures. For example, a massive metal or complex inorganic material (CIM) that has the regulatory status of a substance, will be classified based on the hazard properties of a 1 mm spherical particle following CLP/GHS procedures. A massive metal or CIM that has the regulatory status of being an article, however, is not classified according to the guidance provided in CLP/GHS but can be classified by considering the actual shape and size.

My environmental classification under GHS is different than my classification under CLP. Is this possible?

Yes. The CLP Regulation did not adopt all environmental categories that are included under GHS: Aq.Acute.2 and Cat.3 do not appear under the CLP. Secondly, the CLP Regulation imposes harmonised hazard classifications on a wide range of substances, including several metals and metal compounds, and these are provided in Annex VI of the CLP Regulation. This Annex VI, however, has no legal basis outside of the European Union, and it is therefore possible that some metals, metal compounds and CIMs will be classified differently. Hence, when transporting a metal/metal compound/CIM to a region where different hazard legislation is in place, it is critical to assess whether the hazard classification remains valid.



I am a manufacturer/importer of a Complex Inorganic Material that is considered a substance or a mixture of substances (eg alloys/ores and ore concentrates, UVCBs, pigments, frits) and it contains one or more constituents that are classified under CLP. What are the consequences for my CIM?

A classification must be derived according to the procedure applicable in your specific region. In most cases this procedure will be GHS-based, but nevertheless regional differences do exist. For example, Europe follows the (GHS-based) CLP Regulation, but there are some key aspects within CLP that lead to hazard classifications that differ from those outside the EU; including the implementation of harmonised classifications in the EU (Annex VI of the CLP), and differences in the classification categories that are in place. Therefore, when transporting hazardous materials from one regulatory region to another, a reassessment of the hazard properties is often required.

What are my communication duties?

Anyone who places hazardous material on the market, must communicate these hazards to their workers and to their downstream users via Safety Data Sheets (SDS) and/or adequate labelling. Specific communication requirements may depend on the status of the material (substance, mixture, article) and type of user (industrial users, professional users, consumers). Hazard communication typically involves the use of a signal word, pictograms and hazard/precautionary phrases, and detailed guidance documents on how to communicate hazards correctly have been developed by the various authorities. It is worth noting that there is no tonnage-threshold for the derivation and communication of hazardous properties.

B. Data Requirements and Inputs

Should I use typical or maximum concentrations for hazard assessment calculations in MeClas?

According to the mixture rules, when ranges are provided for the constituents, the maximum values need to be considered. Taking typical/median values could result in an under-classification. This approach may result in a composition where the sum of all constituents exceeds 100%.

Why is it important or relevant to determine the particle size distribution (PSD) and/or the specific surface area (SSA, in mm2/mg) of powders that are assessed in a Transformation/Dissolution protocol test?

The release of a metal from a powder in a T/Dp test can be expressed as dissolved concentration (ie µg/L) or as the release per exposed surface (µg/mm2). With the dissolved concentration, is it possible to derive the environmental classification of the tested material as such. This information, however, cannot be used for the hazard assessment of a finer (or coarser) powder from the same material. When PSD and SSA are known, however, the measured concentration in the T/Dp medium can be converted to a release as a function of exposed surface, and the dissolved concentration can then be calculated for a powder with different PSD/SSA. It should be noted that this approach is not yet standardised or formally recognised in regulatory frameworks. The robustness and reproducibility of the correlations between T/Dp results, PSD and SSA strongly depend on the quality of dissolution and toxicity data. The practical application for classification





purposes should therefore be treated with caution. Application and acceptance of the concept, however, has already contributed to different environmental hazard classifications for Cu massive and Cu powders in regulatory classification processes.

Where can I find Ecotoxicity Reference Values?

Most acute and chronic Ecotoxicity Reference Values (ERVs) are reported in the EU REACH Registration dossiers of the metals and metal compounds and can be found via www.echa.europa.eu. Identification of the correct values, however, can be challenging since some ERVs are pH dependent, and reporting of the values in the REACH Registration dossier is not always clear and consistent. The ERVs that are derived by industry for self-classification of metals and metals compounds can also differ from ERVs that were used by Europe for the determination of a harmonised environmental classification. ERVs are only required when calculating the environmental classification manually. It is therefore recommended to use the MeClas tool (www.MeClas.eu) for an automated calculation that is based on the most recent and relevant ERVs.

C. Testing Strategy

Do I have to perform 24h-screening T/Dp tests?

For metals and complex inorganic materials (eg inorganic UVCBs, ores and ore concentrates, alloys), the screening test is not required. However, 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 (6–8.5) must be considered in full T/Dp testing.

Why should I perform 24h-screening T/Dp tests at different pH levels?

The purpose of a 24h-screening test is twofold. Firstly, the results of the screening test can demonstrate at what pH level the highest metal dissolution(s) take place. Secondly, the function of the screening test is also to identify whether the metal compounds or metal-containing materials 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 to soluble forms). This property is assessed by comparing the metal release at a relevant loading of 100 (classification under GHS) or 1 mg/L (classification under CLP) with the ERV-values. Both T/Dp and ERV should be representative for the same pH. If the release exceeds the ERV, the substance is soluble and should be classified accordingly. Otherwise, a full T/Dp test can be considered.

Why may I have to perform T/Dp tests at different pH levels?

Both the dissolution of metals ions as well as the ecotoxicity of a metal can be pH dependent, and this property is metal-specific. In other words, for some metals the highest dissolution and highest toxicity will be observed at the same pH, whereas an inverse relationship is noted for other metals (ie highest toxicity at the pH that elicits the lowest release). 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. Otherwise, the full T/Dp test must only be performed at the pH with highest metal release.

What is the difference between the T/Dp OECD Guideline No. 29 and the testing procedure that is described in Annex 10 of the UN GHS Document (2025, Rev.11)?

Both protocols are virtually identical, and OECD29 was used as a starting point for Annex 10. The main difference between both guidelines is that Annex 10 of the UN also provides the composition of the T/D medium at pH 8.5. No differences between both protocols are noted regarding the T/Dp medium composition that are provided for pH 6, 7 and 8.

Can I conduct an ecotoxicity test in T/Dp medium as additional validation for the calculated classification?

In general, toxicity tests in T/Dp medium are not recommended as the physico-chemical properties of the T/Dp medium does not conform to the standard test media that are described in OECD Standard Guideline Documents, and modification of the T/Dp media (addition of soluble salts and nutrients) may alter the bioavailability and ecotoxicity of the dissolved metal fraction. Secondly, it may be difficult to control and maintain constant metal concentrations in the medium, especially when long-term tests are performed. However, in situations where information on the substance suggests that a calculated classification may be incorrect, confirmation of a determined classification could be obtained through direct testing. The latter approach, for example, could be considered where there are significant uncertainties in the existing toxicity data used in the calculation.

Can I perform a T/Dp test with the nanoform of an inorganic substance?

Yes, but it should be noted that nanomaterials are a 'difficult-to-test substance', and changes to the protocol may be required. Challenges that are associated with T/Dp testing with nanomaterials include difficulties in separating the nanomaterial from the T/D medium for analytical purposes, proper characterisation of the exposed surface area, and understanding of dissolution/release mechanisms. Hence, case-by-case adaptations to the testing protocol may be required, but changes to the protocol will require proper motivation and justification.

D. Data Interpretation and Calculations

Can I use the results of a 7-day T/Dp test for estimating the dissolution after 28 days?

An extrapolation (release after 28 days = 4 x release after 7 days) can be made, but it generally overestimates the dissolved fraction after 28 days since the dissolution rate tends to reduce over time. Consequently, the calculated environmental chronic classification may be too stringent – ie overly conservative – since it is based on a worst-case release estimate.

Can I use the results of a 28-day T/Dp test for estimating the dissolution after 7 days?

No, this is not recommended because dissolution rate is rarely linear over time and tends to reduce with increasing exposure period. Implementation of a linear extrapolation from 28 days to 7 days by the application of a correction factor of 4 may therefore lead to an underestimation of the dissolved fraction. It is worth nothing that the protocol of a 28-day T/Dp test typically includes an analytical characterisation of the T/Dp medium after 7 days, and therefore it is unlikely that an extrapolation from 28 days to 7 days would be needed.

Can the results of a full T/Dp test with loading of 1 mg/L be used for extrapolating to a lower loading?

Assuming a linear relationship between loading and dissolved concentration is only relevant for a limited concentration range, and the use of an extrapolated value therefore needs proper justification. For substances with very low solubility, the dissolved concentration from 0.1 mg/L and 1.0 mg/L may be the same, and application of a correction factor of 10 would generate an estimated release that is well below the actual release.

E. MeClas Implementation

How often is MeClas updated, and are there any restrictions for who can use MeClas?

There is no fixed update timeline, but MeClas is updated whenever there are (regulatory) changes that have the potential to modify the outcome of the hazard classification (eg new ERVs, new info on human health endpoints, new harmonised classifications). Users must register, and use is free of charge for industry – the only restriction is the number of compositions that can be saved, but these can be continuously modified, and output files can be saved as a PDF file.

F. Edge Cases and Special Situations

How do I perform a T/Dp test with a massive metal/metal compound/CIM?

A massive is defined as a spherical particle with the size of 1 mm, which corresponds to a surface of 3.142 mm^2 (=Sp). Considering the weight of that particle (based on the relative density of the CIM (D, in mg/mm^3)) and the volume of the particle (Vp, in mm^3), it is possible to determine the surface that corresponds to a loading of 1 mg. This will be the surface of the CIM that is exposed to the T/Dp test medium. Laboratories that are certified to conduct T/Dp tests have standardised protocols and procedures for preparing such samples.

How do I perform a test with a powder form of a metal/metal compound/CIM?

For powders, the smallest available particle size is typically used to determine the extent of the transformation in a T/Dp test.

Where can I commission a T/Dp test?

There are several testing facilities that offer T/Dp testing according to OECD Guideline No.29 or according to Annex 10 of the UN GHS Document (2025, Rev.11).

What is the added value of deriving an M-factor for CIMs that have an Aq.Acute Cat.1 and/or Aq.Chronic Cat.1 classification?

It is possible that the CIM can be used in a mixture at some point in time, and when the environmental classification of a mixture is calculated according to the summation rules, M-factors must be considered. Also, according to the CLP Regulation, an M-factor must be determined for all substances that are Aq. Acute/Chronic 1.





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