Guidance Note on the environmental classification of complex inorganic materials (CIMs) containing Pb

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Contents

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1. Background

The 21st Adaptation to Technical Progress (ATP) of the EU CLP includes an environmental classification for Pb metal, with 2 entries[1]:

- **Pb powder (particle diameter < 1mm): Aquatic Acute 1, M-factor 10 and Aquatic Chronic 1, M-factor 100**
- **Pb massive (particle diameter ≥1 mm): Aquatic Chronic 1, M-factor 10**

The 21st ATP was published in the EU Official Journal on 05.01.2024 (EU 2024/197), entered into force on 25.01.2024 and has a transitional period of 18 months for mandatory application in all EU Member States. This transitional period ends on 01.09.2025 which means that, from that date, all manufacturers, importers and downstream users of Pb metal in the EU must classify Pb metal in accordance with the entries included in Annex VI to the EU CLP (Index No 082-013-00-1 for Pb powder and 082-014-00-7 for Pb massive).

The classification applies to Pb metal as a substance but also as a constituent of Complex Inorganic Materials (CIM), which include alloys for example but also More than One Constituent Substances (MOCS[2]) such as UVCBs [3].

A classification under the EU CLP may have consequences on downstream legislations including e.g. Seveso and may be taken into consideration when considering e.g. transport, waste.

This note has been prepared to support companies producing, using and recycling CIMs such as alloys, mixtures, or UVCBs containing Pb. It complements and refers to notes prepared for example by ILA, WVM, EA, IZA, Assomet, on the Pb metal classification.
It will be followed by a more detailed practical guide (Q&A) on the CIM containing classified substances and the updated MERAG classification fact sheet (not limited to Pb metal only).

2. What do you need to be compliant under the EU CLP if you have a CIM containing Pb?

The EU CLP Regulation states that **substances and mixtures** (including MOCS, simple mixtures and alloys) must be classified according to its requirements before being placed on the market. As mixtures are not covered by *harmonised* classification and labelling, classification can be based on individual constituents or information on the mixture itself (for the environmental endpoint). If test data on the mixture is available, it can be directly compared with the environmental hazard classification criteria in Annex I to CLP (section 1.6.3.1).

[1] The classifications of Pb compounds remain unchanged
[2] The 2024 EU CLP revision has introduced the More than One Constituent Substance (MOCS) terminology to refer to such complex substances containing more than one constituent would be classified according to the mixture rules
[3] 'Unknown or Variable composition, Complex reaction products, and Biological materials'

Different situations can be envisaged under the EU CLP depending on whether you are producing an alloy or other types of CIMs, as the CLP recognises the specificities of alloys as 'special mixtures' and the possibility of a matrix effect that influences the properties of these materials. The EU CLP defines 'alloy' as '*a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means*'. The metallic constituents of alloys behave differently when embedded in a multi-constituent crystallographic structure compared to their "pure" metallic forms (e.g., different release rates, solubility), giving properties to the alloy that can differ from the properties of the constituents. Specifically, solubility properties of the alloy may differ significantly from those of individual constituents. **The solubility of the alloy (constituents) can be measured in a relatively simple test, i.e. the Transformation Dissolution Protocol (T/Dp, OECD 29).**

This section of the note distinguishes the situation of an alloy vs. other CIMs:

2.1 You are producing and placing an alloy on the market:

Two scenarios are possible:

Your alloy is considered an *article*

The alloy that you produce and place on the market fulfils the definition of an ***article*** according to the EU REACH Regulation Article 3(3) and the EU CLP definition (article 2): an article is '*an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*.' Examples of articles include alloy sheets, profiles, foils or castings. The EU CLP Regulation only requires the classification of substances and mixtures. In other words, if your alloy is manufactured and put on the market as an article, the **EU CLP requirements to classify and label do not apply.**

Your alloy is NOT considered an article

The alloy you produce does not fulfil the definition of article according to the EU **REACH Regulation Article 3(3)**. Examples are masterbatch alloys, soldering or welding wires, ingots and slugs intended for remelting as part of battery or alloy production. **These alloys should be considered as a *mixture, and* the EU CLP requirements apply.**

What does it mean in practice?

- **Option 1: you have data according to the Transformation Dissolution Protocol (T/Dp)**

The most appropriate way to derive the environmental hazard classification of the alloy is to determine the rate and extent to which its constituents react to convert to water-soluble forms of each element released in a full T/Dp. This test can be conducted in recognised laboratories and is an accepted assay by regulators. T/Dp is referenced in Annex 10 of the **UN GHS** and in Annex IV.5.6 of the ECHA **Guidance** on the Application of the EU CLP Criteria.

For the environmental classification of Pb, this implies that the Transformation Dissolution data of the alloy needs to be compared to the corresponding Ecotoxicity Reference Values (ERVs) of the soluble Pb metal ion to determine the potential for acute and chronic toxicity and to define the applicable environmental hazard categories.

If the criteria for environmental hazard classification are not met, your alloy does not need to be classified for this hazard. Please note that if your alloy needs to be classified, you need to prepare and provide safety data sheets and ensure the appropriate labelling and packaging. If your alloy is a massive form and classified, the exemption from labelling under EU CLP Article 23 may apply[4].

Note: The environmental classification and the resulting documentation of your alloy can also be generated with the MeClas tool (www.meclas.eu), using its Tier 2 to include the T/Dp data.

- **Option 2: you do not have or do not plan to generate data according to the Transformation Dissolution Protocol (T/Dp)**

If you do not have T/Dp data, the environmental classification will be determined according to the CLP mixture rules, i.e., the summation method using the composition and the classification of the constituents. In that case, the rules are as follows:

Step 1: A mixture is classified as Aquatic Acute / Chronic Cat.1 if:
Σ (% Aq.Acute / Chronic Cat.1 * M-factor) ≥ 25%
Step 2: A mixture is classified as Aquatic Chronic Cat.2 if:
(10 * Σ_n (% Aq.Chronic Cat.1 * M-factor)) + Σ (% Aq.Chronic Cat.2) ≥ 25%
Step 3: A mixture is classified as Aquatic Chronic Cat.3 if:
(100 * Σ_n (% Aq.Chronic Cat.1 * M-factor)) + (10 * Σ_n (% Aq.Chronic Cat.2)) + Σ (% Aq.Chronic Cat.3) ≥ 25%
Step 3: A mixture is classified as Aquatic Chronic Cat.4 if:
Σ_n Aq.Chronic Cat.1 + Σ_n Aq.Chronic Cat.2 + Σ_n Aq.Chronic Cat.3 + Σ_n Aq.Chronic Cat.4 ≥ 25%

Note: The environmental classification and the resulting documentation of your alloy can also be generated with the MeClas tool (www.meclas.eu): the classification of the alloy will be based on the composition and classification of the constituents (Tier 0, Tier 1).

2.2 You are producing and placing other types of CIMs on the market:

Those other types of CIMs can be simplex mixtures, or MOCS such as UVCBs.

Simple mixtures will have to be classified following the mixture rules.

Despite some UVCBs may have a matrix effect as in alloys, there is no clear reference in the EU CLP for the consideration of its impact on the UVCB properties and the EU CLP summation mixture rules mentioned under Option 2 above will have to be followed in the absence of T/Dp data.

[4] CLP 2024 states that ' Metals in massive form, alloys, mixtures containing polymers and mixtures containing elastomers do not require a label according to this Annex, if they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the **aquatic environment in the form in which they are placed on the market**, although classified as hazardous in accordance with the criteria of this Annex'. Hence applying this exemption requires documentation -for the enforcement authorities- on why they do not present a hazard

In case T/Dp data is available on some UVCBs, the classification and the resulting documentation of the UVCB can also be generated with the MeClas tool (www.meclas.eu), using its Tier 2 to include this data.

3. How to classify your CIM for transport under ADR[5]/RID[6] (environmental hazard)?

It is the **responsibility of the consignor to establish whether the product being transported meets any of the criteria for classification as dangerous goods**. This is a self-classification (ADR 1.4.2.1.1).

Important notes:

- There is no direct transposition of the CLP classification to the ADR/RID. The classification for the environmental hazard follows a stepwise approach outlined below.
- The degree of danger for transport shall be determined based on the physical and chemical characteristics and properties of the materials/goods. The identified hazards should be relevant for the CIMs as actually transported. Note: this is different from the approach followed under the harmonized classification scheme under the EU CLP where massive and powder forms are classified according to the hazards that are assigned to a worst-case reference sample, i.e. a particle with spherical diameter of 1 mm for massive, and powders according to the smallest relevant particle that is placed on the market. For transport purposes, however, goods are assessed based on their actual size, weight and composition.
- The ADR (section 2.2.9.1.10.1.3) recognises the special nature of metals: *"While the following classification procedure is intended to apply to all substances and mixtures, it is recognised that in some cases, e.g. metals or poorly soluble inorganic compounds, special guidance will be necessary".* A footnote refers to Annex 10 of the UN GHS (Guidance on Transformation/Dissolution of Metals and Metal compounds in Aqueous Media), and the available fraction of inorganic constituents, i.e. the metal fractions that are released in the T/Dp test. This is in line with the and the EU CLP/ECHA Guidance on the CLP criteria Annex IV.5. In a nutshell: only the fraction of a metal that dissolves in a 7-day and 28-day T/Dp test should be considered when deriving the acute and chronic environmental classifications, respectively, of the substance.
- For the transport of pure Pb massive, the International Lead Association (ILA) has prepared a detailed guidance **note**, concluding that Pb metal ingots in massive form (>99.97% Pb) do not need to be classified as hazardous for transportation.

How to evaluate the environmental hazard of your CIM for ADR/RID?

3.1 Check the list of dangerous goods (Chapter 3.2 Table A)

Table A of Chapter 3.2, which contains the dangerous goods list, is central to the use of the ADR and the starting point for any consignor. For goods listed in the table (substances or articles) special

[5] ADR: agreement concerning the international carriage of dangerous goods by road -applies for public roads
[6] RID: agreement concerning the transport of dangerous goods by rail

requirements are to be applied for the carriage of that substance or article and the table refers to the chapters or sections where these specific requirements can be found.

3.2 If your CIM is not listed in Chapter 3.2 Table A:

For substances and articles not listed by name in Table A of Chapter 3.2 to the relevant entry of that table or of sub-section 2.2.9.3, the consignor shall assign the classification.

The sections of interest for the environmental hazard of CIMs are 2.2.9.1.10 (environmentally hazardous substances) and in particular for CIMs, section **2.2.9.1.10.4: mixtures classification categories and criteria**.
It refers to different types of information available for the CIM or its constituents, including (a) data for tested mixtures, bridging data (to comparable mixtures), (c) the use of the summation of classified ingredients and/or an additivity formula (as in CLP, section 2.2.9.1.10.5). Please note that section 2.2.9.1.10.5 is to be used if data for classification according to the criteria of 2.2.9.1.10' is not available (see screenshot below)

> 2.2.9.1.10.5 Substances or mixtures classified as environmentally hazardous substances (aquatic environment) on the basis of Regulation 1272/2008/EC[3].
>
> If data for classification according to the criteria of 2.2.9.1.10.3 and 2.2.9.1.10.4 are not available, a substance or mixture:
>
> (a) Shall be classified as an environmentally hazardous substance (aquatic environment) if it has to be assigned category(ies) Aquatic Acute 1, Aquatic Chronic 1 or Aquatic Chronic 2 according to Regulation 1272/2008/EC[3];
>
> (b) May be regarded as not being an environmentally hazardous substance (aquatic environment) if it does not have to be assigned such a category according to the said Regulation.

In practice, two situations can occur:

a) You have test data (i.e. T/Dp data) or you plan to generate data on your transported CIM:
In that case, you need to use this existing data to evaluate the environmental hazard of your transported good (**testing approach**)

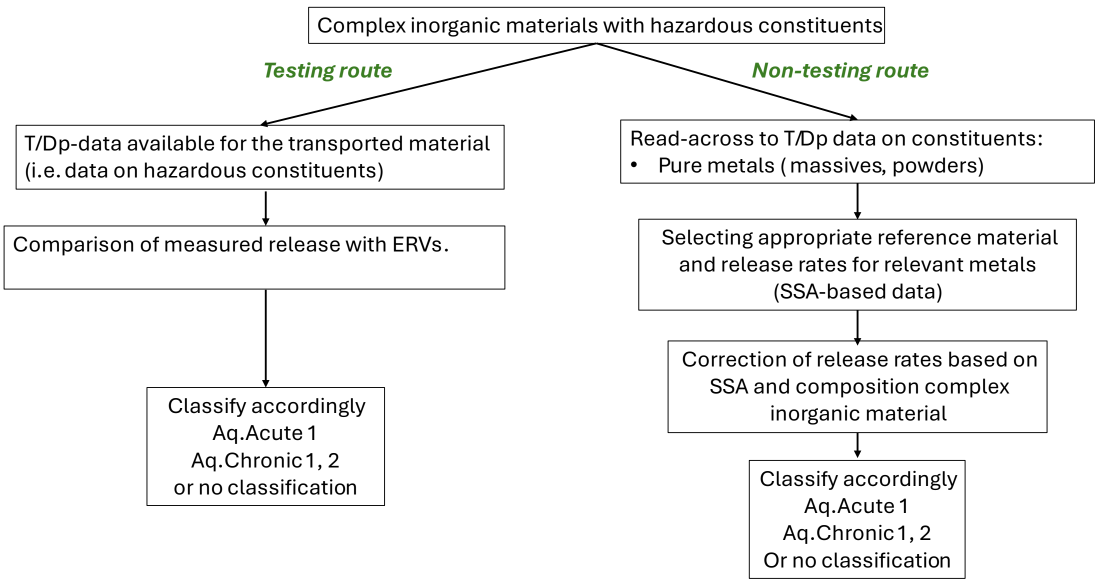
b) You do not have test data (T/Dp data) on your CIM:
It is acknowledged that, in practice,

- it is often not possible to perform T/Dp tests with goods such as metal ingots of several kilograms or to test <u>all</u> possible powder sizes of the goods to be transported[7].
- for some CIMs (e.g. alloys), T/Dp data exists and can be used to derive the classification. However, such data is not necessarily available for <u>all</u> alloys to be transported. It may also be that such data is not accessible to users of these materials. In such a case, the **non-testing approach** outlined below is proposed.

[7] A test lab will normally have to prepare the specific test piece, e.g. a wire sample with a specific amount of surface exposed equivalent to a Pb sphere of 1 mm in diameter. It is also good practice to have the test lab testing Pb metal at the same time as the complex inorganic material to have a control

The two scenarios - depending on the availability of the T/Dp data on the transported CIMs- are outlined in the schematic below:

Self-classification of complex inorganic materials under ADR/RID



The **testing approach** relies on the T/Dp data for the transported good.

The **non-testing approach** is proposed in the absence of T/Dp data and is further explained in Annex. It is based on read-across to **existing data from T/Dp tests performed on the pure metal constituents of the CIMs.** As the non-testing approach involves several calculations, **an automated calculation sheet in excel has been developed to determine the classification of the material following the assumptions detailed in Annex and relying on company data on the transported good (e.g., surface area, weight, composition).**

Notes:

- this non-testing approach (see Annex) relies on the T/Dp data for pure metals for the derivation of the Critical Surface Area (CSA[8]) values, referred to in the ECHA guidance on the application of the CLP criteria. In case this data is not available, the tool assumes 100% bioavailability to remain conservative.
- the CSA can be used for the derivation of a Critical Particle Diameter (CPD) with the formula: CPD = 6 / (CSA * density). Any shape more massive than a spherical particle with a diameter equal to the CPD, will not be classified.
- this non-testing approach will be included in the MeClas tool (www.meclas.eu)

[8] Please note that CSA Approach can also be used to calculate a Critical Particle Diameter (CPD), also referred to in the ECHA Guidance on the CLP criteria

4. Are there consequences for the waste regime?

Classification of waste according to the EU **Waste Framework Directive** and the EU **List of Waste** means that each waste has to be classified by a six-digit number. There are different types of waste codes: absolute non-hazardous waste (number without asterisk), absolute hazardous waste (number with asterisk) and waste codes with a mirror entry (can be hazardous or not depending on the composition). Wastes assigned to absolute non-hazardous entries cannot be allocated to alternative hazardous entries and are not hazardous without further assessment. Typical waste code numbers for non-ferrous metal wastes are: 12 01 03 (non-ferrous metal filings and turnings), 12 01 04 (non-ferrous metal dust and particles), 16 01 18 (non-ferrous metals), 17 04 01 (copper, bronze, brass), 19 10 02 (non-ferrous metal waste) and 19 12 03 (non-ferrous metals), and these are absolute non-hazardous waste code numbers.

There is an exemption for bulk pure metal alloys (usually scrap) in solid form in the annex "**EU List of Waste**", provided they are not contaminated with "hazardous substances". These refer to hazardous substances adhering to the surface (e.g. certain oils, emulsions or coatings), and not to the constituents of the metal alloy itself that are to be classified as hazardous (e.g., Pb in an alloy). The waste alloys that are considered a hazardous waste are specifically enumerated in this list and marked with an asterisk in the List of Waste.

This exemption applies specifically to the solid form. Although the latter is not defined in the List of Waste, one can assume it aligns with the EU CLP definition of massive form (particle diameter ≥1 mm). Hence, based on this, waste in the form of non-contaminated alloys in solid form containing Pb as an alloying constituent or impurity is exempt from classification as hazardous waste. This waste shall be subject to general information requirements for waste shipment (green listed waste) and shall not be subject to the procedure of prior notification and consent as per the Waste Shipment Regulation.

However, this exception does not apply to "non-solid" ("non-massive") Pb-containing waste such as dust, slags or sludges. For these wastes, the waste classification must be applied in conjunction with Annex III of the Waste Framework Directive (Directive 2008/98/EC) on the hazard criteria (HP criteria). A hazardous property can be assessed by using the concentration of substances in the waste as specified in Annex III to Directive 2008/98/EC or by a test (including TDp). The use of the limit values in Annex III of the WFD applies to wastes which, according to the EU List of Waste, fall into mirror categories of hazardous or non-hazardous waste. Substances in waste that are toxic to reproduction in categories 1A and 1B (HP 10) will turn the waste as hazardous waste under waste legislation if present at a concentration ≥ 0.3 % and waste containing substances classified as hazardous to the environment (HP 14) from the respective applicable contents (≥ 0.025% for Pb powder). Where a hazardous property of a waste has been assessed by a test and by using the concentrations of hazardous substances the results of the test shall prevail.

5. What about Seveso?

The **Seveso III Directive** aims to prevent major accidents at facilities storing and using large quantities of dangerous substances listed in **Annex I**. Its applicability depends on substances that trigger coverage, either specifically named in Part 2 of Annex I or classified according to categories in Part 1 of Annex I.

Pb metal is classified as hazardous to the aquatic environment under the EU CLP (H410, H400 (powder)). Thus, the amount of Pb metal stored at a facility contributes to the calculation of the qualifying quantity threshold.

For CIMs **not considered waste**, the presence or absence of T/Dp data (see section 2.1, option 2) will also impact of the application of Seveso III requirements.

- If T/Dp data on the CIM concludes to "no classification" under CLP, then the Seveso requirements do not apply.
- If there is no T/Dp data on the CIM, and if classified under CLP as Aquatic Chronic 1 (≥ 2.5% w/w Pb) or Aquatic Chronic 2 (≥ 0.25% w/w Pb), Seveso III applies. Aquatic Chronic 3 is excluded from Seveso.

For example:

- An establishment storing masterbatch alloys containing Pb classified as Aquatic Chronic 2 (≥ 0.25% Pb) will trigger Seveso III obligations if quantities exceed 200 tons (lower tier) or 500 tons (upper tier).
- For Aquatic Chronic 1 (≥ 2.5% Pb), the thresholds are 100 tons (lower tier) or 200 tons (upper tier).

Seveso III also applies to **waste** if it possesses equivalent hazardous properties to EU CLP-classified substances. HP14 "Ecotoxic" under the Waste Framework Directive is generally considered equivalent to the EU CLP classification "Hazardous to the aquatic environment" (acute or chronic). **Regulation (EU) 2017/997** aligns HP14 with CLP criteria for aquatic toxicity (H400, H410, H411, H412, H413). Therefore, waste classified as ecotoxic falls within the scope of Seveso III unless it is considered a pure metal alloy (usually scrap) in solid form in the annex "**EU List of Waste**", not contaminated with hazardous substances.

Annex: Non-testing approach for the ADR/RID of CIMs

This annex outlines the principles applied in the non-testing approach proposed on page 5 for complex inorganic materials. It starts by explaining the approach followed for mono-constituent substances (e.g. pure Pb) to address subsequently complex inorganic materials (CIMs), in massive or powder forms.

A.1 Hazard assessment of a mono-constituent inorganic material (good under ADR/RID)

The metal release in a T/Dp test can be characterized in two ways: either as metal concentration in the T/Dp medium (µg Me/L) or as metal release as a function of the exposed surface. The correct interpretation of the measured concentration in µg Me/L will also require information on the loading and the tested material (i.e., surface area).

Expressing the metal release as a function of the exposed surface is considered as more appropriate and allows to calculate:

- The Specific Surface Area (SSA) of an inorganic material/good, which represents the relationship between the surface and the weight of the inorganic material/good and is determined by dividing the surface by the weight (mm^2/mg).
- The Specific Surface Area-release ($SSA_{release}$) value (unit: µg Me/mm^2), obtained by dividing the dissolved concentration from the test (µg/L) by the exposed loading (expressed as mm^2/L). This $SSA_{release}$ is expected to be a constant value for the assessed exposure time (7 or 28 days).

The $SSA_{release}$ value, together with the Ecotoxicity Reference Value (ERV) and the loading, are the input data for the derivation of a **Critical Surface Area (CSA)**, expressed as mm^2/mg. This CSA represents the *loading in a T/Dp test that will result in a dissolved concentration in the T/Dp medium that is equal to the ERV, and which would trigger an environmental hazard classification:*
Hence, when the release R (as µg/mm^2) * SA (mm^2/L) = ERV (µg/L), then SA = CSA, or CSA (expressed as mm^2/L) = ERV / R. To convert the CSA to mm^2/mg, the reference loading L that is used in the test has to be considered: CSA (as mm^2/L) / L (mg/L) = CSA (as mm^2/mg). Or,

$CSA_{Acute1} = ERV_{acute} / (R * L_{Acute1})$

$CSA_{Chronic2} = ERV_{chronic} / (R * L_{Chronic2})$

$CSA_{Chronic1} = ERV_{chronic} / (R * L_{Chronic1})$

With:

- CSA in mm^2/mg
- ERV in µg/L
- R in µg/mm^2
- L in mg/L

A loading L of 1 mg/L is considered for the determination of the CSA_{Acute1}. The loading that is used for deriving the $CSA_{Chronic2}$ is 0.1 mg/L for metals that apply the concept of environmental transformation in MeClas (Cd, Co, Cr, Cu, Ni, Zn), whereas a loading of 1 mg/L is used for other metals. For calculating the $CSA_{Chronic1}$ the reference loadings are 0.01 mg/L (for metals with environmental transformation) or 0.1 mg/L (other metals).

In other words:

- when a 7-day T/Dp test is conducted with the Aq. Acute 1 reference loading (1 mg) of a metal substance that has a loading surface area equal to the $CSA_{Acute\ 1}$, the amount of dissolved metal after 7 days will be equal to the ERV_{acute} (and the substance will be classified as Aq.Acute 1)
- when a 28-day T/Dp test is conducted with the Aq. Chronic 2 reference loading[9] (1 or 0.1 mg/L) of a metal substance that has a loading surface area equal to the $CSA_{Chronic,2}$, the amount of dissolved metal after 28 days will be equal to the $ERV_{chronic}$ (and the substance will be classified as Aq.Chronic 2)
- when a 28-day T/Dp test is conducted with the Aq. Chronic 1 reference loading[9] (0.1 or 0.01 mg/L) of a metal substance that has a loading surface area equal to the $CSA_{Chronic,1}$, the amount of dissolved metal after 28 days will be equal to the $ERV_{chronic}$ (and the substance will be classified as Aq.Chronic 1)

Any material that has a SSA below the CSA (i.e., "less surface is exposed per mg") will not have an environmental hazard classification since the released concentration will remain below its corresponding ERV.

This is exemplified below:

Example Box 1: Chronic classification of pure Pb material/good

Input data (available):

- $ERV_{chronic}$: 6.2 µg Pb/L
- Density Pb: 11.35 g/cm^3
- T/Dp results – 28 days test with loading of 1 mg/L massive Pb
  - Specific Surface Area (SSA) in test (surface area/weight) 0.529 mm^2/mg (i.e. equivalent to surface loading of 0.529 mm^2/L)
  - Worst-case Pb-release in 28 days T/Dp test: 52.1 µg Pb/L

Output – Critical Surface Area (CSA):

$CSA = (ERV_{chronic}$ / release chronic T/Dp) * SSA_{test} = (6.2 µg/L / 52.1 µg/L) * 0.529 mm^2/mg = 0.063 mm^2/mg

material #1: Vedanta ingot with dimensions: 535 mm * 85 mm * 75 mm

- Surface area (SA)= 183,950 mm^2
- Weight: 25 kg, or 25,000,000 mg
- SSA_{ingot} = SA/W = 0.00736 mm^2/mg

SSA_{ingot} < CSA of 0.063 mm^2/mg : **no environmental classification required**

material #2: Spherical massive Pb-particle with diameter of 8 mm (radius = 4 mm)

- Surface area (SA)= $4 * \Pi * r^2 = 4 * \Pi * 16$ mm^2 = 201.1 mm^2
- Weight: volume * density = $4/3 * \Pi * r^3 * 11.35$ mg/mm^3 = 4/3 mg * $\Pi * 4^3 * 11.35$ mg/mm^3 = 3042.6 mg
- $SSA_{Pb\text{-}particle,d=8}$ = SA/W = 0.066 mm^2/mg

$SSA_{Pb\text{-}particle,d=8}$ > CSA of 0.063 mm^2/mg: **environmental classification required**

[9] Depending whether environmental transformation is applied or not

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material #3: Spherical massive Pb-particle with diameter of 9 mm (radius = 4.5mm)

- Surface area (SA)= $4 * \Pi * r^2 = 4 * \Pi * 20.25\ mm^2 = 226.2\ mm^2$
- Weight: volume * density = $4/3 * \Pi * r^3 * 11.35\ mg/mm^3 = 4/3\ mg * \Pi * 4.5^3 * 11.35\ mg/mm^3 = 4332.2\ mg$
- $SSA_{Pb\text{-}particle,d=9}$ = SA/W = 0.052 mm^2/mg

$SSA_{Pb\text{-}particle,d=9}$ < CSA of 0.063 mm^2/mg: **no environmental classification required**

A.2 Hazard assessment of a complex inorganic material/good under ADR/RID

The proposed approach can also be applied to multi-constituent complex inorganic materials. In that case, however, a **normalised** SSA of the material needs to be determined for each constituent metal, taking into account the % of the metal that is present in the material. Indeed, the CSA for a metal is only relevant for a pure metal surface, and the comparison with the SSA of a metal containing material is only meaningful if that SSA also represents a pure metal.

Rationale: if a material contains 75% of a specific metal, and a homogenous distribution of the metal in the material is assumed, then the amount of Me released from the surface of the material will only be 75% compared to that of a "pure" inorganic material/good (=100% metal) (note: no matrix effect is assumed, i.e. the release rate is not modified by the presence of other metals).

The normalized $SSA_{IMG,Me}$ is equal to the fraction of the Me * SSA_{IMG}, and this normalised SSA can be compared to the CSA.

The concept is illustrated in Example Box 2, using one of the examples from Example Box 1, but now assuming that only 75% of the 8 mm diameter particle consists of Pb. In Box 2 it is demonstrated – using the normalisation methodology - that a particle with a diameter of 8 mm requires an environmental classification when its composition is 100% Pb, but not anymore when the particle only contains 75% Pb.

Example Box 2: Chronic classification of complex inorganic materials/goods particles with variable Pb-composition

Input data:
CSA pure Pb = 0.063 mg^2/mg

material #2 (see Example Box 1): Spherical massive Pb-particle with diameter of 8 mm (radius = 4mm)

- Surface area (SA)= $4 * \Pi * r^2 = 4 * \Pi * 16\ mm^2 = 201.1\ mm^2$
- Weight: volume * density = $4/3 * \Pi * r^3 * 11.35\ mg/mm^3 = 4/3\ mg * \Pi * 4^3 * 11.35\ mg/mm^3$ = 3042.6 mg
- $SSA_{iPb\text{-}particle,d=8}$ = SA/W = 0.066 mm^2/mg
- SSA_{ingot} > CSA of 0.063 mm^2/mg: **environmental classification required**

material #4: Spherical massive particle with diameter of 8 mm (radius = 4mm), and with 75% of Pb; the remaining 25% represent non-classified inorganic metals, with average density equal to that of Pb (=no impact on weight)

- Surface area (SA)= $4 * \Pi * r^2 = 4 * \Pi * 16\ mm^2 = 201.1\ mm^2$
- Weight: volume * density = $4/3 * \Pi * r^3 * 11.35\ mg/mm^3 = 4/3\ mg * \Pi * 4^3 * 11.35\ mg/mm^3$ = 3042.6 mg
- $SSA_{75\%\text{-}Pb\text{-}particle,d=8}$ = SA/W = 0.06 mm^2/mg
- Normalised $SSA_{Pb\text{-}particle,d=8}$ = 0.75 * 0.06 mm^2/mg = 0.0495 mm^2/mg
- $SSA_{75\%\text{-}Pb\text{-}particle,d=8}$ < CSA of 0.063 mm^2/mg: **no environmental classification required**

When the material contains more than one hazardous metal, the hazard assessment also requires that the toxic contribution of all hazardous constituents is taken into account (cfr Tier 2 in MeClas; Toxic Unit approach):

- The ratio between the $SSA_{Me,normalised}$ and the CSA_{Me} represents a measure for the contribution of the metal to the overall toxicity. For material#4 (Example Box 2), the ratio $SSA_{Pb,normalised}/CSA_{Pb}$ is 0.79 (0.049 mm^2/mg divided by 0.063 mm^2/mg). In other words, the normalised SSA released 79% of the amount of Pb that is released by the CSA, and the latter represents the surface that releases the ERV. In other words, the normalised SSA released 0.79 toxic units. The overall T.U. contribution of multiconstituent inorganic material/good is therefore calculated by the summation of the $SSA_{Me,normalised}/CSA_{Me}$ ratios of all hazardous metals in the material, and a hazard classification is required with the sum is equal or exceeds 1, in line with CLP and GHS.

Important:
The approach proposed above relies on two major generic and/or worst-case assumptions, but it should be noted these can be refined/replaced by material-specific data (testing approach):

1) The approach assumes that the release rates of metals from a multi-constituent complex inorganic material are similar to those of the pure (mono-constituent) form (i.e., there is no matrix effect). When release data are available for e.g. an alloy composition that is representative for the assessed good, alloy-specific CSA-values can replace the generic CSA. For example, an alloy with lower relative release (compared to the pure form) will have a higher CSA.

   However, the use of an alloy-specific CSA for a metal is only meaningful when the release takes the fraction of metal in the alloy into account, i.e., a normalisation to a 100% metal composition is also required.

2) The selection of the generic reference ERVs and T/Dp release data will have a major impact on the outcome of the calculation. In the case of the presented Pb-examples, the lowest ERV of 6.2 µg/L was selected (relevant for pH 8), together with the T/Dp release of 52.1 µg/L which was extrapolated of a pH 5.5 (highest release). This represents a conservative worst-case approach for the determination of the CSA. It can be argued that the derivation of the CSA for a metal

should combine the ERV and T/D at the same pH. As indicated, for Pb the chronic CSA of 0.063 mm^2/mg combines an ERV at pH 8 with T/Dp release at pH 5.5 (=worst-case).

3) For those metals where no T/Dp data is available, 100% bioavailability is assumed as a worst-case

To summarise:

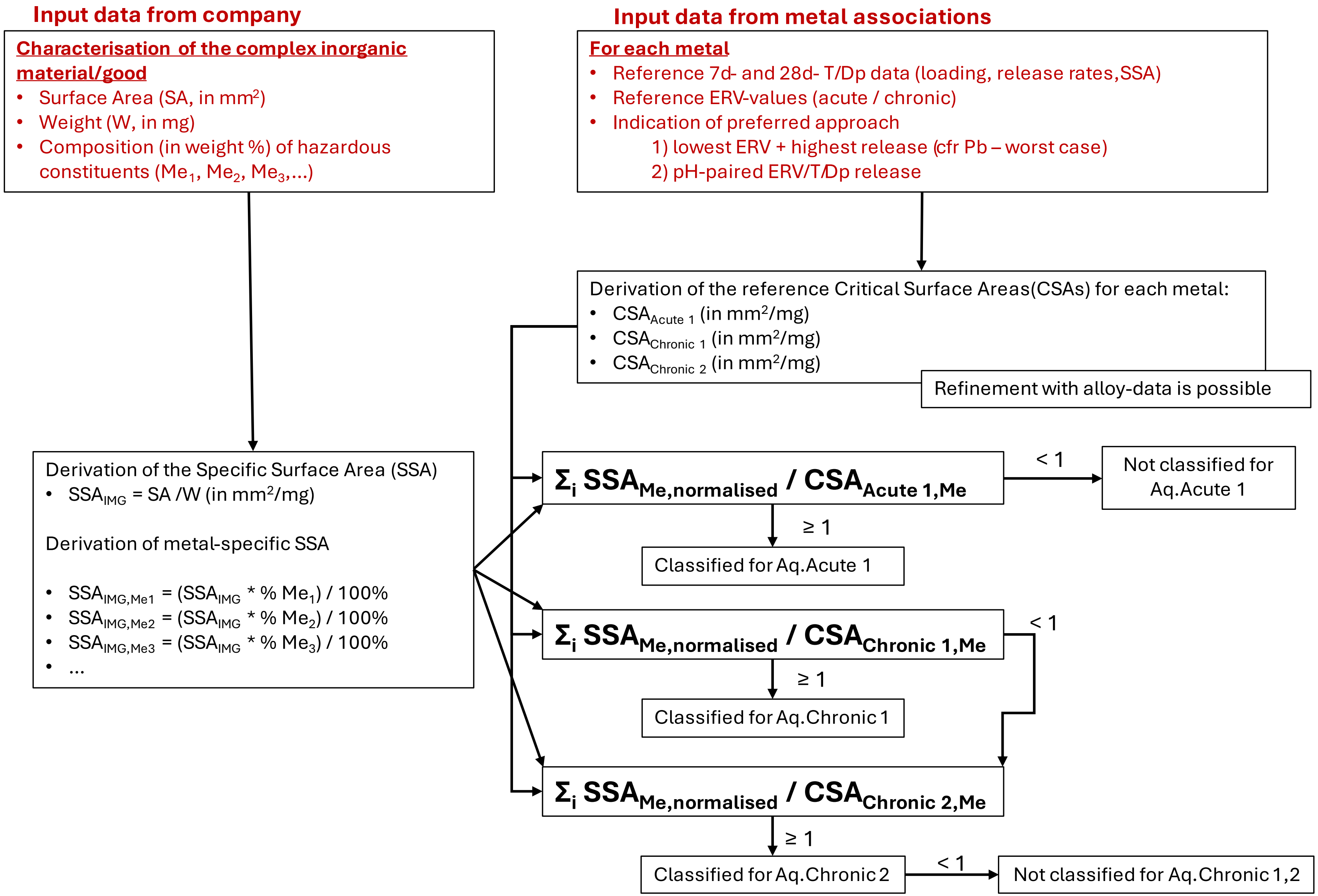
For a transported CIM, the following generic approach can be followed for the derivation of the environmental hazard classification:

- It is classified as Aq.Acute 1 if $\Sigma_i\ SSA_{Me,normalised} / CSA_{acute,Me} \geq 1$
- It is classified as Aq.Chronic 2 if $\Sigma_i\ SSA_{Me,normalised} / CSA_{Chronic\ 2,Me} \geq 1$
- It is classified as Aq.Chronic 1 if $\Sigma_i\ SSA_{Me,normalised} / CSA_{Chronic\ 1,Me} \geq 1$

with

- $SSA_{Me,normalised}$: Specific Surface Area, normalised to 100% metal
- CSA: Critical Surface Area that releases the amount of metal resulting in an Acute 1, Chronic 2 or Chronic 1 classification, respectively, at its appropriate loading in a T/Dp test
- i = every hazardous metal that needs to be considered for classification purposes

A schematic overview of the practical approach and required data is provided below.


Input data from company
Characterisation of the complex inorganic material/good
• Surface Area (SA, in mm^2)
• Weight (W, in mg)
• Composition (in weight %) of hazardous constituents (Me_1, Me_2, Me_3,...)
Input data from metal associations
For each metal
• Reference 7d- and 28d- T/Dp data (loading, release rates,SSA)
• Reference ERV-values (acute / chronic)
• Indication of preferred approach
1) lowest ERV + highest release (cfr Pb – worst case)
2) pH-paired ERV/T/Dp release
Derivation of the reference Critical Surface Areas(CSAs) for each metal:
• $CSA_{Acute\ 1}$ (in mm^2/mg)
• $CSA_{Chronic\ 1}$ (in mm^2/mg)
• $CSA_{Chronic\ 2}$ (in mm^2/mg)
Refinement with alloy-data is possible
Derivation of the Specific Surface Area (SSA)
• SSA_{IMG} = SA /W (in mm^2/mg)
Derivation of metal-specific SSA
• $SSA_{IMG,Me1}$ = (SSA_{IMG} * % Me_1) / 100%
• $SSA_{IMG,Me2}$ = (SSA_{IMG} * % Me_2) / 100%
• $SSA_{IMG,Me3}$ = (SSA_{IMG} * % Me_3) / 100%
• ...
$\Sigma_i\ SSA_{Me,normalised}\ /\ CSA_{Acute\ 1,Me}$
< 1
Not classified for Aq.Acute 1
≥ 1
Classified for Aq.Acute 1
$\Sigma_i\ SSA_{Me,normalised}\ /\ CSA_{Chronic\ 1,Me}$
< 1
≥ 1
Classified for Aq.Chronic 1
$\Sigma_i\ SSA_{Me,normalised}\ /\ CSA_{Chronic\ 2,Me}$
≥ 1
Classified for Aq.Chronic 2
< 1
Not classified for Aq.Chronic 1,2