

**MECLAS (METALS CLASSIFICATION) tool
for the classification and labelling of
complex materials from the metals sector
*vs January 13th, 2011***

TECHNICAL USER MANUAL

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1. Background

The series of mixtures in the metals sector are very complex, often composed of more than 10 different chemical species or minerals with wide and clearly different hazard profiles. In addition, many of these hazard properties are directly or indirectly related to the different physical forms in which they may occur. The classification rules for the hazard assessment of mixtures under the UN Globally Harmonised System (GHS) and its EU implementation (CLP, see below) are complicated and require extensive expert judgement. Appropriate guidance (e.g. from the European Chemicals Agency, ECHA for the CLP) has recently become available, and includes metal-specific guidance. Added to the regulatory time constraints, the complexity of the rules makes it very difficult for metal companies and consortia to ensure the correct and timely hazard classification of these complex materials.

In 2009, ARCHE developed an initial classification tool for complex materials, aimed at providing an automated expert judgement system for the hazard identification and classification of complex inorganic materials. The tool was subsequently amended to be suitable for assessing appropriate hazard identification and classification of ores and concentrates, complex intermediates, and has been proven to be relevant and efficient - but also "data hungry" (e.g. (eco)toxicity reference values have to be provided). The original tool includes several tiers, aiming for a progressive refinement of the classification through recognition of *speciation*, specific *mineral content* and the availability of *test data on the complex material in question*. However, it does not include an extensive database on toxicity reference data sets; neither it does include more complex features such as correction for Transformation Dissolution data (for the environmental classification, see Section 4) or bio-elution (for Human Health classification, see Section 4) and/or labelling guidance.

The original tool now has several limitations, however:

- It has been circulated widely in different versions, meaning that most of them are no longer up to date and no longer fulfil all refinement requirements
- Most complex materials, such as ores and concentrates, UVCB intermediates, slags with a unique EINECS number, and many other complex materials with unique EINECS numbers, will require hazard assessment and appropriate classification. These complex materials contain a spectrum of different metals (compounds) and minerals going beyond what is covered by the REACH consortia, thereby requiring extensive physico-chemical, toxicity and ecotoxicity reference data sets. Consortia do not usually have automatic access to such data from other metals/consortia
- As more (self-) classifications and toxicity reference values become available over time as a result of test- or data-gathering obligations under REACH and CLP, the tool requires continuous and rigorous updating,

In view of this complexity, considering the above-mentioned limitations of the original tool, and based on experience with the original tool, ARCHE and Eurometaux developed the MeClas (Metals Classification tool) aimed at providing *an automated expert judgement system for the hazard identification and classification of complex inorganic materials*.

2. Scope

MECLAS can be used to **automatically** calculate the classification of the complex material. The tool is based on a database containing the human health and environmental classification for each component relevant for classification.

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
 - release tool correction (if relevant) and correction based on test data on the complex material
- A **core block** including the ecotoxicity and toxicity reference values (ERVs and TRVs) values and DSD/DPD, CLP (and UN-GHS) hazard ID rulings, forming the base of the MECLAS tool
- An **open building block structure**, enabling the inclusion of specific side modules if relevant (e.g. for Ores and Concentrates, for Transport Classification, additional reference lists (e.g. Japan), alloys, etc.)
- A **quality control system** for updates on classification rulings and ERV-TRV data (via the quality control group): A quality control group will ensure that all data that enter the MECLAS system are checked for consistency and correctness in order to provide reassurance for the users, since the latter will not be capable of checking proprietary data
- **Confidentiality assurance** for proprietary information: Confidentiality of proprietary data is assured by having the TRV's for such substances hidden
- **Equal participation** and sharing rights:
 - All ERVs-TRVs data holders/providers are treated equally
 - All full licence holders participate in the MECLAS Steering Committee

The **MECLAS database** is fed with:

- Legal classifications as required by Annex VI of the CLP, (or other national references in the future)
- Self-classifications from data owners (e.g. consortia or companies)
- ERV and TRV values from data owners (e.g. consortia or companies),
- Classification rulings from the CLP guidance (for the EU)
- Specific agreed guidance on metals (e.g. from MERAG/HERAG, etc.)

MECLAS is further governed by the following principles:

All licence holders of the model shall agree with these principles when buying licence rights to the MECLAS tool:

- MECLAS follows classification guidance and implements it in accordance with the legal ruling and technical guidance provided (ECHA, UN). For the EU, MECLAS will not deviate from the proposed CLP guidance unless ECHA agrees to the proposed deviation approach
- The MECLAS model will be adapted to the classification ruling when necessary
- MECLAS classifies and ranks ERV-TRV data according to quality and following a strict procedure. New, higher quality information overrules older or lower quality information after assessment by the quality control committee.

- ERVs and TRVs are never made public unless the Consortia provide explicit written agreement to do so.
- All Consortia and Company specific RCS are stored on (a protected part of) the MECLAS server, enabling any changes to the classification system, ERV or TRV values to be conducted automatically and on an immediate basis.

Further information on the legal context and rules of classification can be found under Section 4).

3. How to use MECLAS?

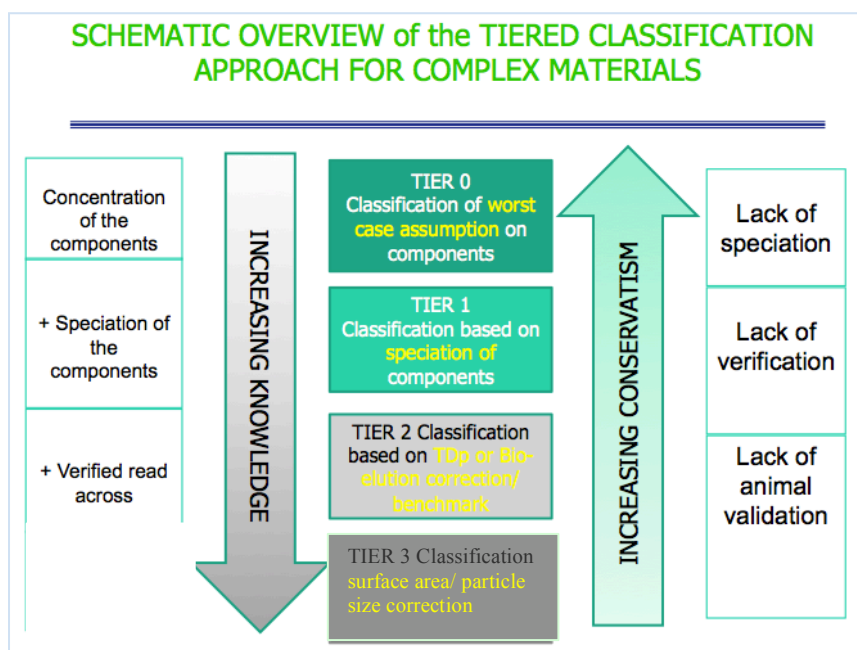
3.1. Technical context

3.1.1 Tiered approach

Complex metal mixtures contain varying amounts of metals and metal minerals. They are considered under REACH as UVCB substances. This section outlines how these complex materials can be identified and analysed, in order to classify and to fulfil REACH and/or CLP requirements in terms of toxicological and eco-toxicological classification.

For complex metal mixtures, the effects are not expected to be adequately described solely by their metal content, i.e. the elemental composition is not sufficient on its own to derive classification. A tiered approach needs to be used for analysis and interpretation.

The following tiers are built into the MECLAS tool.



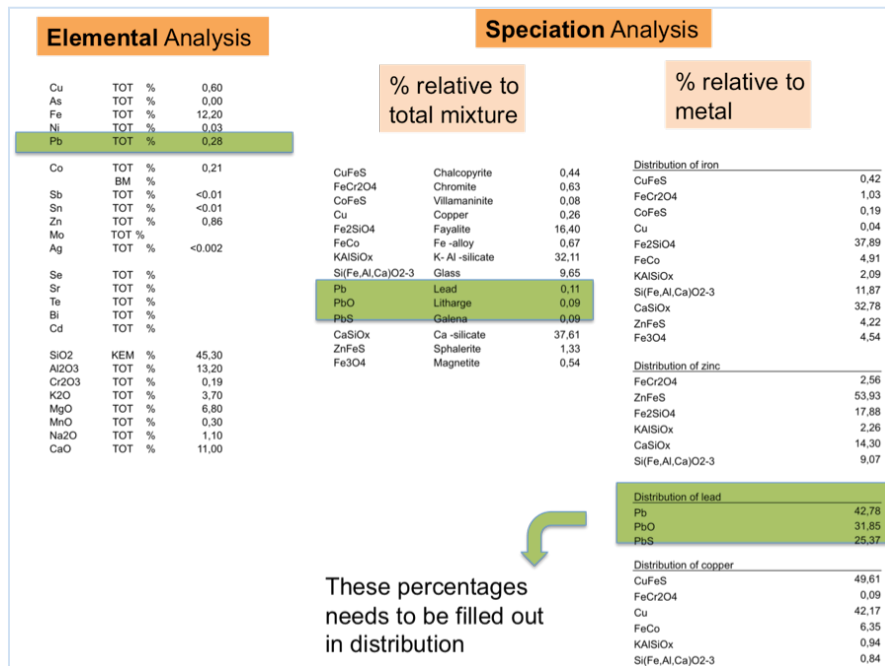
Tier 0: Classification based on worst-case assumption for the elements

This Tier is based on the **concentration of the elements** in the complex metal mixture only. Chemistry /elemental analysis is usually determined using ICP (inductively Coupled Plasma spectroscopy). The classification is based on worst-case speciation/classification for all elements. For example, Cr will be assumed to be in the form of the CrO₃ species because CrO₃ has a worse existing classification than the “Cr compounds”. Tier 0 can be used if speciation data are lacking (therefore not relevant tier for you if you have speciation data).

Tier 1: Classification based on speciation of elements

Metal speciation/metal mineralogy can be assessed from sequential extraction/metal analysis and mineralogical analysis (XRD and microscopes equipped with EDS (Energy Dispersive Spectrometry) and WDS (Wavelength Dispersive Spectrometry) analyzers. The determination of the speciation requires in-depth

knowledge of metal particularities. However, the speciation results can easily be entered in MeClas. Speciation results usually come in two formats (see example figure below): either as relative % to the total mixture (e.g. Lead metal: 0.11%, Litharge 0.09% and Galena 0.09%) or relative % to the metal element, defined as distribution (e.g. Pb metal 42.78%, Litharge 31.85%, Galena 25.37%). Distribution percentages should not exceed 100% for each element. The classification is then based on elemental and speciation data.



Tier 2: Classification based on TDp or Bio-elution correction/benchmark

The tool derives the classification based on Mixture toxicity rules (Summation method; see Section 4). Classifications are then corrected using TDp or Bio-elution data. Transformation dissolution tests (TDp) are conducted to determine the rate and extent to which metals and sparingly soluble metal compounds can produce soluble, available ionic and other metal-bearing species in aqueous media under a set of standard laboratory conditions, representative of those generally occurring in the environment. Bio-elution tests are conducted to estimate the bioaccessible fraction, i.e. the fraction of the material soluble under physiological conditions, by measuring the dissolution of the material in artificial biological fluids. Classification is then corrected for the bio-available elemental and/or speciation data. More explanations on TDp and bio-elution testing and correction can be found in the MERAG/HERAG alloys fact sheet.

Tier 3: Classification with surface area/particle size correction

Surface area is a crucial parameter in environmental classification of powders: any variation in surface area tested may cause a significant change in the levels of metals ions released in a given time-window. Thus, particle size or surface area is **fixed** for the purposes of the **transformation test**, allowing the comparative classifications to be based solely on the loading level.

There may be cases where data generated for a particular metal powder are not considered as suitable for classification of the massive forms. The powder may be classified separately based on the data generated on the powder. However, in normal circumstances it is not anticipated that more than two classification proposals would be made for the same metal.

The particle sizes tested and/or used for classification and labelling depend on the substance being assessed and are shown in the table below:

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

When the surface particle size info of the material that requires classification is different than the measured ones of the test sample, a **surface correction** can be applied.

The surface correction approach can be applied if **following criteria** are met:

1. Measured surface and/or particles size distribution data are available for the test samples
2. Estimated/measured surface particle size info available for the material that requires classification (eg the massive form)
3. Confirmation that "normal handling and use" of the massive form does NOT lead to a production of fine materials during normal handling and use (production, transport and use). (Useful when it is stated that "drums should not contain > 1 % fines at the bottom").

Consequently, based upon the defined/estimated surface of the TDp results for the tested and the sample to be classified, a surface correction factor will be applied and a check will be conducted if the material is still classified or less/more stringent. Tier 3 is only useful if the Tier 2 data (TDP data) are known and filled out.

Tier 4: Classification based on measured toxicity response (testing)

This approach is based on actual (eco-)toxicity testing, and the results can be directly used for classification. This is currently not included in the MeClas tool.

3.1.2 How is this tiered approach built in MeClas?

On the MeClas website, you will find the following table under Tool => own compositions => my compositions.

TIER 3

Surface area (m2/g) from reference material tested in TDP test
 Surface area (m2/g) of other than tested sample

TIER 0,1,2				TIER 1	TIER 2		
Element	Conc. (%)	Classification Entry	Chemical Formula	In the form of	Distribution (%)	TDP (%)	Bio-elution (%)
Ag	<input type="text"/>	Ag	Ag	Ag, AgPb-phosphate, CuTeAgSe-alloy, AgSn, ZnAg, AgZn3, oxide form, sulphate form, NiSbSnAg	<input type="text"/>	<input type="text"/>	<input type="text"/>
		AgNO3	AgNO3	AgNO3	<input type="text"/>	<input type="text"/>	<input type="text"/>
Al	<input type="text"/>	Al	Al	Al, Al2O3	<input type="text"/>	<input type="text"/>	<input type="text"/>
		Al powder pyrophoric)	Al	Al powder (pyrophoric)	<input type="text"/>	<input type="text"/>	<input type="text"/>
		Al powder (stabilised)	Al	Al powder (stabilised)	<input type="text"/>	<input type="text"/>	<input type="text"/>
		Al silicate	Al2SiO5	Al silicate	<input type="text"/>	<input type="text"/>	<input type="text"/>

If only the concentration of the different elements of the complex material is available, then the only classification option is to use Tier 0, which is the worst-case calculation. If, besides concentrations, the speciation column distribution is also filled out, then a Tier 1 approach can be made. When TDp and bio-elution results are available, a Tier 2 approach can be calculated. When the surface area from the TDP tested reference material and that of the material to be classified (other than tested sample) are different and known, the Tier 3 correction can be applied for environmental classification. Obviously, Tier 3 is only useful if TDP data are filled out.

Note: For Tiers 1 and 2, the distribution percentages ALWAYS have to be filled in (even when there is only one form of a specific species). For example, Ag element is in the form of AgNO3 for 100%.

Element	Conc. (%)	Classification Entry	Chemical Formula	In the form of	Distribution (%)
Ag	0.9	Ag	Ag	Ag, AgPb-phosphate, CuTeAgSe-alloy, AgSn, ZnAg, AgZn3, oxide form, sulphate form, NiSbSnAg	<input type="text"/>
		AgCl	AgCl	Ag/Ag compounds (self classification)	<input type="text"/>
		AgNO3	AgNO3	AgNO3	100

3.1.3 How does it work in the background?

As visualised below, in MECLAS, the elements are linked to mineral or speciation forms, which in turn are linked to classification entries.

Element	Conc. (%)	Classification Entry	Chemical Formula	In the form of	Distribution (%)	TDP (%)	Bio-elution (%)	
Ag	<input type="text"/>	Ag	Ag	Ag, AgPb-phosphate, CuTeAgSe-alloy, AgSn, ZnAg, AgZn3, oxide form, sulphate form, NiSbSnAg	<input type="text"/>	<input type="text"/>	<input type="text"/>	EDIT
		AgNO3	AgNO3	AgNO3	<input type="text"/>	<input type="text"/>	<input type="text"/>	EDIT
Al	<input type="text"/>	Al	Al	Al, Al2O3	<input type="text"/>	<input type="text"/>	<input type="text"/>	EDIT
		Al powder (pyrophoric)	Al	Al powder (pyrophoric)	<input type="text"/>	<input type="text"/>	<input type="text"/>	EDIT
		Al powder (stabilised)	Al	Al powder (stabilised)	<input type="text"/>	<input type="text"/>	<input type="text"/>	EDIT
		Al silicate	Al2SiO5	Al silicate	<input type="text"/>	<input type="text"/>	<input type="text"/>	EDIT

1. Link Elements to Mineralogy/Species

To link the elements to the appropriate species/minerals, the results from worst-case assumptions (e.g. in Tier 0, selection of the species with the worst classification), user expert judgment or species/mineralogical analysis (as in Tier 1) is used: e.g.

- As: 100% in the form of FeAs
- Cu: 49% in the form of Cu2S and 51% in metal form
- Pb: 98.65% in the form of PbO; 1.05% in the form of PbS and 0.30% in the metal form

In the case of several species, the percent of distribution can be calculated:

e.g. Pb in the form of Pb metal (4%) and PbO (1%) => percent contribution is respectively 80% Pb metal and 20% PbO. In the case of multiple samples/contributions, the worst case can be taken.

If, for some elements, no mineralogical data are available, the metal, oxide, sulfide or sulphate forms are assumed. This is based on the general form for most metals.

2. Link mineral/species to classification entry

The minerals/species are then linked to classification entries, e.g.

- PbO links to the “Pb compounds” classification
- SbSnO links to the “Sb compounds” classification

Some minerals are linked to several classification entries, e.g. PbAsO links both to the “Pb compounds” and the “As compounds” classification.

In addition, several hypothetical “other metal compounds” were created for CuS, Cu₂O, NiO, NiS, NiSO₄, etc. e.g.

- Cu₅FeS₄ links to the “CuS” classification entry
- FeZnO links to the “ZnO” classification entry
- CoNiSbSO₄ links to both the “NiSO₄” and “CoSO₄” classification entry (and also to the “Sb compounds” classification)

A link can also be made to the “metal massive form” or the “powder form” (particles < 1 mm).

Metal in inter-metallic forms (such as alloys) can be considered as “metal form”. For example: As in AgAs is linked to “As metal” classification.

3. Molecular weight conversion

All elemental percentages have been transformed to the molecular weight of the relevant classification entry,

e.g.

1. For As compounds other than arsenic trioxide and arsenic pentoxide, the molecular weight of As metal is used ("Arsenic compounds", with the exception of those specified elsewhere in this Annex)
2. For PbO, use of the molecular weight of Pb metal ("Pb compounds" entry; a PbO entry does not exist) but ZnO: conversion to molecular weight of ZnO ("ZnO" entry)
3. PbCuO: conversion to the molecular weight of Pb metal ("Pb compounds" classification) and CuO (copper(II)oxide classification)

Special case: "other metal compounds classification entry", e.g.

–"NiS-like compounds" e.g. $Pb_2Ni_3S_2$: conversion to molecular weight of NiS

–"NiO-like compounds" e.g. $CuNiSbO_x$: conversion to molecular weight of NiO

4. Substance classification database

The MeClas database is fed with:

- Legal classifications as required by Annex VI of the CLP, (or other national references in the future)
- Quality controlled self-classifications, ERV and TRV values from data owners (e.g. consortia or companies)

3.2. In practice, MeClas environment

On the MeClas website (www.MeClas.eu), companies can log in by entering their username and password. In order to use the tool, a licence and registration are needed. Registration can be obtained by filling in the "register" page to request an account. More general information about MeClas can be found in the "ABOUT MECLAS" tab. Questions can be asked and further information can be requested by filling out the form in the CONTACT tab.



When logged in, the company can view its profile by clicking 'view profile'. The name of the registrant and the company, the position, e-mail and phone number of the registrant can be filled in or edited. The password can also be changed. If the user has forgotten his password, he can leave their e-mail address and will receive an e-mail with further information on how to obtain a new password.

After registration, an extra tab will pop up (TOOL).

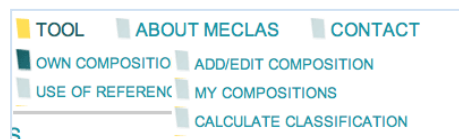


MeClas enables:

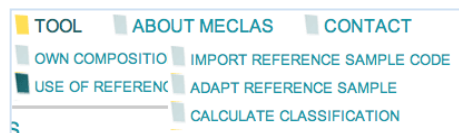
1. Companies to create their own company-specific classification samples, and Consortia (or Technical Lead Companies) to create reference classification samples (i.e. representative samples covering multiple companies)

2. Companies to run company-adapted versions of the Consortia reference classification samples

This is reflected in the tool tab.



The use of **own samples**, in which companies or consortia can add and edit compositions, share compositions via a unique code, view subscribers to the compositions and delete compositions.



The second possibility is to **adapt a reference sample**. The reference sample code can be imported (shared by the consortium) and the reference sample can be adapted.

When the compositions are filled in correctly, the classification will be calculated.



When the maximum number (25) of own compositions is reached, an upgrade is possible. Please send an email to info@meclas.eu in order to find out how to upgrade the account. To find out how many compositions are still left, go to 'Own composition' - 'Add/Edit composition'. For example, "Compositions (3/25)" means there are still 22 compositions remaining.

3.3. User Manual Classification

MECLAS enables:

1. Companies to create their own company-specific classification samples
2. Consortia (or Technical Lead Companies) to create reference classification samples
3. Companies to run company-adapted versions of the Consortia reference classification samples

3.3.1 Companies to create own company specific classification samples

General information

If companies have elemental analysis, speciation, TDP and/or bio-elution tests for their own metal mixtures, classification can be calculated for each sample.

How to?

Select the following possibilities in the TOOL tab:

1 Own composition

a. Add/edit composition

- A new composition can be created by clicking the link 'create a new composition' or an existing composition can be chosen from the dropdown menu. The first time that the company uses the tool, a new composition has to be created.

Compositions (1/25)

info

Show:

Choose a composition from the list above or [create a new composition.](#)

To make a new composition, when you are currently watching/editing another composition, one can also click 'new comp.' Please keep in mind that changes are not saved automatically when using this possibility.

Element	Conc. (%)	Classification Entry	Chemical Formula	In the form of	Distribution (%)	TDP (%)	Bio-elution (%)	NEW COMPOSITION	new comp.

- To edit a composition, select a composition from the dropdown menu.

Cor

info

Show:

- COMPOSITION1
- COMPOSITION2
- COMPOSITION3
- COMPOSITION4

On this page, a name can be given or changed to a new/existing composition (black surrounded box). Click in the black box and confirm new name by pressing enter or click save changes.

Element	Conc. (%)	Classification Entry	Chemical Formula	In the form of	Distribution (%)	TDP (%)	Bio-elution (%)	NEW COMPOSITION	new comp.

The concentration of the different elements can be filled out. Information about the distribution, TDP and bio-elution can also be entered.

Fill out the following fields:

- Tier 0: elemental % only,
- Tier 1: elemental % and distribution %,
- Tier 2: elemental % and distribution % and TDP % and/or bio-elution %.
- Tier 3: surface area of tested sample and of material to be classified (m²/g).

Distribution percentage

Distribution percentages relate to the speciation (Tier 1), and should not exceed 100% for each element. As demonstrated in the Figure below, distribution percentages should not relate to the total composition of the metal mixture, but should relate to the element/metal.

Elemental Analysis

Cu	TOT	%	0,60
As	TOT	%	0,00
Fe	TOT	%	12,20
Ni	TOT	%	0,03
Pb	TOT	%	0,28
Co	TOT	%	0,21
BM	%		
Sb	TOT	%	<-0,01
Sn	TOT	%	<-0,01
Zn	TOT	%	0,86
Mn	TOT	%	<-0,002
Ag	TOT	%	<-0,002
Se	TOT	%	
Sr	TOT	%	
Te	TOT	%	
Bi	TOT	%	
Cd	TOT	%	
SiO2	KEM	%	45,30
Al2O3	TOT	%	13,20
Cr2O3	TOT	%	0,19
K2O	TOT	%	3,70
MgO	TOT	%	6,80
MnO	TOT	%	0,30
Na2O	TOT	%	1,10
CaO	TOT	%	11,00


Speciation Analysis

% relative to total mixture

CuFeS	Chalcopyrite	0,44
FeCr2O4	Chromite	0,63
CoFeS	Villamaninite	0,08
Cu	Copper	0,26
Fe2SiO4	Fayalite	16,40
FeCo	Fe -alloy	0,67
KAlSiOx	K- Al -silicate	32,11
Si(Fe,Al,Ca)O2-3	Glass	9,65
Pb	Lead	0,11
PbO	Litharge	0,09
PbS	Galena	0,09
CaSiOx	Ca -silicate	37,61
ZnFeS	Sphalerite	1,33
Fe3O4	Magnetite	0,54

% relative to metal

Distribution of iron		
CuFeS		0,42
FeCr2O4		1,03
CoFeS		0,19
Cu		0,04
Fe2SiO4		37,89
FeCo		4,91
KAlSiOx		2,09
Si(Fe,Al,Ca)O2-3		11,87
CaSiOx		32,78
ZnFeS		4,22
Fe3O4		4,54
Distribution of zinc		
FeCr2O4		2,56
ZnFeS		53,93
Fe2SiO4		17,88
KAlSiOx		2,26
CaSiOx		14,30
Si(Fe,Al,Ca)O2-3		9,07
Distribution of lead		
Pb		42,78
PbO		31,85
PbS		25,37
Distribution of copper		
CuFeS		49,61
FeCr2O4		0,09
Cu		42,17
FeCo		6,35
KAlSiOx		0,94
Si(Fe,Al,Ca)O2-3		0,84



These percentages needs to be filled out in distribution

By default, 100 % distribution in the worst-case form is applied for each element. If detailed information is available about the form in which each element appears in the composition, one can manually change the distribution percentages (and remove the 100 % next to the worst-case form to avoid double calculations). If this kind of information is not available, maintain the default value to avoid underestimation of classification. All numbers should be filled out without mentioning the unit (%). For example, when Ag is present in a concentration as 5 % AgNO₃, it should be entered as 5 (not as 0.05 or as 5%). This is also valid for the elemental, TDP and bio-elution percentages.

The sum of the distribution percentages of each element must be equal to 100%. This example is not possible (sum is 400%):

Al	3	Al	Al	Al, Al2O3	100
		Al powder (pyrophoric)	Al	Al powder (pyrophoric)	100
		Al powder (stabilised)	Al	Al powder (stabilised)	100
		Al silicate	Al2SiO5	Al silicate	100

This, on the other hand, is correct (sum is 100%):

Al	3	Al	Al	Al, Al2O3	5
		Al powder (pyrophoric)	Al	Al powder (pyrophoric)	80
		Al powder (stabilised)	Al	Al powder (stabilised)	
		Al silicate	Al2SiO5	Al silicate	15

Note: For Tiers 1 and 2, the distribution percentages must ALWAYS be filled in and the sum must equal 100 %. If you don't have information about the exact form, please leave the default form.

Element	Conc. (%)	Classification Entry	Chemical Formula	In the form of	Distribution (%)
Ag	0,9	Ag	Ag	Ag, AgPb-phosphate, CuTeAgSe-alloy, AgSn, ZnAg, AgZn3, oxide form, sulphate form, NiSbSnAg	
		AgCl	AgCl	Ag/Ag compounds (self classification)	
		AgNO3	AgNO3	AgNO3	100

TDP percentage

In the column with TDP percentages a default value of 100% (related to complete solubility and noted in MeClas as "100") for every element is initially filled out. These predefined percentages can be replaced by

actual TDP translation factors derived from TDP test results. The TDP translation factors that should be entered correspond to the % solubility at 1, 10 or 100 mg/L sample loading (7 days test results) for each tested metal. The % solubility can be calculated from the mean metal release and the maximum metal release expected from the sample composition (taken into account the sample loading rate).

On the MeClas website (Tool < Own composition < Add/Edit compositions) a simple excel calculator sheet is provided that can be used to calculate the value that should be entered in the TDP column.

Below you can find a screen shot of the calculator sheet mentioned above. Dependent on the sample loading rate (1-10-100 mg/L) that was assessed the top, middle or bottom panel should be used to calculate the TDP translation factor. For each tested metal, fill out the mean TDP result ($\mu\text{g/L}$) and the metal concentration (%) that was initially present in the sample (fields that should be completed are highlighted in orange). The TDP translation factor that should be entered in MeClas appears then in the yellow field.

Loading rate 1 mg/L - 7 days				
Metal	T/D result, mean ($\mu\text{g/L}$)	Concentration in original tested sample (%)	Maximum expected ($\mu\text{g/L}$) = Theoretical content at 1 mg/L	Solubility (%) = Translation factor
	200	40	400	50

Loading rate 10 mg/L - 7 days				
Metal	T/D result, mean ($\mu\text{g/L}$) - 10 mg/L	Concentration in original tested sample (%)	Maximum expected ($\mu\text{g/L}$) = Theoretical content at 10 mg/L	Solubility (%) = Translation factor
	2000	40	4000	50

Loading rate 100 mg/L - 7 days				
Metal	T/D result, mean ($\mu\text{g/L}$) - 100 mg/L	Concentration in original tested sample (%)	Maximum expected ($\mu\text{g/L}$) = Theoretical content at 100 mg/L	Solubility (%) = Translation factor
	20000	40	40000	50

If the release of one of the tested metals is below the detection limit, zero should be filled out as TDP percentage. For metals where no TDP results are available, the default value of 100 should be maintained to avoid an underestimation of the classification result. Note that the TDP translation factor for metal powder can be entered in the same field as for metal massive.

Bio-elution percentage

General note: The methodology and regulatory acceptance for bio-elution correction is still ongoing and will be updated as soon as more information becomes available.

The bio-elution percentages that should be filled out correspond to the % solubility at **200 mg/L sample loading** for each tested metal. An excel calculator sheet can be found on the MeClas website (Tool < Own composition < Add/Edit compositions).

Below you can find a screen shot of the calculator sheet mentioned above. For each tested metal fill out the mean bio-elution result ($\mu\text{g/L}$) and the metal concentration (%) that was initially present in the sample (fields that should be completed are highlighted in orange). The bio-elution translation factor that should be entered in MeClas appears then in the yellow field.

Sample loading 200 mg/L				
Metal	bio-elution result, mean ($\mu\text{g/L}$)	Concentration in original tested sample (%)	Maximum expected ($\mu\text{g/L}$) = Theoretical content at 100 mg/L	Solubility (%) = Translation factor
Cd	16000	40	40000	20

In case of gastric bio-elution tests, one can assume that the measured metals in the gastric fluid will be present in the form of soluble metal compounds. Bio-elution percentages should then be filled out in the row of the soluble compound (in general the sulphate form is used for gastric test). The value of zero should be entered for the other compounds of that metal. If the bio-elution for one of the tested metals is below the detection limit, zero should be filled out as bio-elution percentage. For metals where no bio-elution results are available a default value of 100 should be entered in the row that corresponds with the speciation form selected for Tier 1.

It is important to note that currently the bio accessibility correction is done for all human health endpoints. This is not always correct (e.g. gastric test results are not relevant for dermal endpoints). This will be further fine-tuned as soon as more guidance will become available.

The correct way of filling in the different fields of the composition is demonstrated with the following example. Sample x contains 40% cadmium, which is completely present in the form of sulphides. According to a 7 days TDP test 50% of the cadmium in sample x is leaching out at 1 mg/L sample loading. The result of a gastric bio-elution test (200 mg/L sample loading) showed that 20% of the cadmium in sample x is bio accessible. Note that the bio-elution percentage is linked to the cadmium sulphate form since one can assume that the measured cadmium in the gastric fluid will be present in the form of a soluble compound.

					sample X		new comp.
Element	Conc. (%)	Classification Entry	Chemical Formula	In the form of	Distribution (%)	TDP (%)	Bio-elution (%)
Cd	40.00000	Cd (pyrophoric)	Cd	Cd (pyrophoric), SbCdZn		50.00000	
		cadmium compounds, with the exception of cadmium sulphoselenide (xCdS.yCdSe), mixture of cadmium sulphide with zinc sulphide (xCdS.yZnS), mixture of cadmium sulphide with mercury sulphide (xCdS.yHgS), and those specified elsewhere in this Annex	Cd	Cd compounds, with the exception of cadmium sulphoselenide (xCdS.yCdSe), mixture of cadmium sulphide with zinc sulphide (xCdS.yZnS), mixture of cadmium sulphide with mercury sulphide (xCdS.yHgS), and those specified elsewhere in this Annex			
		Cd (non pyrophoric)	Cd	Cd (non pyrophoric)			
		Cd compounds excluded from classification: cadmium sulphoselenide, mixture of cadmium sulphide with zinc sulphide, mixture of cadmium sulphide with mercury sulphide	Cd	xCdS.yHgS, xCdS.yZnS, xCdS.yCdSe			
		CdO	CdO	CdO			
		CdS	CdS	CdS, ZnSe(Mo,Cd)S	100.00000		
		CdSO4	CdSO4	CdSO4, Sulphate form			20.00000

Save changes

When the composition is filled in, click the “save changes” button or press “enter”. The composition is then saved (green marked lines). If an element or (self-)classification entry is missing, please send an email to info@meclas.eu. The new entry will be evaluated (quality control) by Eurometaux’s selected quality control group, for inclusion in MeClas.

b. My compositions

To **delete** compositions, go to the ‘My compositions’ page (tool > own compositions > my compositions) and delete the required compositions.

To **change** the name of your composition, go to the ‘My compositions’ page and click on the composition you want to change. Once the compositions sheet is displayed, click in the black box and type your new name. Confirm by pressing enter or ‘save changes’.



c. Calculate classification

A metal mixture should be chosen here. When a composition is chosen, an output method can be selected by clicking on the Tier. Depending on the input, Tiers 0, 1, 2 and 3 can be selected. More information about the different tiers can be found in Section 3.1.

For every endpoint, the classification is given. The major driver for this classification is also mentioned. In addition, the pictograms for labelling are given for the different classified endpoints.

A summary report with the assumptions and the classification result (CLP and Directive 1999/45/EC) can be downloaded in PDF or Excel by clicking on the icons above right:



3.3.2 Consortia to create reference classification samples

General information

For some complex metal mixtures, due to the intrinsic similarities of the composition depending on the process or source, a complete mineralogical analysis is not required. Samples can therefore be selected and fully analyzed for representative UVCB processes and original materials (= Representative Samples, Reference Samples). In view to characterize a reference sample, the following points need to be considered:

- For each complex mixture, the range in elemental compositions within and across all companies should be assessed.
- For each complex mixture, detailed information on the different process conditions (if any) should be evaluated in view of potential differences in resulting mineralogy (i.e. speciation). For each specific process type, a representative sample can be selected and the metal species and/or mineralogical forms can be determined (by means of XRD analysis).

Consequently, **the speciation/mineralogical pattern determined for a sample that is representative of a particular process or source and conditions is the same for all materials produced or mined according to the same process, source or conditions.**

How to proceed?

Information on how to create and edit a composition can be found in Section 3.3.1. To share compositions with subscribers, go to the 'My compositions' page under 'Own compositions', 'TOOL'.

My compositions

On this page you can **share** your compositions via a unique code (select and copy the code), **view** subscribers to your compositions and **delete** compositions. When compositions are deleted, the users who are subscribed to this composition will lose their data! In this list it is also indicated whether or not the consortium is the author of a certain composition (indicated with *).

3.3.3 Companies to run company adapted versions of the Consortia reference classification samples

General information

Companies can use their site-/process-specific Elemental Compositions (e.g. analysis is usually part of process & quality control) and adapt the Reference Samples as defined in the consortium to derive Classification of their company-specific UVCB substances.

Company-specific Elemental compositions are linked to metal species present or leaching, derived from various analyses of Representative samples (see Example Cu intermediates consortium Fig. 1).

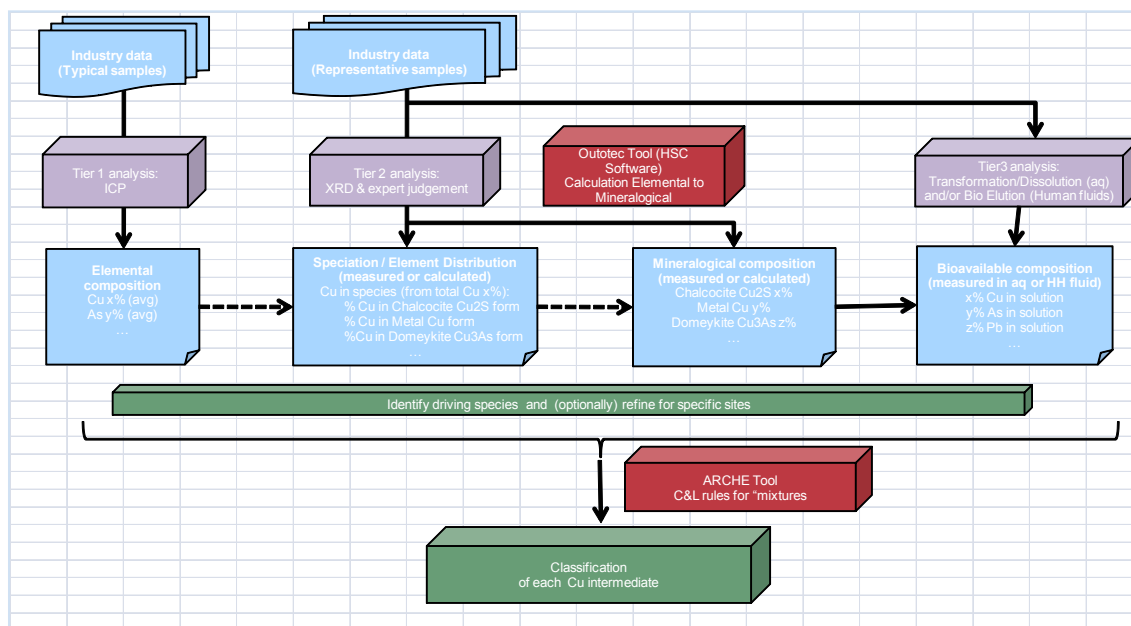


Fig 1: General principles for classification of Copper intermediates

The advantage: once (bioavailable) species are determined for a representative sample, there is no need to perform additional mineralogical or TDP/bio-elution testing on all samples.

The information on the mineralogical composition (distribution pattern for each constituent of the complex metal mixture) is incorporated into MECLAS by the consortium, so that the elemental composition (in % total element) is automatically converted into %w/w of compounds/species.

How to proceed?

Go to the 'use of reference sample' page in the 'TOOL' tab, 'Use of reference sample'

a. Import reference sample code

If the company has received a composition code from a consortium or another company, it can be entered in the field to gain access to the input and output data of this composition. The company is asked whether it wants to add this composition to the input and output list. Click 'yes'. To view or adapt the composition go to 'adapt reference sample'.

b. Adapt reference sample

The objective of the input sheet is to adapt the elemental composition of a reference sample. For this, input specific values will overwrite default reference values where necessary when the adapted company-specific classification is calculated. If input boxes are left blank, the value of the reference sample for that element is considered. However, if you do not wish to assume default concentrations, overwrite the value from the reference sample by inserting zero ("0"). Note that the changes are user-specific and will not overwrite the default values from the reference samples. Other users that share the same reference sample will not view your adaptations.

Firstly, select a metal mixture in the dropdown menu. Again, all percentages have to be filled out without mentioning the unit. For example, when the element is present in a concentration of 5%, it should be entered as 5, not as 0.05 or 5%). This is also valid for the distribution percentages. The sum of the percentages of the elements should be equal to 100%. The distribution percentages should not relate to the total composition of the metal mixture, but should relate to the element/metal. The sum of the percentages of the distribution (relating to speciation) should not exceed 100% for each element.

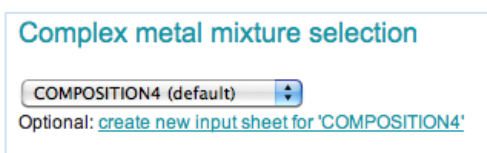
The following elements can be seen on the screen:



*To save the changes, click 'save changes'. The message Your changes have been saved. appears on the screen.

*'Clear all' can be used if all new input has to be cleared and the user wants to start from scratch. If the input is already saved, clicking this button does not undo this. It only clears the input to be able to adapt the reference sample for a second, third... time.

*Clicking 'Show selected entries' selects the lines where the distribution is filled in (from reference sample or adapted input) so as to give an overview of all selected entries. 'Show all' shows all possible elemental and classification entries.



You can save multiple instances (unlimited) of one Reference Sample by selecting "create new input sheet for 'your composition'".

Give a name to the new instance and click on "save and continue". The new sheet has been added to the list; the name of the new instance is put between brackets next to the name of the reference sample. Unlimited instances of one Reference Sample can be saved. To further adapt the reference samples, select the composition from the dropdown menu.

c. Calculate classification

A metal mixture and the tier have to be selected. More information can be found in Section 3.3.1.

4. Legal context and rules

Important note: This section is currently draft and under further development

The Globally Harmonised System (GHS) is an international standardised system for classifying chemicals and communicating their health and environmental hazards to consumers, workers, transport workers and emergency responders. The system is undergoing worldwide implementation at national or regional level. It also provides a basis for the harmonization of rules and regulations on chemicals at national, regional and worldwide level. Its main aims are to facilitate international trade in chemicals and to maintain the existing level of protection of human health and the environment. The UN GHS incorporates a “building block” approach to facilitate implementation, leaving it to the discretion of legislators to decide on the extent of implementation. The drawback of this building block approach is that classification rules may still differ between regions.

Important note: At this stage, MECLAS is focusing on the EU implementation of GHS, i.e. the EU CLP. Other regional implementations of GHS will be considered in MECLAS in the future.

4.1. The EU CLP

The CLP is the Regulation on the Classification, Labelling and Packaging of substances and mixtures. This Regulation aligns the previous EU legislation on Classification and Labelling of Substances (Dangerous Substances Directive DSD, 67/548/EEC) and Preparations (Dangerous Preparations Directive DPD 1999/45/EC) to the UN GHS.

The CLP Regulation was published in the Official Journal on 31 December 2008 and entered into force on 20 January 2009. According to the Regulation, the deadline for substance classification according to the new rules is December 2010, while for mixtures the deadline is June 1, 2015. The CLP Regulation will ultimately replace the existing rules for Classification and Labelling of substances and preparations (DSD and DPD) after this transitional period.

The legal text of the CLP can be found on: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R1272:EN:NOT>

The guidance developed by ECHA for the application of the CLP criteria can be found on: http://guidance.echa.europa.eu/docs/guidance_document/clp_en.htm?time=1282299273

This guidance includes specific guidance for the environmental classification of metals and metal compounds.

An overview of the mixture rules for the different hazard endpoints according to CLP and DPD can be found below for human health and the environment:

4.1.1 Human health

a) according to CLP

Endpoint	Method	Concentration Limits			
		Cat. 1	Cat. 2	Cat. 3	Cat. 4
Acute toxicity	Sum	$0 < ATE_{mix}^{(*)} \leq 5$	$5 < ATE_{mix}^{(*)} \leq 50$	$50 < ATE_{mix}^{(*)} \leq 300$	$300 < ATE_{mix}^{(*)} \leq 2000$
Skin corrosion/irritation	Sum	Skin corr cat. 1A, 1B or 1C $\geq 5\%$ (H ₂ SO ₄ : C $\geq 15\%$)	1% \leq Skin corr cat. 1A, 1B or 1C $< 5\%$ (H ₂ SO ₄ : 5% \leq C $< 15\%$)		
			Skin irr cat. 2 \geq		

			10% (NiSO ₄ : C ≥ 20%)		
			(10* Skin corr cat. 1A, 1B, 1C) + Skin irr cat. 2 ≥ 10%		
<i>Serious eye damage/eye irritation</i>	Sum	Eye effects cat. 1 or Skin corr cat.1A, 1B, 1C ≥ 3%	1% ≤ Eye effects cat. 1 or Skin corr cat.1A, 1B, 1C < 3% (H ₂ SO ₄ : 5% ≤ C < 15%)		
		Skin corr cat. 1A,1B, 1C + eye effects cat. 1 ≥ 3%	Eye effects cat. 2 ≥ 10%		
			(10* Eye effects cat. 1) + Eye effects cat. 2 ≥ 10%		
			1% ≤ Eye effects cat. 1 + Skin corr cat.1A, 1B, 1C < 3%		
			10* (Skin corr cat.1A, 1B, 1C + Eye effects cat. 1) + Eye effects cat. 2 ≥ 10%		
<i>Respiratory or skin sensitisation</i>	Min. 1	≥ 1% (NiSO ₄ : C ≥ 0,01%)	NR		
<i>Germ cell mutagenicity</i>	Min. 1	cat. 1A or 1B ≥ 0,1%	cat. 2 ≥ 1%		
<i>Carcinogenity</i>	Min. 1	cat. 1A or 1B ≥ 0,1% (CdSO ₄ and CoSO ₄ : C ≥ 0,01%)	cat. 2 ≥ 1%		
<i>Reproductive toxicity</i>	Min. 1	cat. 1A or 1B ≥ 0,3%	cat. 2 ≥ 3% (CS ₂ : C ≥ 1%)		
<i>Specific target organ toxicity – single exposure</i>	Min. 1	cat. 1 ≥ 10%	1% ≤ cat. 1 < 10%	cat. 3 ≥ 20% (CrO ₃ : C ≥ 1%)	
			cat. 2 ≥ 10%		
<i>Specific target organ toxicity – repeated exposure</i>	Min. 1	cat. 1 ≥ 10% (CdSO ₄ : C ≥ 7%; CS ₂ and NiSO ₄ : C ≥ 1%)	1% ≤ cat. 1 < 10% (CdSO ₄ : 0,1% ≤ C < 7%; CS ₂ : 0,2% ≤ C < 1%; NiSO ₄ : 0,1% ≤ C < 1%; CdS: 0,1% ≤ C < 10%)		
			cat. 2 ≥ 10% (Pb compounds: C ≥ 0,5%; Hg compounds: C ≥ 0,1%)		
<i>Aspiration hazard</i>	Sum	cat. 1 ≥ 10%, kin. visc. ≤ 22,5	NR		

		mm ² /s (40°C)			
--	--	---------------------------	--	--	--

$${}^{(1)}ATE_{mix} = (\sum n C_i / ATE_i)^{1.1} * 100$$

where C_i = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATE_i = Acute Toxicity Estimate of ingredient i

= 0,5 for ingredient with acute tox cat. 1

= 5 for ingredient with acute tox cat. 2

= 100 for ingredient with acute tox cat. 3

= 500 for ingredient with acute tox cat. 4

b) According to the Dangerous Preparations Directive 1999/45/EC 1999/45/EC

Endpoint	Method	Concentration Limits			
<i>Acute toxicity</i>	Sum	T ⁺ ≥ 7% => T ⁺	1% ≤ T ⁺ < 7% => T	0,1% ≤ T ⁺ < 1% => X _n	
			T ≥ 25% => T	3% ≤ T < 25% => X _n	
				X _n ≥ 25% => X _n (CS ₂ : C ≥ 10%; Pb compounds: C ≥ 1%)	
<i>Corrosion/ irritation and damage to eye</i>	Sum	C, R35 ≥ 10% => C, R35 (H ₂ SO ₄ : C ≥ 15%)	5% ≤ C, R35 < 10% AND C, R34 > 0% => C, R34	C, R35 < 5% => X _i , R41	1% ≤ C, R35 < 5% AND X _i , R36/37/38 > 0% => X _i , R36/37/38 (H ₂ SO ₄ : 5% ≤ C < 15%)
			C, R34 ≥ 10% => C, R34	C, R34 < 10% => X _i , R41	5% ≤ C, R34 < 10% AND X _i , R36/37/38 > 0% => X _i , R36/37/38
				X _i , R41 ≥ 10% => X _i , R41	5% ≤ X _i , R41 < 10% AND X _i , R36 > 0% => X _i , R36/37/38
					X _i , R36/37/38 ≥ 20% => X _i , R36/37/38
<i>Respiratory or skin sensitisation</i>	Min. 1	R42 ≥ 1% => R42	R43 ≥ 1% => R43 (NiSO ₄ : C ≥ 0,01%)		
<i>Germ cell mutagenicity</i>	Min. 1	cat. 1, R46 ≥ 0,1% => cat. 1	cat. 2, R46 ≥ 0,1% => cat. 2	cat. 3, R68 ≥ 1% => cat. 3	
<i>Carcinogenity</i>	Min. 1	cat. 1, R45 or R49 ≥ 0,1% => cat. 1	cat. 2, R45 or R49 ≥ 0,1% => cat. 2 (CdSO ₄ and CoSO ₄ : C ≥ 0,01%)	cat. 3, R40 ≥ 1% => cat. 3	
<i>Reproductive toxicity</i>	Min. 1	cat. 1, R60 or R61 ≥ 0,5% => cat. 1	cat. 2, R60 or R61 ≥ 0,5% =>	cat. 3, R62 or R63 ≥ 5% => cat. 3	

			cat. 2	(CS ₂ : C ≥ 1%)	
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4.1.2 Environment

a) according to CLP

Hazardous to aquatic environment	Sum	M*cat. 1 ≥ 25% => acute or chron. cat. 1 note: M = 1 (CoSO ₄ , CoO, CoS, CuSO ₄ . 5H ₂ O, Cu ₂ O, ClCuO: M = 10)	(M*10* chron. cat. 1) + chron. cat. 2 ≥ 25% => chron. cat. 2 note: M = 1 (CoSO ₄ , CoO, CoS, CuSO ₄ . 5H ₂ O, Cu ₂ O, ClCuO: M = 10)	(M*100*chron. cat. 1) + (10*chron. cat. 2) + chron. cat. 3 ≥ 25% => chron. cat. 3 note: M = 1 (CoSO ₄ , CoO, CoS, CuSO ₄ . 5H ₂ O, Cu ₂ O, ClCuO: M = 10)	chron. cat. 1 + chron. cat. 2 + chron. cat. 3 + chron. cat. 4 ≥ 25% => chron. cat. 4

b) According to the Dangerous Preparations Directive 1999/45/EC 1999/45/EC

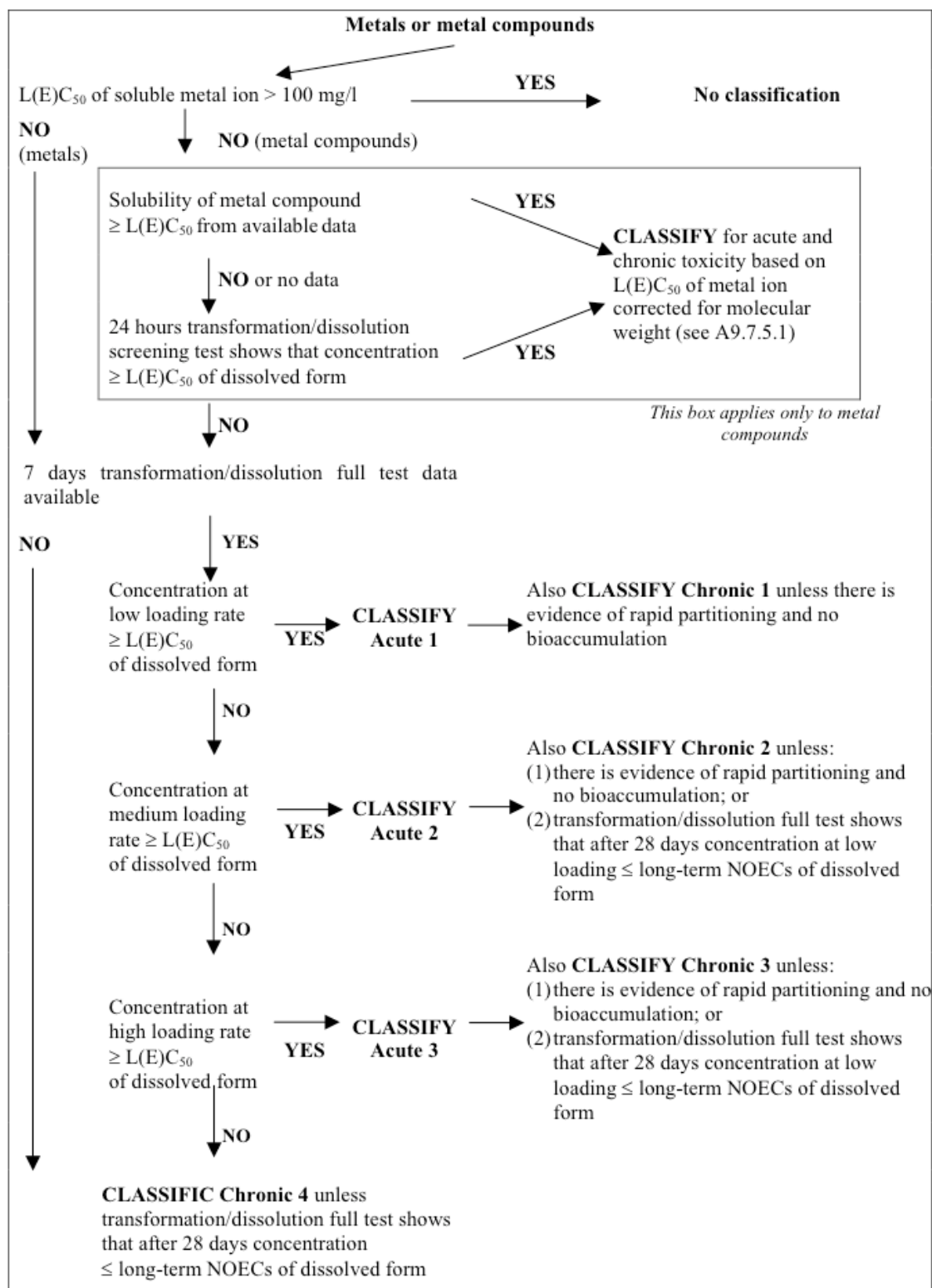
Hazardous to aquatic environment	Sum	N, R50-53 ≥ 25% => N, R50-53 (CoSO ₄ , CoO, CoS, CuSO ₄ . 5H ₂ O, Cu ₂ O, ClCuO: C ≥ 2,5%)	2,5% ≤ N, R50-53 < 25% => N, R51-53 (CoSO ₄ , CoO, CoS, CuSO ₄ . 5H ₂ O, Cu ₂ O, ClCuO: 0,25% ≤ C < 2,5%)	0,25% ≤ N, R50-53 < 2,5% => N, R52-53 (CoSO ₄ , CoO, CoS, CuSO ₄ . 5H ₂ O, Cu ₂ O, ClCuO: 0,025% ≤ C < 0,25%)	
			N, R51-53 ≥ 25% => N, R51-53	2,5% ≤ N, R51-53 < 25% => N, R52-53	
				N, R52-53 ≥ 25% => N, R52-53	

Additional information on relevant protocols, methodologies for classification of metals and metal compounds are included here below:

Transformation/dissolution tests

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) as outlined in Annex 10 of the GHS (GHS, 2007). The T/Dp is an experimental procedure (Skeaff et al, 2006; Skeaff et al, 2008, GHS Annex 10) in which weighed quantities of the metal-bearing substance are added to an aqueous medium and agitated for a fixed time period. The rate and extent at which metal ions are released is a measure for the reactivity of the metal mixture. The **24h DST** is only used for metal compounds or as recommended above for use of the bridging method. Two types of **full T/D tests** are available: a 7-day (acute) and a 28-day (chronic) "full" test.

In accordance to the EU hazard classification system, the evaluation of the short term and long term aquatic toxicity is accomplished by comparison of (a) the concentrations of the metal ions in solution, produced during transformation or dissolution in a standard aqueous medium with (b) appropriate standard ecotoxicity data as determined from tests carried out with the soluble metal species (acute and chronic values). Classification is derived according to the strategy scheme below. More explanations can be found in the Metal Specific Section of the CLP Guidance (Annex VI).



To derive the aquatic hazard classification for metal mixtures a Toxic Unit (TU) approach was applied assuming additive metal toxicity (in accordance to the CLP guidance for preparations). This approach implies the calculation of Toxic Units (TU):

$$\text{Acute TU} = \sum (\text{soluble metal concentration after 7 days} / \text{acute reference value})$$

$$\text{Chronic TU} = \sum (\text{soluble metal concentration after 28 days} / \text{chronic reference value})$$

A TU >1 indicates toxicity and may lead to classification.

Bio-elution

Information on bioavailability can be derived from *in vivo* sources (toxicokinetic or toxicological tests providing exposure and effect data). In situations where the bioavailability of a metal or mineral substance is not known or where it is not feasible to determine this *in vivo*, the amount of ion “available for absorption” may be measured using *in vitro* methods. In this application, the release/dissolution of metal ion in simulated biological fluids (e.g. gastric juice, intestinal fluid, artificial sweat, lung lavage/alveolar fluid, etc.) is measured. The resulting value is termed **bioaccessibility**, and is defined as the fraction of a substance that is soluble under physiological conditions and therefore potentially available for absorption into systemic circulation. The simulated biological fluids represent exposure- relevant exposure routes (e.g. dissolution in sweat is used to estimate bioavailability after dermal exposure, etc.).

To be further developed (see ores and concentrates guidance)

4.2. Others

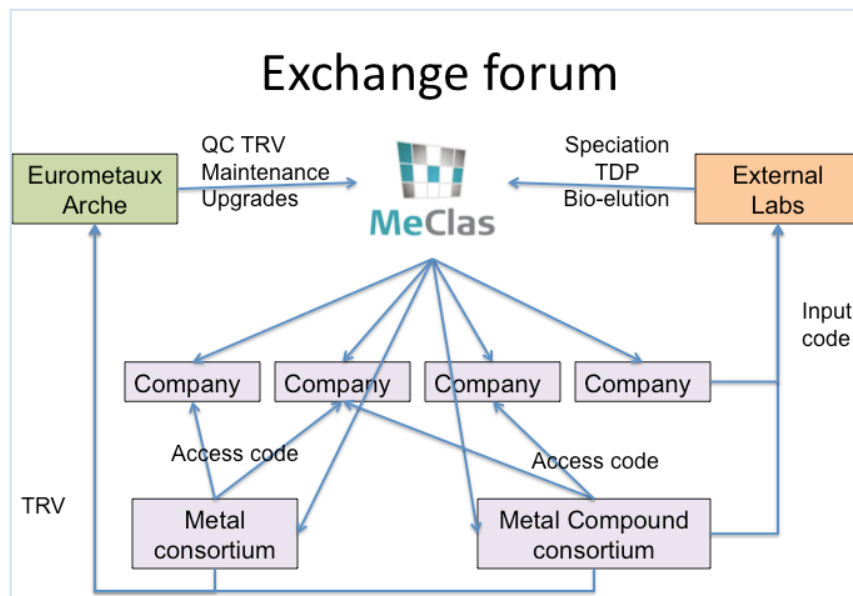
To be included in the future

5. Exchange forum

External labs have carried out experiments on different complex mixtures (Reference samples) provided by the metal consortia and metal compound consortia. The results of these speciation, TDP and bio-elution tests are integrated in MeClas. Furthermore, Eurometaux and Arche included the legal classifications as present in Annex VI of the CLP, TRV values from data owners (e.g. consortia or companies), classification rulings from the CLP guidance and the agreed specific guidance on metals (e.g. from MERAG/HERAG, etc.).

Individual companies can use MeClas to create their own company-specific classification samples. Moreover, for metal and metal compounds, Consortia can create reference classification samples, which can be used and adapted by companies if the access code is communicated.

Access to MeClas by external labs is to be developed.



6. Disclaimer

The MECLAS tool aims to generate classifications for complex metal mixtures. Although prepared with great care, flawless operations cannot be guaranteed. Users of the MECLAS tool need to be aware of this. By using the MECLAS tool, users accept full responsibility for their calculations. Neither Arche, Eurometaux nor the data providers can take liability for (mis)use of the results. Please mention any flaws, etc...

7. References

EU. 2008. "Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006", *OJCE* (L353): 1–1355, 2008-12-31, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF> (the "CLP Regulation")

ICMM. 2007. MERAG Fact sheet 8: Classification – classification for effects on the aquatic environment of metals/metal compounds and alloys. <http://www.arche-consulting.be/Metal-CSA-toolbox/MERAG>

ICMM. 2009. HERAG Fact sheet. Working draft: Alloy-specific approach to classification based on bioaccessibility. www.icmm.com/document/659

ICMM. 2009. Ores and concentrates. An industry approach to EU Hazard Classification. <http://www.arche-consulting.be/Metal-CSA-toolbox/Ores-and-concentrates-guidance-on-EU-hazard-classification->

UN. 2007. *Globally Harmonized System of Classification and Labelling of Chemicals* (Second revised ed.), New York and Geneva: United Nations, 2007, ST/SG/AC.10/30/Rev.2, ISBN 978-92-1-116957-7, http://www.unece.org/trans/danger/publi/ghs/ghs_rev02/02files_e.html ("GHS Rev.2")

8. Glossary

Alloy means 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; alloys are considered to be mixtures for the purposes of the GHS draft Regulation;

Aspiration means the entry of a liquid or solid chemical product into the trachea and lower respiratory system directly through the oral or nasal cavity, or indirectly from vomiting;

Carcinogen means a chemical substance or a mixture of chemical substances which induce cancer or increase its incidence;

CAS means "Chemical Abstract Service";

Competent authority means the authority or authorities or bodies established by the Member States to carry out the obligations arising from the GHS draft Regulation;

Contact sensitiser means a substance that will induce an allergic response following skin contact. The definition for "contact sensitiser" is equivalent to "skin sensitiser";

Corrosive to metal means a substance or a mixture which by chemical action will materially damage, or even destroy, metals;

Dermal corrosion: see *skin corrosion*;

Dermal irritation: see *skin irritation*;

Downstream user means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) REACH Regulation shall be regarded as a downstream user;

Dust means solid particles of a substance or mixture suspended in a gas (usually air);

EC50 means the effective concentration of substance that causes 50% of the maximum response;

EC Number or (ECN) is a reference number used by the European Communities to identify dangerous substances, in particular those registered under EINECS;

EINECS means "European Inventory of Existing Commercial Chemical Substances";

EU means the "European Union";

Eye irritation means the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application;

GESAMP means the "Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection of IMO/FAO/UNESCO/WMO/WHO/IAEA/UN/UNEP";

GHS means the "Globally Harmonised System of Classification and Labelling of Chemicals";

Hazard categories means the division of criteria within each hazard class;

Hazard class means the nature of the physical, health or environmental hazard;

Hazard statement means a phrase assigned to a hazard class and category that describes the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard;

IMO means the "International Maritime Organisation";

Intermediate means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis");

Label means an appropriate group of written, printed or graphic information elements concerning a hazardous product, selected as relevant to the target sector (s), that is affixed to, printed on, or attached to the immediate container of a hazardous product, or to the outside packaging of a hazardous product;

Label element means one type of information that has been harmonised for use in a label, e.g. pictogram, signal word;

LC50 (50% lethal concentration) means the concentration of a chemical in air or of a chemical in water which causes the death of 50% (one half) of a group of test animals;

LD50 means the amount of a chemical, given all at once, which causes the death of 50% (one half) of a group of test animals;

L(E)C50 means LC50 or EC50;

MARPOL means the “International Convention for the Prevention of Pollution from Ships”;

Mist means liquid droplets of a substance or mixture suspended in a gas (usually air);

Mixture means a mixture or solution of two or more substances which do not react; Note: Mixture and preparation are synonymous

Mutagen means an agent giving rise to an increased occurrence of mutations in populations of cells and /or organisms;

Mutation means a permanent change in the amount or structure of the genetic material in a cell;

NOEC means the “no observed effect concentration”;

OECD means the “Organisation for Economic Cooperation and Development”;

Pictogram means a graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information;

Precautionary statement means a phrase and/or pictogram that describes recommended measure(s) to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use;

QSAR means “quantitative structure-activity relationships”;

REACH database means the classification & labelling inventory established under Article 113 of the proposed REACH Regulation;

REACH Regulation means the Regulation (EC) No... concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals;

Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria means the latest revised edition of the United Nations publication bearing this title, and any published amendment thereto;

Recommendations on the Transport of Dangerous Goods, Model Regulations means the latest revised edition of the United Nations publication bearing this title, and any published amendment thereto;

Respiratory sensitiser means a substance that induces hypersensitivity of the airways following inhalation of the substance;

RID means The Regulations concerning the International Carriage of Dangerous Goods by Rail [Annex 1 to Appendix B (Uniform Rules concerning the Contract for International Carriage of Goods by Rail) (CIM) of COTIF (Convention concerning international carriage by rail)], as amended;

SAR means “Structure Activity Relationship”;

SDS means “Safety Data Sheet”;

Serious eye damage means the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application;

Signal word means a word that indicates the relative level of severity of hazards to alert the potential reader of the hazard; the following two levels are distinguished: (a) *Danger* means a signal word indicating the more severe hazard categories; (b) *Warning* means a signal word indicating the less severe hazard categories.

Skin corrosion means the production of irreversible damage to the skin following the application of a test substance for up to 4 hours;

Skin irritation means the production of reversible damage to the skin following the application of a test substance for up to 4 hours;

Skin sensitiser means a substance that will induce an allergic response following skin contact. The definition for

“skin sensitiser” is equivalent to “contact sensitiser”;

Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

Supplemental label element means any additional non-harmonised type of information supplied on the container of a hazardous product that is not required or specified under the GHS. In some cases this information may be required by other competent authorities or it may be additional information provided at the discretion of the manufacturer/distributor;

Symbol means a graphical element intended to succinctly convey information;

UNCETDG/GHS means the “United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonised System of Classification and Labelling of Chemicals”;

UN means the “United Nations”;

UNEP means the “United Nations Environment Programme”;

WHO means the “World Health Organisation”;