

**MECLAS (METALS CLASSIFICATION) tool
for the classification and labelling of
complex materials from the metals sector
vs June 7 2010**

Background

The CLP rules for mixtures are complicated and requiring extensive expert judgement. Appropriate ECHA guidance on these rules has only recently become available, including metal specific guidance. This, in addition to the time constraints, makes it difficult for companies and consortia to ensure correct hazard classification. While it is generally assumed that mixture classification will only be required after 2010, this is often not the case for the metals sector. Indeed, **complex materials** like 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 before the end of 2010.**

In 2009, ARCHE-Consulting 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 but does not include an extensive data base on toxicity reference data sets neither does it include more complex features like correction for Transformation Dissolution data (for the environment) or Bio-elution (for Human Health) or labelling guidance.

The original tool 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.

Need for, and generic objectives for an updated and integrated Classification and labeling tool for Complex inorganic materials

While the interest of the mining and mineral sector in having such a tool was well known, demand for a flexible and up-to-date tool rose sharply over the past few months, as testified by the number of commodities, REACH Consortia and other interested parties (companies, etc.) that have requested offers from the consultant or contacted Eurometaux.

Most complex materials in the metals sector contain a spectrum of different metals (compounds) and minerals, going beyond what is covered by the consortium, 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. Moreover, any Classification and Labelling tool will require continuous and rigorous updating, 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.

Potential users have confirmed the relevance of upscaling the present Excel tool to a more generic, multi-metallic, flexible but user-friendly tool to define the classification of complex materials; bringing together the efforts and interests of various Consortia, companies and others.

The main advantages of developing such a generic tool for the hazard identification and classification of complex materials from the metals sector include:

- Ensuring the **metals sector is up to date with the complicated classification ruling** for complex materials as provided by the CLP guidance and especially the specific guidance on metals, and this in a uniform way.
- **Efficiency gains** through collective action and combined commitment to provide TRV values
- **Consistency gains** through using the same reference values for a metal (compounds) across metals and including up-to-date interpretation of the regulatory and scientific aspects
- The tool **facilitates information exchange** between consortia, and would be easier to update on a regular basis and to control the correctness and adequacy of the classification ruling
- And finally, it would provide a common system to **ensure the quality and confidentiality of proprietary data**

Several potential options for developing the tool were envisaged: 1) developing it on a **purely private basis**, 2) developing it for **the REACH consortia only** under the Eurometaux REACH Consortia programme or 3) developing it for **regional/international organisations with the cooperation and involvement of Consortia** and making it available to other members (companies -federations, etc.) as well as external partners.

After careful consideration of the costs, benefits, knowledge combination aspects, it was agreed to go for the last option.

Outline of the principles of the tool

MECLAS would be built on a limited number of simple and basic principles:

1. **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
2. **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
3. **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.)
4. **A quality control system** for updates on classification rulings and ERV-TRV data (via the quality control group)
5. **Confidentiality assurance** for proprietary information
6. **Equal participation** and sharing rights
 - All ERVs-TRVs data holders/providers are treated equally
 - All full license holders participate to the MECLAS Steering Committee

The MECLAS data base would be fed with:

- Legal classifications as required by Annex 6 of the CLP, (or other national references in the future)
- 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.)

A **quality control group** would ensure that all data that enter the MECLAS system would be checked for consistency and correctness in order to provide reassurance for the users, since they will not be capable of checking proprietary data.

In order to **ensure consistency**, MECLAS will be a web-based registered tool so that the most recent version is always available and assured.

“Added value” blocks can be developed as an option, for example on downstream consequences such as Seveso, Alloys, 3rd GHS revision update, transport, etc.

MECLAS principles

MECLAS is governed by the following principles. All licence holders of the model shall agree with these principles when buying license rights to the MECLAS tool:

- MECLAS follows classification guidance and implements it accordingly to the legal ruling and provided technical guidance (ECHA, UN). For the EU, MECLAS will not deviate from the proposed CLP guidance unless ECHA agreed with the proposed deviations approach
- The MECLAS model will be adapted to the classification ruling when needed.
- MECLAS classifies and ranks ERV-TRV data according to quality and following a strict procedure. New higher quality information overrules older or lower quality info after assessment by the quality control committee
- ERVs and TRVs are never made public unless the Consortia provides explicit written agreement in doing so
- All Consortia and Company specific RCS are stored on (a protected part of) the MECLAS server allowing any change to the classification system, ERV or TRV values to be conducted automatically and on an immediate basis.

Timing and planning

In view of the urgency of preparing joint REACH registration dossiers (e.g. for intermediates) and the CLP/REACH group classification (e.g. for ores and concentrates) it is proposed to launch the initiative as soon as possible. The tool can be developed fairly quickly by building on the experience gained with the Excel sheet for current work. The first version of the tool should be made available before the summer, and will be presented mid June.

The table below summarizes potential interest in the building blocks for 2010 and the near future

Consortia/Commodities	Companies
In 2010 : <ul style="list-style-type: none"> - complex intermediates - ores and concentrates - group classifications of other UVCB's 	In 2010 : <ul style="list-style-type: none"> o single legal entity registrations and classifications not covered by Consortia o recalculation for complex materials based on company-specific data o labelling recommendation
In 2011 and later : <ul style="list-style-type: none"> o classification of other mixtures o Update to 3rd GHS revision (2nd ATP) o alloys 	In 2011 and later : <ul style="list-style-type: none"> - company-specific mixtures that are not intermediates (2015) - specific alloys
(Other countries)	Other countries
	Transport

Financial plan and government

A financial plan has been developed for the base building block, including IT, expertise and quality screening/assurance and administration. The cost for MECLAS would be equally shared amongst all License holders and would comprise a *development cost* and an annual maintenance cost with a requested commitment for 3 or 4 years. Full recognition will be provided to those Consortia or organisations that have already invested in the spreadsheet development. Consortia would be encouraged to share their ERVs- TRVs

values on a cost-free basis, recognising that the MECLAS user cannot use them for regulatory purposes other than classification and with full protection of the proprietary information.

The cost of a scenario for 12 participating Consortia is estimated as being in the range of 6250 € for development and licensing, and +/- 2250 € from year 2 on for annual maintenance, updating and expansion of options. Both costs decrease if more participants join.

Steering Committee

The governance of the project will be in the hands of Eurometaux and the Consultants. While a Steering group overviews the progress and advices and decides on priorities for the next year. Every full license holder of MECLAS is considered as a Steering Committee member. A steering meeting defining guidance and priorities will be organised at least once a year. :

- The Steering Committee members define the need, priority and timing of the updates according to the budget possibilities.
- The following updates are however already fixed :
 1. Labelling recommendation (autumn 2010)
 2. Update to include the environmental classification system as introduced by the 3rd GHS (autumn 2010 ?)
 3. environmental classification scheme (early 2011) if agreement at ECHA level can be achieved
- The Steering Committee decides by quality majority (2/3) in favour of a proposal

Confidentiality and other challenges

Confidentiality of proprietary data will be assured by having the TRV's for such substances hidden. Quality screening and review should provide assurance that best practices are being applied.

The ownership of the present Excel spreadsheet is unclear, due to different contributing partners. The latter's financial contributions will be acknowledged in the financial plan, thereby providing value to the historically invested cost. The new tool will be made available by licensing agreements to Consortia and Companies providing partial and restrictive ownership.

Request to the REACH Forum:

- To solicit interest in principle, so that a refined financial contribution can be calculated
- To confirm interest in sharing data under confidentiality agreement and accepting peer review in accordance with REACH/CLP requirements (unless this is already certified)

This request will be extended to the REACH Consortia, Eurometaux and ICMM member companies and other interested parties.

MECLAS funding and License principles

This annex aims at defining the funding and License fee principles of the MECLAS project.

Proposed Funding and License principles

- Consortia share ERV/TRV's on a free basis as part of the License agreement and remain ownership of this info if confidentiality applies. ERV/TRV info remains confidential for other License holders unless the owner release confidentiality or confidentiality is released for other reasons.
- The costs of the License agreement covers the development cost of MECLAS (first year) and subsequent updates (latter years). The cost/licensee decreases when more participants pay License fee for the MECLAS tool. 6250 € is proposed at this moment for a scenario with 12 users for the first year and 2500 € update and extension cost / y for year 2-3 and 4). A reduction is provided for multiyear commitments.
- License costs for Consortia and Companies are equal and cover a maximal number of classification scenario's
- Consortia Licensees maintain ownership of Reference sample (RCS) composition and classification
- Company Licensees maintain ownership of company specific company classification scenario's

ERVs and TRVs

- The ERVs and TRVs are provided at no cost basis to the MECLAS management team. Consortia that do not provide any ERV/TRV data pay an additional fee to the License costs (An additional fee of 1000 € is proposed).
- The data selection and evaluation procedure is documented in a specific guidance note (already drafted for ecotox, human health will follow soon)
- The ERVs and TRVs are screened for quality, priority and relevance by the quality control group and put into a database that is only accessible/visible by the MECLAS management team, to assure confidentiality
- Specific ERV's and TRV's can be made public IF the provider releases confidentiality or is obliged to release confidentiality (e.g. expiry period data protection rights)

Consortia

- Consortia can obtain a license at a fixed cost. For this Licence fee they can create up to a maximum of 25 Reference (sample) Classification Scenarios (RCS).
- Additional access can be purchased at a price of 150 €/RCS, or 2000 € for additional 25 RCS
- Consortia can create RCS for given materials, usually Reference Samples
- Consortia cannot circulate the MECLAS model but can print, download and circulate the outcome of it
- Confidentiality for the Consortia is assured by :
 - o Providing the Consortium with a metal Consortia Access Code(ConAC) and a Unique Access Code (UAC). These codes restrict the access for Consortia to those RCS they have included into MECLAS
 - o Data put into the system as well as the RCS are consultable only with the UAC

- Consortia define the rulings under which companies can obtain the ConAC. This will allow them to charge non Consortia members for data development and ownership

Companies

- Companies can obtain a license at a fixed cost. For this License fee, they can create up to a maximum of 25 Company (sample) Classification Scenarios (CCS)
- Additional access can be purchased at a price of 150 €/CCS, or 2000 € for additional 25 CCS
- Companies cannot circulate the model but can print, download and circulate the outcome of it.
- Companies obtain access to MECLAS through a Unique Access Code (UAC)
- Companies have access to the Consortia-specific RCS for which they have received a ConAC (e.g. Cu and/ or Precious metals).
- Companies can create company specific RCS, consult Consortia specific RCS for which they have an access code and create an additional run on the Consortia RCS with company amended information (e.g. different concentrations)
- Confidentiality of the Companies is assured by :
 - o Only the holder of the UAC can access the Company CCS
 - o None of the CCS are visible for the Consortia

The **above described system allows** for:

- Consortia to create reference sample templates and classifications (Consortia RCS)
- Companies to run company adapted versions of the Consortia RCS
- Companies to create own Company specific RCS (Company specific CCS)