

Inorganic UVCB Intermediate Dossiers in the EU Non-Ferrous Metals sector
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Intermediate substances in the non-ferrous metals sectors are mainly UVCBs. These are complex inorganic substances containing varying amounts of metals, metal compounds and/or minerals, which may occur naturally (e.g. mineral ores) or be manufactured during the various refining streams of the metal and mineral industry (e.g. inorganic intermediates). The main identifiers of UVCBs are their name and their description, which typically includes the “origin of the substance, its production process (if applicable) and its main constituents”.

Because of the spatial and temporal variability and because of the complexity in composition, inorganic UVCBs pose challenges for unambiguous and complete identification, thus becoming a challenge to appropriately and adequately perform risk assessment.

The existing REACH guidance on Substance Identity¹ (“*Guidance for identification and naming of substances under REACH and CLP*”) does not currently address inorganic UVCBs. Inorganic UVCBs are nevertheless quite peculiar and very different from other organic UVCBs.

Associated with the need to register complex UVCB substances and/or to upgrade UVCB intermediate dossier (Article 17, Article 18) to regular dossiers (Article 10), EM had a meeting with ECHA experts from Substance Identity and Evaluation Units, on May 21. During the meeting, the methodologies and approaches that metal industry is developing when confronted to UVCB assessment/identification were presented. As outcome, a one-day workshop possibility was agreed upon, in order to present practical examples, explaining and documenting inorganic UVCBs assessment (from substance identification to risk assessment).

A guidance for preparing/reading a UVCB dossier will be prepared for internal use.

Considerable part of the UVCB assessment exercise has started in the SCC Technical Task Force (under the EM umbrella). To address these changing needs, the task force has been renamed REACH Intermediates Task Force, as a platform to share learning and best practice on UVCB assessment. The Task Force comprises of representatives from commodity associations, REACH consortia and member companies. All have been working in re-evaluating the strategy regarding intermediates under REACH as prompted by the release of the December 2010 Guidance on Intermediates. Activities of this SCC taskforce are summarized on the one-pager dated 19 July 2012.

In the present document, the activities undertaken by the REACH Intermediate Task Force and the tools developed by the various consortia and/or EM are outlined.

A strict planning was set in place to develop appropriate guidance and examples on Risk Assessment of inorganic UVCBs under REACH. This shall respond to ECHA expectations and provide a comprehensive overview of on-going actions and efforts.

The action plan reported in Table 1 below demonstrates the exercise the non-ferrous metals industry is performing, in order to develop representative and comprehensive examples on inorganic UVCB, while preparing guidelines on how the risk assessment and related issues are performed, structured and reported (also responding to possible upgrade necessity for intermediates).

¹ ECHA Website: http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf

Table 1: Activities launched by the metals industry to address REACH requirements for inorganic UVCB intermediates. Please note that activities performed under the SCC intermediate tasks are provided in the separate SCC TF one-pager.

Action Plan	Tentative Timeline
REACH Intermediate task force	
<p>The EM SCC Task Force identified the need to rename itself as REACH Intermediates Task Force and have a special focus on inorganic UVCB intermediates. On July 6, a first meeting was planned for the new Task Force. Aim of the meeting was to define the list of actions to be carried out and the work modalities. Three parallel activities were identified: technical, administrative and communication-like actions.</p> <p>In order to move forward efficiently and quickly, small groups were defined.</p> <p>A first outline has been prepared and shared within the taskforce to be used as potential table of contents of the guidance. The goal is to explain how to perform/read the risk assessment of an inorganic UVCB.</p> <p>Main activities are summarized below.</p>	<p>June-July 2012</p> <p>11 July 2012</p>
1 Technical aspects	
<p>Technical aspects on how to appropriately and univocally identify a UVCB substance in the non-ferrous metal sector have to be screened. Substance identity (SID) needs to be clearly evaluated and reported, with a clear link to hazard assessment (HA) and classification (CL). Then, the exposure assessment (EA) strategy needs to be defined and explained, to finally link HA and EA to the Risk Characterization Ration (RCR).</p> <p>During the first meeting of the REACH Intermediate taskforce, subgroups were organised to work on specific tasks and develop practical examples:</p> <ul style="list-style-type: none"> • Substance ID • Environmental Effects assessment • Human effects assessment • Classification • Exposure assessment • Risk Characterisation <p>On August 23, another REACH Intermediate TF meeting is foreseen to discuss examples under development mainly on SID and HA.</p>	<p>July 2012-ongoing</p> <p>6 July 2012</p>
2 Methodology	
<p>Aim: increase confidence that metal sectors is developing science-based methodology to assess difficult inorganic UVCBs.</p> <p>Each step that is at the basis of the UVCB assessment - from description to the tools that are used - will be addressed for explanation and documentation.</p> <p>The following topics are addressed:</p> <ul style="list-style-type: none"> • Terminology • Processes/Sources • Analyses • Variability/Ranges 	<p>August 2012-...</p>

3 Documenting

August 2012

Aim: providing a inorganic-UVCB standardized and unique way of reporting information, preparing the IUCLID file and the CSR and compiling SDS.

The following topics are addressed:

- Standardized reporting
- IUCLID
- CSR
- SDS

After the REACH Intermediate TF meeting on August 23, a subgroup will be organized to explore related issues and start preparing this documentation.

4 Administration

6 July 2012 – ongoing

Aim: together with the technical aspects, administrative actions need to be addressed to understand the impact of the activities on costs and resources, versus timing necessary.

The following topics are addressed:

- Costs
- Resources
- Fees
- Timing

A subgroup working on this task was identified at the July 6 REACH Intermediate TF meeting. The subgroups' first activity is to work on a proposal/template for LoA agreement.

5 Communication

July 2012 – ongoing

Main objective is to regularly update the REACH Forum on what is done and ensure that relevant information is provided, when needed, to Consortia, ECHA, Companies, etc..

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