# MISA 3 Workshop: "How to prepare the REACH inorganic UVCB Dossiers, from Substance Identification (SID) to Risk Assessment, demonstrating safe use"
# Brussels - 5 November 2019

## Executive summary

The third MISA workshop, focusing on the risk assessment of inorganic UVCBs, was attended by about 50 participants.
Addressing inorganic UVCBs in the MISA programme was estimated quite relevant as those high volumes complex substances are critical for the sector due to i) resource scarcity, ii) the increasing complexity of materials and materials to be recycled and iii) the Circular Economy targets. These materials are affected by a high variability and contain hazardous substances: it is important to have a correct and understandable assessment to allow the most appropriate risk management.
Over the last years, industry has developed -in interaction with ECHA- an ad hoc risk assessment strategy to evaluate and document as accurately as possible the links between "SID- uses – assessment - risk management - safe uses" of inorganic UVCBs. The strategy is described in an industry guide that aims at supporting the inorganic UVCBs registrants.

The objectives of the workshop were to agree on the assessment strategy, identify possible gaps and needs and ensure a good understanding of the different perspectives (ECHA, Member States, industry).

In preparation of the workshop consortia had been invited to carry out an assessment of their UVCB registration files, using a self-assessment tool developed by Eurometaux (SAT-UVCBs). The results of these self-assessments allowed to a) provide an overview of the situation of the dossiers/approaches when it comes to data/strengths, b) give indications where work may be needed, and c) identify recurrent questions/elements around which to structure the workshop.

The 5 November workshop was built around a specific UVCB case, allowing on the one hand industry to explain the risk assessment approach they propose and on the other hand, ECHA to outline their expectations with regard to completeness and transparency of the assessment. The different steps of the assessment, from SID to the characterisation of combined risk were discussed one by one, after a scene-setting presentation. The workshop allowed to identify where industry and ECHA agree and where further actions are needed to be able to move to successful dossiers updates.

A detailed report of the workshop, reporting in detail the discussions held on 5 November was prepared and reviewed by ECHA/Eurometaux. It is available for the MISA participating metals/inorganics. The key learning lessons are reported below by topic addressed during the workshop.

## *Key messages*

**Substance Identification (SID)**

1. SID describes what the substance is actually like, what is manufactured or put on the market. The SID needs to link with hazard assessment, risk assessment and communication so ensure that EC/CAS number, name and description adequately reflect the substance.

2. It is acknowledged that variability is a frequent characteristic of the inorganics UVCBs. Still, one needs to pay attention to the scoping of the substance and how broadly the substance variability is defined. A very broad scope may create ambiguity and complicate the assessment. Registrants should consider that "multiple boundary compositions" are possible.

3. A clear SID is a pre-requisite for all REACH and CLP processes! In order to be able to conclude that an assessment approach is adequate, there needs to be a clear description of a registered substance in the dossier and the information in the different sections of the dossier needs to be linked (e.g. under SID the composition and analytics). The summary table copied below may provide a template to show the 'links' between the different sections of the dossier, e.g. when it comes to speciation, the known, unknown etc.

4. Describe the substance (iUVCB) as unambiguously as possible: clearly document both what is known and what is unknown, for completeness and transparency.

5. If the EC entry does not fully correspond to the substance, ECHA may (under specific conditions) provide the service of changing identifiers.

6. Three parameters must be analysed for the iUVCB identification: source material, process and composition (elemental and mineralogical). To consistently assess the identification parameters, each of them is analysed to define whether it is "**decisive"/"indicative"** or **"others"** and on this basis sameness is defined and reported accordingly by the industry in the SIP as supportive information.

7. Avoid combination of significantly different sources and/or processes that will systematically lead to different compositions.

8. Composition needs to reflect the actual constituents as coming from the manufacturing process and their concentration ranges. They need to reflect the actual variability in the composition, i.e. represent the substance as manufactured.

9. Composition should normally sum up to 100% (or as close as possible, unknown constituents to be reported!).

10. Re-check the SID at the different steps of the risk assessment to identify uncertainty. Account for concentration variability to ensure that risks are not underestimated.

**Hazard assessment and classification**

11. Different approaches can be used to assess UVCBs in general (see e.g. ECHA Guidance R.11), however for most of the inorganic UVCBs the constituent-based approach (preferably using the Assessment Entity approach in IUCLID), seems most appropriate. The risk related to the use of the iUVCB is then the combined risk of the "assessment entities" of the inorganic UVCB. A whole substance approach can still be used for certain endpoints (e.g. for phys-chem ).

12. Any test result leading to refinement in the Assessment Entity selection and/or risk assessment will need to be explained (e.g. explain how Transformation Dissolution protocol tests results are used).
13. For the assessment, all (relevant) constituents identified as components of the iUVCB substance under IUCLID section 1 need to be covered under the phys-chem, fate and (eco)tox sections in IUCLID and then further with the information on uses, exposure and risk assessment.

14. A constituent can be covered by providing data on the constituent itself and/or data on its worst -case speciation (i.e. when the actual speciation is unknown). In the latter case, it needs to be explained why it is considered as worst case (per endpoint) and a (read-across) justification must be reported to support the selection. If a constituent is not considered relevant for a specific endpoint and/or for the overall assessment of the UVCB a scientifically justified explanation needs to be be submitted.

15. Constituents of a substance need to be characterised where possible to the level needed to carry out the hazard assessment. For classification, industry recommends to preferably use the MeClas tool, making the best use of the available information. When higher tiers of the MeClas tool are used (e.g. Tier 1 with a defined speciation or Tier 2 with a correction for bioavailability), it is important to provide the supportive data.

16. Consider the effect of speciation for metals where this impacts the hazard (typical examples include: Cr, V, Sb).

17. If the transformation product assessment entity approach is used for the ecotoxicity/toxicity endpoints, please document and justify the reasoning that supports the use of the transformed products (i.e. the speciation the environment is exposed to) and the selection of the (worst-case) speciation.

18. It is important to integrate the data on constituents in order to provide a coherent and complete story to be able to provide accurate RCRs and ensure safety of the UVCB substance as a whole.

19. Please consider that the way uncertainty and variability in composition is approached (i.e. consideration of unkown speciation and concentration data) between classification and hazard assessment can differ . There may be differences between the speciations and concentrations of the constituents considered for classification (realistic worst case assessed at the max concentration reported) and hazard assessment (speciations to which exposure occurs and that is assessed regardless its concentration in the iUVCB). This should be explained and documented

(e.g. using the table below that summarises the outcomes of the assessment, MeClas report, …). The assessment must cover all constituents.

**Exposure**

20. Ensure the representativity of the iUVCB data is documented and that the approach taken is clear, also on pooling the data.

21. Ensure that it is documented how the exposure assessment of the workplace covers exposure to all iUVCBs at the workplace.

**Combined risk**

22. The combined risk assessment is based on a tiered approach taking into account the information on the individual assessment entities (AEs), to have overall (not an overall DNEL!) RCRs for the individual types of DNELs.

23. Understand and map out the uncertainties and conservatism related to the approach.

**Name UVCB: e.g.**

**Summary table. Overview of the selected speciation of name UVCB constituents/assessment entities for substance identification, classification and exposure/hazard and risk assessment and information sources.**

| | | SID | CL | | EA, HA + RA | | |
|---|---|---|---|---|---|---|---|
| **element** | **% range** | **species[1]** | **species** | **source** | **ENV species** | **HH species** | **source** |
| e.g. Ag | 0 -10 | Metallic | Ag (other not classified compounds/species) | not classified | Ag ion | Ag, AgNO3 | EPMFAg metal, Ag2O, AgNO3 |
| e.g. Cr | 0 - 0.1 | Oxides? | Cr2O3 | self classification | Cr (VI) ion | CrO3 | public sources CrO3 |
| e.g. Cu | 2.1 - 37.5 | Oxides, silicate, metallic | Copper (I) oxide | Annex VI | Cu ion | Cu, CuSO4, Cu2O | LoA Cu metal, Cu2O, CuSO4 |
| e.g. Pb | 0.1 - 44.4 | Silicate, oxides, sulphates | lead compounds with the exception of those specified elsewhere in Annex VI | Annex VI + self classification | Pb ion | Pb | LoA Pb metal, PbS |
| e.g. Bi | 0 - 2 | Oxides | Bi | not classified | Not further assessed as not classified and low emission potential | | |
| | | | | | | | |
| Rh | 0 - 0.006 | unknown | Rh compounds | self classification | Rh ion | Rh | public sources Rh |
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SID: Substance Identification, CL:Classification and Labelling, EA : Exposure Assessment, HA : Hazard Assessment, source: refers to parent dossier

[1] When available, the constituents for SID shall be reported as identified in the analytical report. If the speciation is uncertain, it is proposed to refer to a generic entry e.g. sulphates if you have different mineralogical sulphate forms