Brief descriptions

„REACH Practical Guide on Safe Use Information for Mixtures under REACH“ and „Mixtures under REACH - exemplification of LCID Output in the safety data sheet”

1.) Safe Use Information for Mixtures under REACH and the Lead Component Identification (LCID) Methodology

Under the Chemicals Regulation REACH (EC) No. 1907/2006, the concept of an Exposure Scenario (ES) was introduced as a new element of a chemical safety assessment (CSA). An ES was identified as the means to communicate the safe use conditions of a substance to Downstream Users (DUs) along its various supply chains.

As most substances are usually used in producing mixtures, formulators need a way for applying the component ES information received from their suppliers and to derive safe use information for their mixtures – with the idea that this information be communicated to further DUs via Safety Data Sheets (SDSs).

Under the joint CSR/ES Roadmap of authorities and industry[1], a Task Force composed of Cefic (European Chemical Industry Council) and VCI (German Chemical Industry Association) representatives committed to developing a logical and technically defensible methodology, based on their previous experiences. This led to the creation of the Lead Component IDentification methodology “LCID” (Roadmap Action 4.4A on mixtures) that is presented here.

The underlying principle of the LCID methodology is that if the risks are controlled for the most hazardous component(s), then the risks from the other substances in the mixture are also likely to be controlled. The methodology relies on concentrations of the components, the DNELs and PNECs[2] available from REACH registrations and the classification of the components of the mixtures as communicated via extended SDSs.

[1] Chemical safety report/Exposure scenario roadmap - ECHA

[2] DNEL: Derived No-Effect Level; PNEC: Predicted No-Effect Concentration

Cases considered

The LCID methodology takes into account the following cases, addressing both human health and environmental hazards:

- Priority substances: Carcinogens and mutagens (CLP Categories 1A, 1B and 2) that are non-threshold substances, as well as PBTs/vPvBs and PMTs/vPvMs[3]
- Classified substances with DNELs and PNECs
- Classified substances which lack DNELs or PNECs but have available other toxicity reference values or classifications (e.g., NO(A)EL, LD_{50} value, M-factor)[4]
- Additive effects of substances that have similar modes of action and similar biological effect
- Substances with local effects (e.g. eye, skin, respiratory tract irritation/corrosivity and sensitisation)
- Ozone depleting potential
- Specific conditions affecting exposure

Structure and content of the Practical Guide

A practical guide was elaborated, outlining the LCID methodology (first published 2016, corrigendum 2019, update 2024). Chapters 1 to 6 introduce the topic and the concrete tasks that formulators need to carry out to derive safe use information for their mixtures. Chapter 7 explains how to identify lead components and includes a detailed workflow and descriptions of all steps, considerations and calculations to be performed. Test examples are provided in Annex III to demonstrate how the methodology can be applied in practice. Annex IV includes the technical rationale for decisions taken in this approach.

The development of the LCID methodology was accompanied by consultations, inter alia, with experts on exposure scenarios (ENES platform). The methodology was successfully tested by a cross-stakeholder group to confirm its comprehension and reproducibility.

The Cefic/VCI Mixtures Task Force in charge of the project would like to express its gratitude to the numerous individuals, companies and organisations that contributed, inter alia, with their fruitful discussions, comments on draft versions and participation in a test-run prior to publication of the first version. They helped shape and add robustness to this methodology.

[3] PBT: Persistent, bioaccumulative and toxic; vPvB: very persistent and very bioaccumulative; PMT: Persistent, mobile and toxic; vPvM: very persistent and very mobile

[4] NO(A)EL No-observed (adverse) effect level; LD_{50}: Lethal dose resulting in 50 % mortality of experimental animals; M-Faktor: Multiplying factor that gives increased weight to substances classified as hazardous to the environment

2.) Project report on communication of results from application of the LCID method in a safety data sheet

The project report first published in the year 2019 (updated in September 2024) summarises experiences from applying the LCID method. Practical safety data sheet examples show how safe conditions of use can be communicated within the supply chains.

The project report and the safety data sheet examples

Within the framework of the ENES working programme until 2020[5], among others, further guidelines on supply chain communication have been developed. Therefore, a Cefic/VCI Task Force has developed practical guidance and examples on how to communicate results from the application of the LCID methodology in the safety data sheet (SDS) of a mixture.

Seven project examples are provided that describe a diverse set of situations, including:

- Mixtures classified as human health hazards and/or environmental hazards
- Safe use information integrated in selected sections 1 - 16 of the SDS or as an annex in various formats
- Various application fields of mixtures (e.g. home care, coatings) and user groups (e.g. industrial / professional users, formulators, end users)

Table 1 in chapter 2.3 of the project report gives an overview of the characteristics of the project examples. The examples themselves are presented as an appendix to the report. Details of considerations, guidance and recommendations in the decision-making steps for creating the examples can be found in chapter 3.

Each example consists of an introduction (including user group, relevant input and output data of the LCID methodology and case-specific remarks), and a display of the relevant SDS excerpts. The data resulting from applying the LCID methodology are highlighted in the SDS excerpts by a coloured frame.

Format options

Two main format options are available for the presentation of safe use conditions of a mixture:

- *Embedding in the main body of an SDS*
  The content of the sections of the main body of an SDS is defined in Annex II Part B of the REACH regulation. In these sections, in addition to the

[5] ENES_Work_programme to 2020.docx

recommendations for safe handling of a mixture, differentiation can be made between single activities or a reference to an exemption for a specific activity.

- *Provided in an annex to an SDS*
  No mandatory format for providing safe use information of mixtures in an annex is stipulated under REACH. The report presents several types of formats: Annex similar to an exposure scenario (extracted from the chemical safety report of a substance), annex similar to a DUCC template (DUCC: Downstream Users of Chemicals Group) or a tabular format.

Criteria for embedding or annexing safe use information to the SDS of a mixture

Safe use information on mixtures can be communicated down the supply chain either by embedding the information in the main body of the SDS, or by annexing the information to the SDS in a format best suited to the recipient and the author of the SDS.

The project report provides an explanation of the decision-making criteria for the placement of this information. In addition, the project report includes a decision tree (figure 1) that summarizes the key questions to decide whether the safe use information for a mixture could be embedded in the main body of the SDS or better communicated as an annex attached to the SDS.

It is particularly important to decide whether risk management measures should be differentiated across all relevant uses and/or contributing activities. In this case, an annex is preferable to embedding the information into the SDS.

The more complex the details, the better option may be to incorporate these into an annex. While local effects such as eye corrosivity can generally be addressed by personal protective equipment for all uses, systemic effects are often more task specific, so an annex may be the preferred option.

Consolidation of information

There will be cases when information received in the SDSs from suppliers for the relevant mixture components (use descriptions, use conditions, risk management measures) may require consolidation to avoid conflicting information.

In addition, adaptations may help to provide more understandable, relevant and adequate information, corresponding to the hazards of the mixture and the recommended use conditions.

Whereas most formulators prefer non-consolidated safe use information coming from the exposure scenarios of Lead Components, end-users potentially might give preference to more consolidated safe use information or even further customization of such advice to their needs.

Chapter 4 of the project report gives general hints regarding consolidation and adaptation and refers to respective project examples.