Safe Use Information for Mixtures under REACH and the Lead Component Identification (LCID) Methodology – A Brief Description

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, 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 available from REACH registrations and the classification of the components of the mixtures as communicated via extended SDSs.

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, and PBTs/vPvBs
- 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)
- Additive effects of substances that have similar modes of action and similar biological effect

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- Substances with local effects (e.g. eye, skin, respiratory tract irritation/corrosivity and sensitisation)
- Biodegradability, ozone depleting potential
- Specific conditions affecting exposure

A practical guide was elaborated, outlining the LCID methodology. 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. A supplementary Excel-based tool was prepared to partially automate the methodology.

The development of the LCID methodology was accompanied by consultations, inter alia, with experts on exposure scenarios (ENES platform). The methodology and the tool were 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. They helped shape and add robustness to this methodology.