Writing ExtSDS for Mixtures – LCID, SUMIs & SWEDs

Under the REACH regulations there is no formal obligation for any actor within the supply chain to prepare an exposure scenario for a mixture. However, a formulator must include relevant exposure scenarios and other relevant information from the SDS supplied to him when compiling their own SDS/extSDS so the information on safe used if communicated through the supply chain.

How to develop the safe use information for mixtures

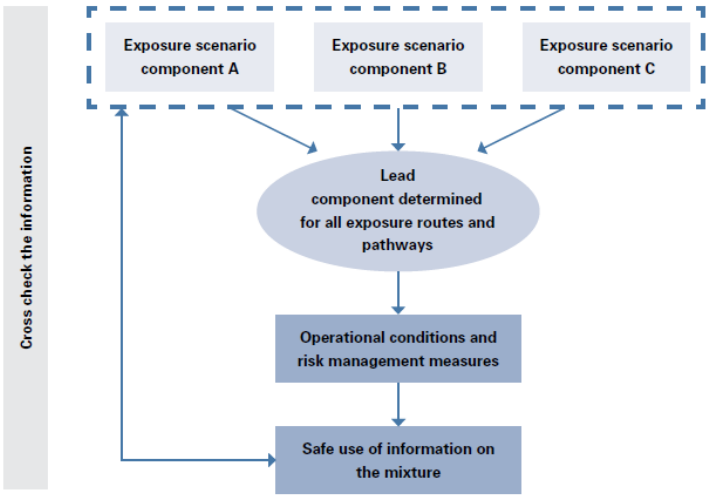
There are two approaches in which the safe use information can be generated for mixtures;

1. Top- down approach using the Lead Component Identification methodology (LCID) developed by Cefic (The European Chemical Industry Council) and VCI (Verband der Chemischen Industrie e.V.).
2. Bottom- up approach using Safe use of mixture information (SUMI) and Sector specific worker exposure description (SWED)

Top- down approach: LCID

This method uses the information received in the exposure scenarios from substance(s) to derive the safe use information for the mixture. The main element is to select the lead components of the mixture for all the exposure routes and pathways. These lead components then drive the selection of the operational conditions and risk management measures required for that mixture. The premise of this approach is that if the risks associated with the most hazardous components are adequately controlled then the risks from the other substances within the mixture will also be controlled. Figure 1: *Top- down approach flow chart* shows the step by step process for this method.

Figure 1: Top down approach flow chart



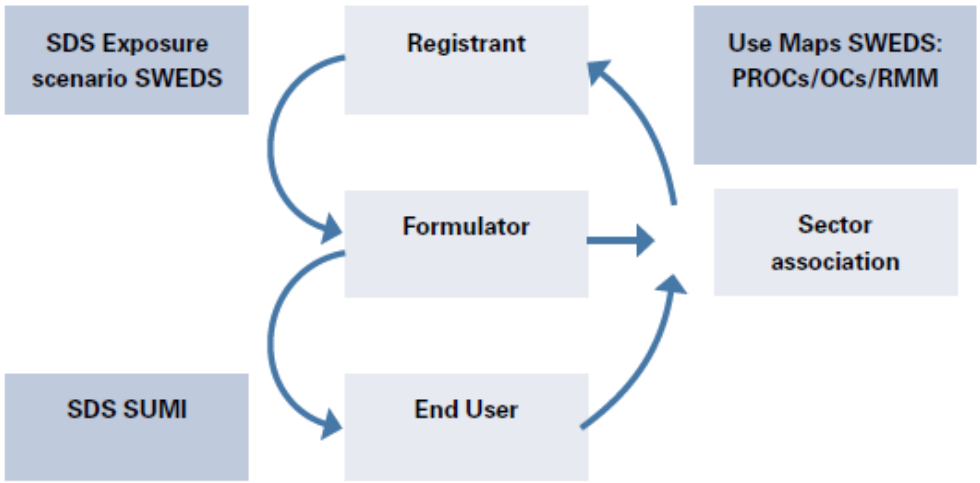
The LCID methodology collates information on the substances within the mixture including; CLP classification, DNELs and PNECs, local effects such as irritation and sensitisation as well as specific conditions of use which could affect exposure (formation of vapours etc.). This information is used to determine the lead component for each exposure route and pathway. It also take into account priority substances for example those classified as carcinogens and/or mutagens or classified substances that lack DNELS but have other toxicity reference values available such as NO(A)ELs or LD_{50}. For the full LCID methodology please reference the Cefic guidance *REACH Practical Guide on Safe Use Information for Mixtures under REACH; The Lead Component Identification (LCID) Methodology.*

Once the lead component has been identified the risk management measure can be selected for safe use for each specific contributing activity. Please note that physical hazards classification such as; flammability and aspiration hazards are not addressed by the LCID methodology. You should also take into consideration that independent action is a basic assumption of the LCID methodology. Therefore, this method assumes that the chemicals act independently from each other through different modes of action that don't influence each other. Moreover, the methodology does not cover synergistic or antagonistic effects within mixtures and if there is potential for these effects to occur the evaluation of the properties of the mixture can only be assessed on a case by case basis using expert knowledge.

Bottom – up approach: SUMIs & SWEDs

This bottom-up method focuses on the composition and uses of the mixture in a generic way. To summarise, sector groups gather data on how the mixture is used, its composition and hazard profiles for specific sector products. The formulators of the mixture then use this safe use information for assessing their mixtures. A benefit of this approach is that a large number of mixtures can be covered by a few generic sets of safe use information. Figure 2, *Bottom-up approach flow chart* highlights the steps to this method.

Figure 2: Bottom-up Approach flow chart



The basic principles of this approach are that the sector association will create use maps and SWEDs based on how the end users and formulators are using that mixture. The registrants can use the information available in the use maps when completing worker's chemical safety assessment for the substances they are registering. The registrant will pass the safe use information for the substance to the formulator making a reference to the SWED used via the SDS. The formulator validates that the exposure scenarios they receive are covered by their selected SWED and that it covers all the conditions of use. From this the formulator can pick the corresponding SUMI and attaches this to the SDS for the mixture. The end user receives the SUMI for the mixture with their conditions of use covered.

Both the top-down and bottom-up approaches are appropriate to fulfil the REACH requirements for passing safe use information down the supply chain. It does however; depend on the specific situation of the actor within the supply chain when deciding which approach should be used to develop the safe use information for a mixture.

Further help

REACH Practical Guide on Safe Use Information for Mixtures under REACH: The Lead Component Identification (LCID) Methodology (February 2016). This guide will aid formulators in writing exposure scenarios for mixtures and address their other obligations under REACH.
http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/REACH-Practical-Guide-on-Safe-Use-Information-for-Mixtures-under-REACH-The-LCID-Methodology.pdf

Sector-specific approaches towards developing and communicating information for the safe use of mixtures (December 2015). DUCC members have developed "bottom-up" approaches for deriving information on the safe use of mixtures.
http://www.ducc.eu/documents/Sector%20specific%20approaches%20towards%20developing%20and%20communicating%20information%20for%20the%20safe%20use%20of%20mixtures%20FINAL.pdf

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