CIA Chemical Industries Association

Working for chemical and pharmaceutical businesses

Compiling Extended-Safety Data Sheets – March 2018

Tips for writing extSDS for mixtures

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This document is aimed at providing basic tips and recommendations to writers of extended-Safety Data Sheets for mixtures. It reflects the feedback provided by CIA members based on their practical experience in writing extended-Safety Data Sheet and also includes a number of suggestions extracted from existing ECHA guidance documents and supporting industry material.

This document is part of a series of guidance documents on Extended-Safety Data Sheets produced by the CIA.
Titles in this series include:

Compiling Extended-Safety Data Sheets: Tips and recommendations for substances

Compiling Extended-Safety Data Sheets: Tips and recommendations for mixtures

Receiving Extended-Safety Data Sheets: 5 steps for assessing and extracting information

Obligations for writing Exposure Scenarios for mixtures

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.

There are three options in which a downstream user can use in order to communicate the safe use information that they receive.

1. Annexing

The downstream user can annex the relevant exposure scenario(s) that they have received for the substances that are used within the mixture to the SDS for the mixture. It is only possible to forward on exposure scenarios for substance(s) if the information within them are aligned with each other and there are no contradictions to the information in the mixture SDS. Please note that this method would make the SDS document very long and possibly difficult for the user to extract the relevant information they require to ensure safe use of the mixture.

2. Consolidating

The downstream user can take all the information from the exposure scenarios of the substances within the mixture and consolidate it into an annex which is attached to the mixture's SDS. This method is particularly useful if the mixture is an end- use product that can be used under several different conditions. It allows for use specific risk management measures to be defined within the annex of the SDS. Whereas, the main body of the mixture SDS can contain the information that is relevant for all uses of the mixture. If there are scaling options available for the user of the mixture, these can be easily communicated within the annex structure rather than within the main body of the SDS. This method is worth considering as if the safe use information for a mixture is delivered in a structure way it becomes easier for the downstream user to determine if they comply with the information provided.

3. Extracting

The downstream user can extract the relevant information, from the received exposure scenarios for the substances used within the mixture on the operational conditions and risk management measures. These can be summarised and then included within the sections of the main body of the mixture SDS. This method may work well for mixtures that have an end use product for a well-defined user group. This enables the operational conditions and risk management measures to be described within the main body of the SDS rather than defining the operational conditions and risk management measures for each different conditions of use.

Overall, it does depend on the specific situation of the actor within the supply chain to determine which of these options is the most appropriate for forwarding on the safe use information down 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)

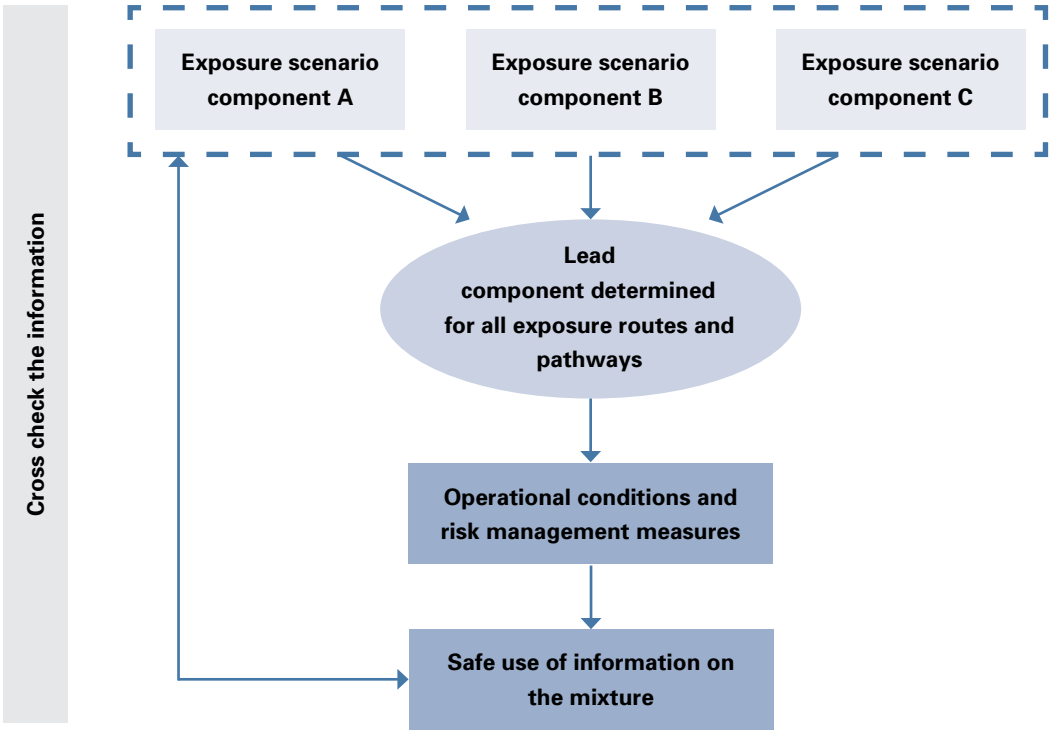
Top-down approach: LCID

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.

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 LD50. 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;

Figure 1: Top-down approach flow chart



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.

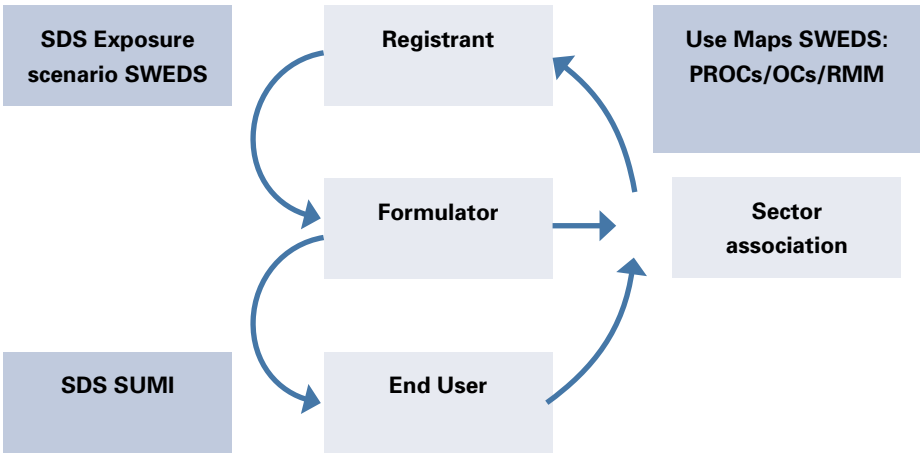
Bottom-up approach: SUMIs and SWEDs

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.

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.

Figure 2: Bottom-up Approach flow chart



A mixture within a mixture

In many cases formulators could be using mixtures as their raw materials to make a new mixture therefore, establishing safe use information for the new mixture is slightly more complex. It is recommended that the formulator should only rely on the information provided at substance level and not the mixture level when determining the safe use information to use. This can be achieved by identifying the components that are driving the hazard classification by consulting section 3 of the SDS Followed by deriving their final concentrations within the new mixture that is being formulated. It is advised that if the safe use information has been derived using the bottom up approach you should still attempt to determine the lead components that are driving the hazard classification for the exposure routes and pathways that you are concerned with.

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Disclaimer: This guidance document is intended as a starting point only and should not be used in isolation. It is not designed to inform the reader of what is an extended-safety data sheet, exposure scenario etc. A selection of additional sources of information is provided in a separate document to help the reader further.