Mixtures under REACH – exemplification of the LCID output in the safety data sheet

- Communication of safe use information for mixtures resulting from application of the Lead Component Identification (LCID) Methodology
- Report on experiences gained and Safety Data Sheet examples

Version 1.1 – September 2024

This report (originally published on 30 September 2019) provides guidance and examples of how the results from applying the Lead Component Identification (LCID) methodology[1] can be incorporated into a mixture Safety Data Sheet ("SDS"). It is a contribution to the "ENES Work Programme to 2020"[2].

The current updated version takes into account the update of the Practical Guide on the LCID methodology (September 2024, consideration of new CLP hazard classes that entered into force in April 2023).

Examples were reviewed related to data and format and updated where needed.

[1] REACH Practical Guide on Safe Use Information for Mixtures under REACH. The Lead Component Identification (LCID) Methodology, Cefic/VCI. Final updated version 6.2.0 2024: https://www.vci.de/vci-online/themen/chemikaliensicherheit/reach/cefic-vci-issue-practical-guide-on-safe-use-of-mixtures-under-reach-lead-component-identification-methodology.jsp

[2] See Action 4.2; http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

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1. Background

As a follow-up to the CSR/ES Roadmap, and under the ENES Work Programme (2017 - 2020), contributors were requested to focus on raising awareness of the systems and programs they developed as part of the Roadmap. To this end, this document's purpose is to provide practical guidance and examples how the results from the application of the Lead Component Identification (LCID) methodology might be communicated in the safety data sheet (SDS) of a mixture.

As set forth under Art. 31 of REACH, suppliers of hazardous mixtures must comply with SDS requirements. In doing so, according to Art. 31 para. 7 any downstream user shall include relevant exposure scenarios from the safety data sheet supplied to him when compiling his own (mixture) SDSs for identified uses.

This document provides explicit guidance and examples related to this task as well as more practical recommendations based on experiences gained to date. The LCID methodology is provided in detail in a separate document (Practical Guide3). Focus here is on how the safe use information (i.e., operational conditions (OCs) and risk management measures (RMMs)) from the relevant components identified by the LCID methodology might be consolidated and communicated to DUs.

Methodological details and rules, for example how to derive Lead Components, are out of scope of this report; please refer to the Practical Guide for such information. However, if such methodological aspects are necessary to better understand the appropriate guidance, then such details are addressed. The same applies where mention may be made to deliverables from other projects, e.g. SDS formats, where reference is made to the original source, but discussion is limited to its role in this exemplification project.

1.1. LCID Methodology

The Exposure Scenario (ES) concept was introduced by Regulation (EC) No. 1907/2006 (REACH)[4] as a new element in supply chain communication. The ES includes a description of conditions of safe use, the operational conditions and risk management measures that shall be communicated to Downstream Users (DUs) of a substance along its various supply chains.

[3] Practical Guide on LCID methodology: https://www.vci.de/vci-online/themen/chemikaliensicherheit/reach/cefic-vci-issue-practical-guide-on-safe-use-of-mixtures-under-reach-lead-component-identification-methodology.jsp

[4] REACH regulation (EC) No 1907/2006: http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32006R1907

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

Under the joint CSR/ES Roadmap umbrella of authorities and industry (Network of Experts: Chemical Safety Report/Exposure Scenario), a task force of Cefic (European Chemical Industry Council) and VCI (German Chemical Industry Association) developed a logical and technically defensible methodology for identification of the risk (management) driving components (lead components) in mixtures. This led to the creation of the Lead Component Identification (LCID) methodology.[5]

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, the classification of the components of the mixture as communicated via extended SDSs, vapour pressure and biodegradability.

The LCID methodology considers the following cases, addressing both human health and environmental hazards:

- Carcinogens and mutagens (CLP Categories 1A, 1B and 2) that are non-threshold substances, and PBTs/vPvBs as well as PMTs/vPvMs[6]
- Classified substances with DNELs and PNECs, including endocrine disruptors and reprotoxicants
- Classified substances which lack DNELs or PNECs but have available other toxicity reference values or classifications (e.g. NO(A)EL, LD50 value, M-factor)
- Additive effects of substances that have similar modes of action and similar biological effects
- Substances with local effects (e.g. eye, skin, respiratory tract irritation/corrosivity and sensitisation)
- Ozone depleting potential
- Specific conditions affecting exposure (e.g. aerosol, embedding in a matrix)

[5] Action 4.4 under CSR/ES Roadmap

[6] Abbreviations PBT, vPvB, PMT, vPvM: P: Persistent, B: Bioaccumulative, M: Mobile, T: Toxic, v: very

The relevant mixture's components identified via the LCID method as potential risk driving ones include:

- Priority substance(s): Carcinogens and mutagens (CLP Categories 1A, 1B and 2), related to Human Health (HH) and/or Environmental (ENV) hazards (PBTs/vPvBs or PMT/vPvM ≥ 1 %)
- Lead Component(s) for the exposure routes and pathways: Human Health (inhalation, dermal, oral); Environment (involves air, water, soil); ozone hazard
- Components driving local effects for eye, skin, inhalation
- In addition, an Msafe, indicating the daily amount of material that can safely be handled within the boundaries of the use, might be calculated for the mixture based on the components' Msafe values.

The identification of relevant components is mainly done based on hazard. Exposure is considered when identifying the exposure scenario(s) of the above-mentioned components that are applicable to the relevant uses of the mixture.

In February 2016, the Cefic/VCI Mixtures Task Force published the "Practical Guide on Safe Use Information for Mixtures under REACH - The Lead Component Identification (LCID) Methodology"[7]. The Guide was updated by a corrigendum of August 2018 and related to CLP hazard classes in September 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 (as well as Priority Substances and components driving local effects). It 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.[8]
Advanced automatisation requires inclusion of the approach in professional software applications.

[7] Practical Guide on LCID methodology: https://www.vci.de/themen/chemikaliensicherheit/reach/cefic-vci-geben-praxisfuehrer-zur-sicheren-verwendung-von-gemischen-unter-reach-heraus-lead-component-identification-methode.jsp

[8] These earlier deliverables were provided under the auspices of the Exchange Network on Exposure Scenarios (ENES) tasked with implementing actions identified under the joint CSR/ES Roadmap of authorities and industry. The development of the LCID methodology was a response to Action 4.4A of the Roadmap on mixtures: Support to formulators; Converting substance exposure scenarios into advice on the safe use of a mixture; Top-down approach.

1.2. Exemplification of LCID output

Workflows and calculations in the Practical Guide on the LCID methodology result in the listing of the relevant components mentioned above – the Priority Substances, Lead Components, components driving local effects. Related risk management measures are addressed within the calculation templates. However, aspects on how to communicate safe use information, based on the results are not described in detail.

Therefore, this report is written to provide further guidance. For example:

- How to handle if the mixture has more than one identified use or contributing activities of a use have different conditions of use?
- How to consolidate data/information resulting from applying the LCID methodology?
- How to include safe use information by integration within the body of the SDS?
- How to include safe use information as an annex to the SDS?
- What terminology is appropriate and what level of detail?

The LCID methodology has been launched and now there is more experience in its implementation applying different authoring tools and formats. As a result, the authors of the Practical Guide were asked by industry representatives and the ENES Programme contributors to provide practical recommendations and examples with respect to such topics.

Thus, the goal of this report is to provide examples of how the output of applying the LCID methodology might be communicated via the SDS of a mixture, either integrated into the body of the SDS or an annex.

Any downstream user compiling a mixture's SDS has to check whether the intended use(s) of the mixture he formulates is (are) covered by the eSDS received from suppliers of the ingredient substances. This check is not detailed in this report as it is not specific to the application of the LCID methodology and depends on processes established in the respective company.[9]

[9] See e.g. ECHA Guidance for downstream users, chapters 4 and 5 (Oct. 2014); http://echa.europa.eu/documents/10162/23036412/du_en.pdf/9ac65ab5-e86c-405f-a44a-190ff4c36489

2. Project approach

2.1. Scope

The starting point for this project was to compile actual or realistic examples of mixture SDSs generated by companies after having applied the LCID methodology, representing a diverse set of situations, including:

- Mixtures classified as hazardous to human health, environment, or both
- Safe use information integrated into the body of the SDS vs. as an annex
- Differences in SDS formats
- A variety of industries/applications (e.g. home care, coatings, automotive)
- A variety of different types of DUs (i.e. position in a supply chain), including formulators, industrial/professional users, end users
- Mixtures where there may be differing Lead Components based on exposure route

The project approach included the following tasks:

- Selection of case studies/project examples that cover different kinds of hazards, uses and communication options taking into account the aspects mentioned above
- Drafting of safety data sheet examples, whereas these include two parts
    - an introduction to each example to explain its characteristics, the data decisive for running the LCID method, the LCID output, and the option chosen for communication in the supply chain (in the body of the SDS or an annex to the SDS)
    - the safety data sheet of the mixture itself. Thereby, parts of the SDS not relevant with regard to LCID application and communication of safe use conditions might be omitted

  For more details see chapters 2.3 and 3.3.
- Produce a report that briefly introduces to the project, describes the project approach, the SDS examples and rationales for options chosen for communication of safe use information in the SDS

This project is a contribution to the ENES Work Programme until 2020", Action 4.2.[10]

[10] ENES Work Programme until 2020: http://echa.europa.eu/de/-/enes-work-programme-improving-safe-use-of-chemicals-in-supply-chains-until-2020

Without any judgement on their relevance, the following topics and aspects are out of scope of this report:

- Safe Use of Mixtures Information (SUMI) Package:

  This package offers companies in a common industry (e.g. personal care, adhesives), a standardised way to communicate OCs and RMMs for end-uses. These conditions of use in the SUMI refer to a typical use of the product and they depend on the application rather than on its chemical composition. This approach is based on downstream sector use maps[11].

- Conformity check:

  Guidance on how to perform a conformity check is not detailed in this report; such information is provided e.g. in ECHA's guidance for downstream users[12].

2.2. Options - safe use information in the mixture SDS and/or its annex

If a registrant prepares an exposure scenario for a substance used in the supply chain, it is obligatory for him to communicate this exposure scenario. For DUs who prepare their own product SDSs, there is no legal obligation to prepare their own exposure scenarios if their uses are covered by the exposure scenarios of their component suppliers. For them it is, however, compulsory to include relevant information which they have received with the extended SDSs of their raw materials from their suppliers into their own safety data sheet for the mixture (REACH Art. 31.7). Once having established that the composition, uses and use conditions of the mixture are in line with the exposure scenarios received, the inclusion of ES information into the SDS for the mixture can be done in various ways:

1. Annex relevant exposure scenarios for the substances in the mixture as they are.

   The exposure scenarios for relevant uses (uses corresponding to the uses of the mixture further down the supply chain) can be simply forwarded (without modification).

   Note: When forwarding the substances' exposure scenarios without any modification, the downstream user/formulator should ensure that the information in these ESs is consistent with the information in the main body of his mixture SDS. Otherwise, adaptation of the SDS main body may be needed.

[11] ECHA webite „Use maps": http://echa.europa.eu/csr-es-roadmap/use-maps/concept

[12] ECHA Guidance: https://echa.europa.eu/guidance-documents/guidance-on-reach

2. Annex content-consolidated safe use information for the mixture to the SDS based on the received ESs for the ingredient substances.
   This information may be presented in an ES-like way, but also other formats and layouts are used in practise, as examples in this report exemplify. This should focus on OCs and RMMs differentiated according to activities where needed. This might include re-phrasing or re-formatting.

3. Integrate content-consolidated extract of the relevant information on OCs and RMMs from the received ESs in the relevant sections of the SDS for the mixture. This might include re-phrasing or re-formatting.

4. If the immediate DU is the formulator of a product to be offered or sold to the general public, he can use another option, i.e., extract, summarise and include the relevant information on OCs and RMMs in information that can be made available to the consumer/public. This option is possible only if no safety data sheet is mandatory.

As a matter of principle, it is a company's decision which of these options will be most appropriate for them. It may depend on their customers, and different options may even be used for different products. Some practical hints are already included in the Practical Guide.

In this report, we share in Chapter 3 further considerations and / or recommendations of the different options and their preferred domains of applicability.

2.3. Overview of examples

Project examples have been elaborated to show how safe use information derived by applying the LCID methodology can be communicated in a SDS of a mixture.

Focus is on showing how such input data and results from applying the methodology may be consolidated, where to place such information and in which format/layout to present the information. Also hints regarding appropriate terminology are included, e.g. using standard phrases or sector-specific terminology.

The examples cover a variety of situations as explained previously. Generally, for the SDSs in which the safe use information is embedded into the body of the SDS, sections 1, 2, 3, 7, 8, 9 and 16 of the mixtures' SDS are shown. If in an annex, then the annex is displayed. Thereby, the actual phrases are generally dictated by the capabilities of the contributing organisation's SDS authoring system.

Table 1 provides an overview of the characteristics of the project examples. Details regarding current practice in the decision-making steps of authoring the examples as well as rationales are provided in the Chapter 3.

The examples themselves are provided as an appendix to this report. Each example consists of an introduction and then a display of the SDS excerpt under discussion. The data resulting from applying the LCID methodology are highlighted by a green-coloured outline.

The introduction of each example includes:

- Purpose of the example
    - Information on the mixture: composition/concentration of components, classification, use
    - Hazardous substances entering in the composition of the mixture: DNEL(s), PNEC(s) or other limit values and further environmental parameters of the components and their classification according to the CLP regulation
- Outcome of the LCID methodology, as applicable
    - Priority substance(s) Human Health (HH) and/or Environment (ENV)
    - Lead Component(s) HH inhalation, HH dermal, HH oral, environment, ozone hazard
    - Components driving local effects for eye, skin, inhalation
    - Re-calculated M_{safe}
- OCs and RMMs associated with the Priority Substances, Lead Components and components driving local effects for the selected use of the mixture
- Consolidated OC/RMM for inclusion in the mixture SDS
- Comments on the decision-making processes

The SDS excerpt that is displayed includes, as applicable, the sections where the safe use information is embedded, or the annex itself. The reproduction of other SDS sections might be limited to their headers, omitting further details.

It is also worth mentioning that the examples presented in this report provide options on how a meaningful communication can be achieved, but in no way set any standards nor prescribe any mandatory rules.

Example number	1a*	1b*	2a*	2b*	3	4	5a	5b	6a	6b	7
Type of mixture	**Cleaning agents**	**Cleaning agents**	**Solvent mixture**	**Solvent mixture**	**Polyol for Production of PU**	**Polyol for Production of PU**	**Coatings**	**Coatings**	**Antifreeze Coolant**	**Antifreeze Coolant**	**Resins**
Mixture destination	End use	End use	End use	End use	End use or formulation of mixtures	End use or formulation of mixtures	End use	End use	End use	End-use	End use
Range of uses	Narrow (1)	Narrow (1)	Narrow (1)	Narrow (1)	No info	Wide (5), 3 shown	Narrow (1)	Narrow (1)	Narrow	Narrow	Narrow (1)
Range of contributing activities	Broad (9)	Broad (9)	Narrow (1)	Narrow (1)		Broad (14)	Broad (10)	Broad (10)	Broad (8)	Broad (8)	Broad
Mixture classification for human health local effects	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes
Mixture classification for human health systemic effects	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Mixture classification for environment	No	No	Yes	Yes	No	No	Yes	Yes	No	No	Yes
Number of risk driving components** identified with the LCID method	2	2	1	1	2	2	2	2	2	2	2
The uses and/or contributing activities in the ES for the Lead Components are described in a similar manner	N/A	N/A	N/A	N/A	N/A	No	Yes	Yes	No	No	No
Conditions of use in the ES for the Lead Components expressed in similar manner	N/A	N/A	N/A	N/A	N/A	No	Yes	Yes	No	No	No
Way of including component ES info	Embedded	Attached	Embedded	Attached	Embedded	Attached	Attached	Embedded	Embedded	Attached	Attached
Conclusion (preference for annex or main body or no preference)	No preference		No preference		N/A	N/A	Attached		Attached		N/A
Processing of OCs/RMMs of two or more risk driving components**	Consolidated		N/A		Consolidated	Consolidation of contribu-ting scenarios	Consolidated		Consolidated		Not consolidated
Attachment format/style (if relevant); ES-like refers to styles applied for substances so far	--	Company style, ES-like	--	Company style, ES-like	Not relevant	Company style, ES like	CHESAR style, ES-like		N/A	DUCC SUMI style	Tabulated format
Contributing activities expressed with:	--	PROC name	--	ERC name	None	List of PROCs	Generic name	Generic name	N/A	PROC name	Sector-specific terminology

Legend: N/A = not applicable; PU: Polyurethane, *: Examples 1 and 2 were already addressed in the Practical Guide (Annex III) as examples 2 and 8; **: risk driving components – Priority Substances, Lead Components and/or substances classified for human health local effects

Table 1: Overview of the characteristics of the project examples

3. Communication of safe use information for end-uses in the SDS or in an annex: guidance and examples

3.1 Aspects for deciding on embedding safe use information in the main body of the SDS versus as an annex

Safe use information on mixtures needs to be communicated down the supply chain. As mentioned earlier, this can be done by embedding the information into the main body of the SDS or by annexing the information in a format best suited to the recipient and author of the SDS. This can be obviously influenced by the authoring tool used and the target audience but there are other factors worth considering in making such decisions.

One of the points of consideration is where the user is placed in the supply chain as this influences the preferences of customer and supplier. Further, the number and variety of OCs and RMMs may affect the decision in addressing placement of safe use information for the SDS (see 3.1.1).

A different approach might be to decide based on the hazards associated with the mixture (see 3.1.2). While local effects like e.g. serious eye damage can generally be handled by personal protective equipment (PPE) for all uses, systemic effects will often have to be addressed more task specific.

The flow chart below summarizes the key questions to decide if the safe use information for a mixture could be embedded in the mixture SDS core body (sections 1 – 16) or should better be annexed to it. Further details are provided in the chapters below. Overall, the main driver for the decision is the need for differentiating control measures across uses and/or contributing activities.

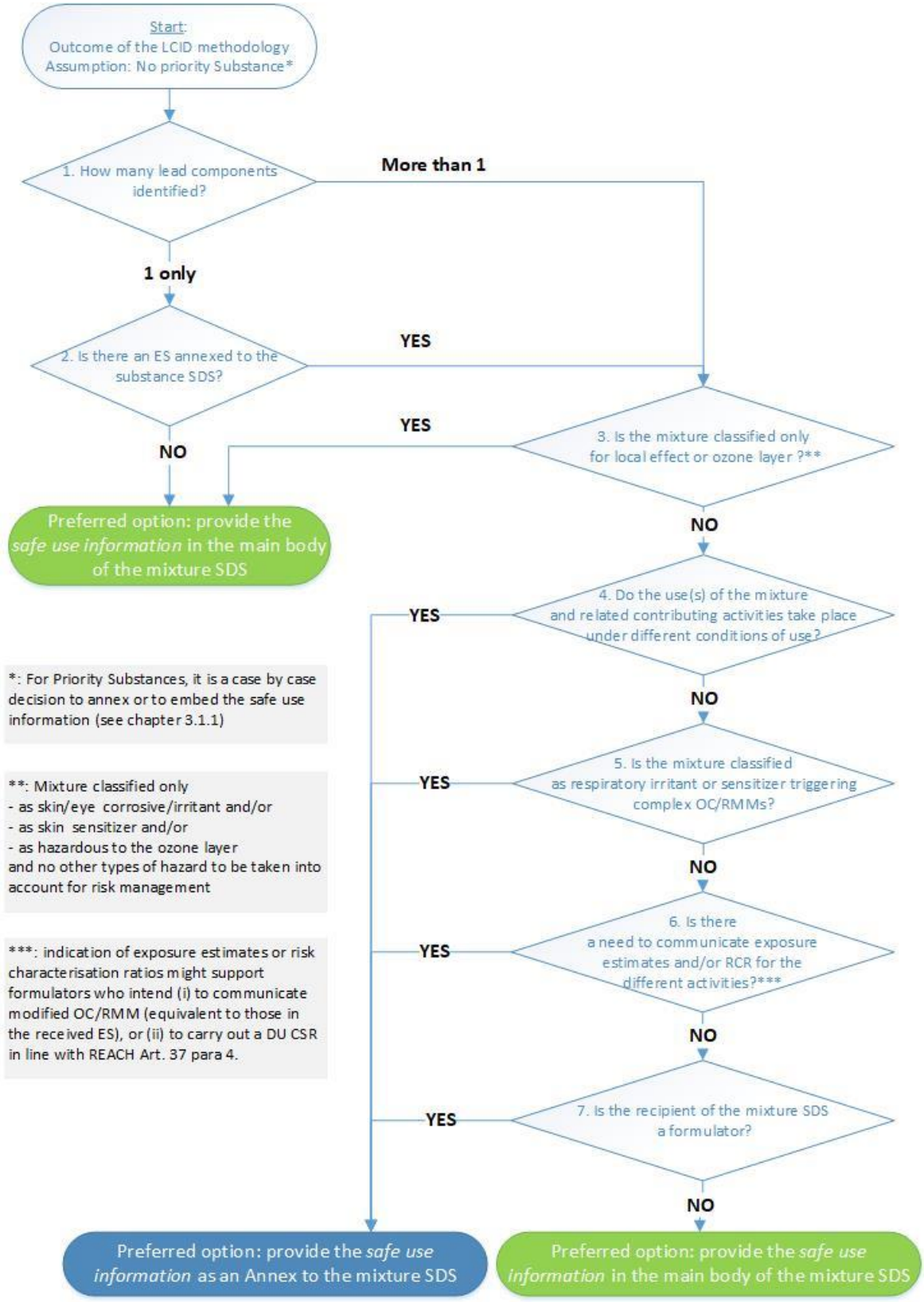

Figure 1: Key questions to decide to annex or embed the safe use information to/in the mixture SDS[13]

3.1.1 Decision based on position in supply chain

One criterion for the decision to embed the safe use information for a mixture in the main body of the SDS or to provide it in an annex is the position in the supply chain. Aspects which are connected to this include the following:

- The intended audience of the SDS
- The number of relevant uses
- The variety of RMMs and OCs for the contributing activities

The intended audience of the SDS

Scope and preferences of the audience of the SDS can vary considerably. Examples might be:

- End users may favour other approaches compared to companies further up the supply chain which generate mixtures to produce other formulations (“mixtures for use in mixtures”)
- Professional workers might prefer a different format than industrial workers supported by HSE managers.
- Preferences might depend on the sector to which the mixture is supplied

If a mixture is supplied to another formulator, providing an annex with safe use information (consolidated ES(s) or ES(s) for the identified Lead Components of the mixture and covering relevant uses) will often be the best option. Formulators will often prefer an annex to embedding the safe use information into the core SDS. One reason is that formulators are usually familiar with the concept and format of exposure scenarios from substance eSDSs. Moreover, an annex with information in a format similar to a substance’s exposure scenario gives formulators more flexibility, e.g. for using the information after identifying the new mixture’s Lead Component, for determining appropriate OCs and RMMs when creating the SDS for their own mixture, or for applying scaling.

In many cases, formulators might even wish to have forwarded entire substance ES information with the mixture SDS. Here, LCID might be an option to have a more concise annex compared to forwarding the ESs of all hazardous components. By annexing the ES of the priority and/or lead components only, it is avoided to forward non-relevant information from less critical components (see example 4). When doing so, issues when processing the information down the supply chain are not expected.

If the audience of the SDS is known to the formulator, there are certain other considerations. End users, especially professional end users, will often prefer the

[13] No distinction is made related to different kinds of annexes

information to be embedded within the more familiar main body of the SDS (see examples 1a, 2a and 3). On the other hand, using an annex can provide further options to customize the safe use information to a specific audience, for example, using industry/application-specific terms or even icons (see examples 5, 6b and 7).

Moreover, it might not be easy to embed all relevant information in the core SDS (e.g. because of the number of uses or there is a high variety of RMMs and OCs for the contributing activities (see example 4)). In such cases an annex to the SDS should be considered (see section 3.2 for examples on format options).

The number of relevant uses

In addition to preferences of the recipients of the SDS, it should be considered whether only one, a few, or even multiple uses should be covered by the mixture SDS.

SDSs supplied to formulators will have to cover at least two different relevant uses because formulation is not the last step in a supply chain. In many cases, an annex to the SDS will be the better choice as it will be difficult to integrate the RMMs and OCs for multiple uses into the main body of the SDS (see examples 4 and 6b).

The number of relevant uses will usually decrease as the position of the DU approaches closer to the end of the supply chain. If the mixture has very specific, limited, or single use(s), it might become easier to integrate the information in section 7 and/or 8 of the SDS (see examples 1a and 2a).

The variety of RMMs and OCs for the contributing activities

Another aspect for deciding on embedding safe use information in the main body vs. annexing is the variety of RMMs and OCs for the contributing activities.

If all applicable uses and their associated contributing activities (i.e. PROCs) have the same OCs and RMMs, it may be practical to embed the safe use information in the core SDS (see example 3).

If one OC or RMM differs between contributing activities (PROCs), it could be checked whether it is reasonable to add only the strictest condition to the main body of the SDS to cover all tasks. An example is if the room ventilation is 1 - 3 air changes per hour for some PROCs, but 3 - 5 air changes per hour for other PROCs. In this case the stricter 3 - 5 air changes per hour could be added to section 8 of the SDS.

Integrating safe use information into the main body is also an option if there is only one differing OC (e.g. duration, concentration) or RMM (e.g. respiratory personal protection, ventilation controls) which can be accommodated by making a one-off distinction (e.g. “except in the case of spraying where the maximum duration is 4 h“; see example 1a).

If there is a higher variety in the OCs and RMMs for different contributing activities an annex might be needed to communicate the conditions of use for the different tasks.

3.1.2 Decision based on classification of the mixture

The hazard profile of a mixture can determine how much information on safe use is needed to handle it in a safe way and how complex the information will have to be.

Some relevant aspects are:

- Mixtures with identified priority substances according to LCID
- Mixtures classified for environmental hazards only
- Mixtures classified for skin and / or eye irritation and / or dermal sensitisation effects only
- Mixtures with a broad hazard profile

Mixtures with identified priority substances according to LCID

The LCID methodology identifies PBT or vPvB and PMT or vPvM substances as well as substances classified as carcinogenic or mutagenic as priority substances.[14] It is the nature of these components to require very strict OCs and RMMs to be handled at an acceptable risk level. If a priority substance has been identified, annexing its substance exposure scenarios can be a pragmatic way forward. Applying this will generally increase the visibility of the information. But embedding is an option if OCs and RMMs cover worst case situations.

Mixtures classified for environmental hazards only

For products only classified for hazards to the aquatic environment or ozone depletion, an environmental lead component needs to be derived. The safe use information regarding this endpoint must be communicated while any other information (e.g. hazards to workers) regarding this substance will in general not be of relevance for the mixture not classified as posing health hazards. Depending on the complexity of the relevant safe use information, both annexing and embedding are options (see examples 2a and 2b).

Mixtures classified for skin and / or eye irritation / dermal sensitation only

OCs and RMMs controlling local effects to the skin or eyes are mostly straightforward using gloves or safety goggles. Simple measures like these can easily be communicated in Section 8 of the core SDS where DU are used to finding this information already. The situation is often more complex for local effects via inhalation. Some uses might be safe using local exhaust ventilation while others might limit

[14] Without threshold value

temperatures or even require the use of personal protection equipment. Depending on this complexity either annexing or embedding are options.

Mixtures with a broad hazard profile

Products with a broad hazard profile usually require multiple RMMs addressing various routes of exposure and situations. Embedding safe use information into the main body of an SDS will therefore either be a worst case approach with a reduction of communicated options or very lengthy to the potential confusion of the DU with an SDS having an unusual and complex format. In cases like these, using an annex to provide safe use information will in general be the better choice (see examples 4, 5, 6b, 7).

3.2 Format options

Whereas the sections of the main body of the SDS are predetermined by Part B of REACH Annex II, there is no mandatory format for providing safe use information of mixtures in an annex. Often the annex's format is dictated by the company's (software) programme for generating (e)SDSs of their products. Nonetheless, in this section of the report we offer some examples of formats for providing safe use information for mixtures SDSs for consideration.

For use descriptions in substance eSDSs, the use descriptors as provided in Chapter R. 12 of the ECHA guidance on information requirements and chemical safety assessment are broadly used[15]. Therefore, some project examples include such descriptors.

In this report we describe findings from applying the following format options (non-exhaustive enumeration) for providing safe use information for a mixture.

- Integration into the main body of the SDS:
  The format of the sections 1 to 16 of the SDS is prescribed by Annex II of the REACH regulation. Current practices for locating the items used for running the LCID methodology (e.g. concentration of components, DNELs, PNECs) and the output (operational conditions, risk management measures) are explained. Operational conditions (OCs) and risk management measures (RMM) are generally placed in section 7 and/or 8, relevant DNELs and PNECs in section 8, relevant component concentrations in section 3.2. In addition, applicable standard phrases are mentioned.
- Annex similar to exposure scenarios:
  Safe use information might be supplied as an annex in a format that is similar to that

[15] ECHA guidance on information requirements and chemical safety assessment: https://echa.europa.eu/de/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

of pure substance exposure scenarios.
Whereas no mandatory ES format is prescribed in REACH, based on ECHA guidance and Chesar a format of exposure scenarios has emerged that is similar across many registrants and several software solutions. Such formats are obviously used when attaching component ES to the mixture SDS, but they can also be applied when including consolidated ES information from the lead components in the mixture SDS by annex.

- Annex similar to DUCC format
  Safe use information might be provided as an annex in a format similar to the Downstream Users of Chemicals Group (DUCC) template[16]: DUCC has developed a template that was designed to be simple and comprehensible for end-users of mixtures. It is intended to be attached to the SDS as an annex. The template includes a general description of the process/use covered (e.g. use descriptors), OCs and RMMs and optional chapters on additional good practices. It might include relevant pictograms. In the current project this format is taken for including consolidated ES information from the lead components into the mixture SDS by annex, used after having applied the LCID methodology.
- Annex with tables
  Some authors of SDSs make use of tables to handle different contributing scenarios and respective differentiation of safe use information for a mixture.

3.3 Examples – brief description

This Chapter briefly introduces to the examples assessed in our project and learning from these case studies. More general learnings regarding whether inclusion of safe use information in the sections of the SDS or the annex might be the preferred option are explained in chapter 3.1; findings regarding consolidation aspects and further optional adaptations of safe use information are discussed in Chapter 4.

Examples 1a, 2a, 3 and 6a are provided to demonstrate how, once determined by the LCID methodology, safe use information for a mixture can be communicated concisely within the main body of the SDS without an annex. This is mainly applicable when the conditions of safe use are mostly concurrent across all the contributing activities.

[16] Safe use of Mixtures Information for end-users (SUMI):
https://static.ducc.eu/media/file/2021-08/SUMI%20template.docx

3.3.1 Example 1

Examples 1a and b are in fact Example 2 from Annex III of the Cefic/VCI REACH Practical Guide[17] and do not necessarily reflect real formulations.

In these cases, safe use information pertaining to human health can be integrated into the main body of the SDS (example 1a) or annexed (example 1b) without further modification. In both cases, the DNELs for all components are presented in section 8.1 of the SDS. In example 1a the accumulated OCs and RMMs for the Lead Component (e.g. the most stringent personal protection measures) are provided in section 8.2. Therefore appropriate (EuPhraC) phrases can be used. In cases where stringent RMMs are not necessary for single activities for example, it is also possible to communicate exemptions in section 8.2. For instance, in a way presented in example 3, where safe use information is provided in section 8.2 in a generalised form, since the mixture is classified for local effects only. In example 1b however, a complete scenario with all PROCs is presented as an annex. The corresponding RMMs and OCs for the Lead Component together with additional RMMs to cover local effects, are presented in differentiated detail for each single activity.

3.3.2 Example 2

This example corresponds to example 8 from the Cefic/VCI REACH Practical Guide, whereas no specific RMMs were identified in that previous document. So, for providing examples within the current report on how safe use information for environmental hazards would appear either embedded in or annexed to the SDS, somewhat vague information is provided. These RMMs therefore primarily serve illustrative purposes and do not reflect the outcome of a profound assessment.

Example 2a demonstrates how safe use information derived from the environmental Lead Component, i.e., cyclohexane, can be conveyed in the main body of the SDS. According to the workflow described in the LCID for the environment, all relevant OCs and RMMs of the Lead Component are transferred to the mixture SDS without any modifications. Hence, emission factors for air, water and soil were transcribed exactly as they were provided for cyclohexane – to section 7.1. (Precautions for safe handling) of the mixture SDS.

Furthermore, a generic phrase[18] was added saying that specific refinements relating to sewage treatment plant (STP) conditions and/or dilution defaults, which would

[17] REACH Practical Guide on Safe Use Information for Mixtures under REACH and the Lead Component Identification (LCID) Methodology, version 6.2.0 – 30 September 2024: : https://www.vci.de/themen/chemikaliensicherheit/reach/cefic-vci-geben-praxisfuehrer-zur-sicheren-verwendung-von-gemischen-unter-reach-heraus-lead-component-identification-methode.jsp

[18] Phrase used: “Default values for the capacity of a Sewage Treatment Plant as well as for freshwater and marine dilution have been applied in the risk assessment for the use.”

potentially trigger further deliberation by the customer, were not applied in the exposure assessment of the Lead Component.

In the same section 7.1., further information about the assessment method used and, in particular, the M_{safe} is provided. Of special note, this is not the M_{safe} of the Lead Component but the M_{safe} of the product – hence, it is the only piece of information originating from the Lead Component that has actually been modified for communication on the mixture SDS. The M_{safe} of the mixture has been recalculated to also consider the contributions of other components classified for environmental hazards (for more details on the approach please see the Cefic/VCI REACH Practical Guide).

The Predicted No Effect Concentrations (PNECs) are made available in section 8.1. (control parameters). Here, typically the PNECs of the Lead Component are stated – as PNECs based on actual testing of the mixture are usually not available. Nevertheless, it appears meaningful to add a phrase clarifying the origin of these reference values[19].

Finally, RMMs are provided in section 8.2. (Exposure controls). According to the procedures defined in the LCID methodology, the source of those RMMs is the exposure assessment of the Lead Component, and they are used without modification. As indicated earlier, the RMMs of this specific example as well as the corresponding efficiencies stated are not based on an actual assessment, but were approximated for illustration.

Example 2b demonstrates how LCID output may be communicated via an Annex to the SDS. It is important to point out that the identical information (like for example 2a) has been used for its development. Therefore, both examples together allow for a straight comparison of the two different approaches taken. The format chosen in example 2b corresponds largely to that of exposure scenarios for substances. This can be useful and simplifying for a technical implementation of the SDS generation for mixtures, but is in no way mandatory.

Example 2 primarily serves to enable a direct comparison of the two output variants based on the same data situation. Therefore, clear and substantiated preferences for one or the other approach cannot be derived. Due to the fact that this is a rather simple example with only one, narrowly defined end application, integration into the main body appears to be advantageous. On the other hand, the annex offers the possibility to communicate exposure estimates and risk characterisation at a defined and familiar place, if needed.

[19] Phrase used: „Data refer to Lead Component”

3.3.3 Example 3

This mixture is to be classified for local effects only – skin and eye irritation. Consequently, no further Lead Components need to be determined. Rather general safe use Information is sufficient in this case.

Example 3 demonstrates how safe use information for a mixture can be communicated concisely within the main body of the SDS. This is mainly applicable when the conditions of safe use are mostly concurrent across all the contributing activities.

3.3.4 Example 4

Example 4 demonstrates how safe use information for a mixture can be communicated in the form of an annex similar to the format of an exposure scenario for a pure substance.

The ES corresponding to the Lead Components (two of the hazardous components of the mixture) and uses of the mixture are annexed to the mixture SDS. Section 8.2 remains generic and largely untouched. Example 4 illustrates a situation where the DUs are also formulators, and hence can process, or even prefer to process, the exposure scenarios for each single Lead Component. In this case, the LCID is mainly used to reduce the number of exposure scenarios to be forwarded from 4 to 2.

Example 4 highlights the challenges that a formulator could face when attempting to consolidate OCs and RMMs from various substance SDSs. While the consolidation is rather straightforward and easy when the substance SDSs have the same format or have been created using the same methodology (cf. Example 5), the same exercise becomes almost impossible in case the input formats are too different or contain conflicting information (cf. Example 4).

Example 4 illustrates therefore a situation where the ESs of the Lead Components relevant for the uses of the mixture have been attached to the mixture's SDS as received from the supplier. The only modification done is the removal of contributing activities (PROC) where support is lacking in one of the ESs. No attempt has been made to consolidate the information from the two incoming ESs into one piece of safe use information for the end-users of the mixture. However, the formulator can provide a case-by-case support if a DU comes back with questions.

Another aspect of annexing safe use information instead of integrating it in the core body relates to the scope and origin of the sections 7 and 8 information, which corresponds to the mixture as such and may contain information not addressed by a REACH CSA. Such information may, for example, relate to hazardous substances without CSR (not registered under REACH, or registered < 10 t/a). A formulator may choose to keep sections 7 and 8 completely untouched when including exposure scenario information into the annex of the mixture SDS (see Example 4). Depending on the nature of the substances, the composition of the mixture and the foreseen uses, the personal protective equipment (PPE) specifications for the single components as stated

in the exposure scenario may need to be replaced/complemented with PPE specifications for the whole mixture (using professional judgement).

Providing the information in a substance 'ES- like' format supports easy transfer into the receiving systems at customer level, as the information structure does not differ from the structure for substances as such.

3.3.5 Example 5

Example 5a demonstrates how safe use information for a mixture can be communicated in form of an annex similar to the format of an exposure scenario for a pure substance. The OCs and RMMs are consolidated into a new 'ES-like' format which is annexed to the mixture SDS. Section 8.2 in the SDS for the mixture is maintained, as no obvious inconsistencies with the newly created annex were identified. The information on glove material corresponds to the mixture and not to the information for the single components.

Different to Example 4, Example 5 illustrates a situation where consolidating OCs and RMMs from two Lead Component SDSs is rather straightforward, as the exposure scenarios have the same format or have been created using the same methodology.

Providing the information in a substance 'ES- like' format supports easy transfer into the receiving systems at customer level, as the information structure does not differ from the structure for substances as such.

Example 5b shows how the information from the Annex can be integrated into section 8 of the SDS, while maintaining the reference to the different contributing activities. Compared to example 5a, most of the information in section 8.2 has been replaced by more specific information from ESs. Only a few pieces of information that were not present in the ESs of the raw materials remain in this section. One drawback of this alternative is that the RMMs referring to one contributing activity have to be distributed over the different subsections of section 8. Another drawback is the confusion that may arise when combining in one section information from the raw material ESs with SDS information for the mixture.

3.3.6 Example 6

Example 6a demonstrates how safe use information can be communicated within the main body of the SDS, when risk management measures differ for various contributing activities. It only has minor variations but shows how this approach may be complicated when ESs cover multiple contributing scenarios, where different measures will need to be applied/communicated. This may result in a need to create multiple new phrases to communicate such measures efficiently, and also raises the issue for the reader how to find the necessary/applicable measures. This format can be used as preferred option when a mixture is considered to pose only local effects, when the mixture has only limited uses (limited number of contributing activities) or both.

Example 6b describes an alternative layout, i.e. an annex using the DUCC developed format / template for communicating safe use information of mixtures[20]. This layout is optimal for communicating safe use information to end-users such as professional and industrial workers. This example is also intended to show how the DUCC SUMI-like layout complements the content of the SDS. The annex reflects the results of the chemical safety assessment(s) carried out on the Lead Component(s) under REACH and provides information in a layout that helps to develop workplace safety cards/instructions required under worker protection regulations.

The DUCC SUMI layout focuses only on protection of human health (interlinked with a SWED) and does (so far) not cover environmental protection. In Example 6b, an additional section is introduced, “Environmental measures”. It is an optional sub-header and intended to be added when a mixture is classified as hazardous to the environment and therefore specific prevention measures must be put in place.

This sub-section includes information on any disposal considerations, organisational and technical measures to prevent release into the environment.

Where a product has more than one intended use, it is assumed that an annex will be created for each use. When the contributing activities involved in a given use require the same set of measures, or it is possible to clearly differentiate between them, then these may be covered in one annex. Otherwise, it may be necessary to create separate annexes to cover each process category (PROC).

3.3.7 Example 7

Example 7 demonstrates how safe use information (human health and environment) for a mixture with two Lead Components can be annexed to the SDS in a tabulated layout. The layout is particularly aiming to provide the end-user with a short overview of the required measures for each of the activities with the mixture. This overview is also supported with icons for the personal protective equipment.

Another particular feature in this example is the sector-specific terminology for identifying the relevant contributing activities. This terminology is thought to be helpful for the user audience to map the safe use information in the SDS to their own activities onsite.

Another aspect illustrated in this example is the simultaneous presence of two components classified for environmental effects, and where the lead component and the non-Lead Component differ so much in terms of physicochemical properties that the risk management measures for the Lead Component cannot control releases of the other

[20] DUCC, Sector specific approaches towards developing and communicating information for the safe use of mixtures, December 2025: https://static.ducc.eu/media/file/2021-08/Sector%20specific%20approaches%20towards%20developing%20and%20communicating%20information%20for%20the%20safe%20use%20of%20mixtures%20FINAL.pdf

component. Hence both sets of conditions need to be communicated with the SDS for the mixture.

Example 7 also illustrates a situation where information gaps in the exposure scenarios for the raw materials are carried through into the safe use information for the mixture.

4. Consolidation considerations

In some cases when drafting SDSs for mixtures, information received in the SDSs from suppliers for the relevant components, especially the OCs and RMMs, might require

- consolidation to avoid conflicting or superfluous information,
- adaptation for better comprehension by the user or
- adjustment due to components ESs from suppliers being only provided for the substance as such but concentrations in the mixtures are much lower.

To a certain extent registrants and component SDS suppliers can contribute from the beginning to keeping the number of modifications and adaptations required by formulators limited: Realistic and state of the art use description and related use conditions already prevent some issues. For example, when the use(s)/use conditions of the components fit well with the typical use(s) of the component in mixtures, when the ES refers to typical concentrations of a substance in a mixture or when ES refers to risk management measures commonly applied in the sector of use.

With this, prerequisite consolidation steps performed by a formulator of a mixture have two aspects that should be taken into account:

- It must be workable for the formulator: So far consolidation steps are often manual tasks. More automatization might in future support broader application of such considerations.
- It must fit the needs of the recipient of the SDS: For example, an end-user wants to receive advice that is applicable without extensive further individual decision making whereas for a formulator certain consolidation might be superfluous as he anyhow would draft his mixture SDSs based on component data.

Under REACH, Article 31 (7) stipulates that any DU shall include relevant exposure scenarios, and use other relevant information from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses. At the same time the formulator should

- ensure that the RMM for the mixture communicated to customers are adequate (i.e. enabling to take the necessary measures) and
- keep in mind the needs and experiences of the user audience (see Annex II point 0.2.1 and 0.2.3).

Note: The check whether a use is covered by an ES is another important action by the formulator; however, it is not specific to the application of the LCID methodology.[21]

[21] For explanation of use coverage check see ECHA Guidance for downstream users (Oct. 2014): http://echa.europa.eu/documents/10162/23036412/du_en.pdf/9ac65ab5-e86c-405f-a44a-190ff4c36489

Therefore, this topic is not elaborated, and focus in this report is on consolidation of applicable ESs from relevant lead components.

Consolidation and/or adaptation of items from the relevant and applicable component ESs mainly aims to

- provide clear, relevant and adequate information, corresponding to the hazards of the mixture, the uses covered and the use conditions
- avoid conflicting or misleading information regarding safe handling and exposure controls for the mixture
- avoid duplication of information (in particular when slightly differently phrased)
- avoid generic information when more specific information is present on the same condition of use
- avoid transfer of information on uses not covered and/or not relevant for the mixture

In addition, consistency and coherence between pre-existing information in chapters 7 and 8 of the SDS[22] and newly included information from ESs of the Lead Components should be assured.

In the following subchapters more details are provided related to situations where consolidation of information is needed when including ESs for ingredient substances into the mixture's safe use information, and reference is made to relevant aspects in the project examples.

4.1 Consolidation of data/information resulting from applying the LCID methodology

How to combine the exposure scenarios from different lead components into the safe use information for the mixture with regard to Human Health Hazards

If there is a Priority Substance (or Lead Component) identified in a mixture, the LCID workflow foresees to routinely check whether in addition any local effect has to be

[22] OCs and RMMs attributed to SDS sections 7 and 8 by the mixture formulator before receipt of component ESs might remain in versions updated after receipt of such ESs. The same might apply to OCs and RMM derived based on the mixture's classification. At least conflicting information should be avoided and the formulator should try to avoid duplications as far as possible.
This point is mainly relevant for personal protection equipment. For example, for a mixture that as such is classified as skin corrosive/irritant gloves are required and the formulator might have fixed his choice. In addition, the component(s) driving this local effect would be assed routinely when applying the LCID methodology and the glove specification(s) of the relevant component(s) might differ from the one already specified by the formulator.

considered. RMMs for local effects (most often PPE) are then transferred to the mixture's SDS in addition to the measures related to the priority substance (or Lead Component). One case is where a Lead Component and a local effect are identified related to the inhalation pathway. In cases where protection for local effects (for all contributing activities) is already fully covered by OCs/RMMs derived for the priority substance (or Lead Component) such additional measures might be deleted.

Lead Components are derived by the LCID methodology per pathway/exposure route. Also substances having DNELs with a common route of exposure for which additivity principles are applicable are considered by the methodology's workflow. However, if there are more than one Lead Component triggering OCs/RMMs that have an effect on the same pathway/route of exposure it must be ensured that the safe use advice communicated is coherent and does not provide conflicting information items. Some of these aspects are covered in Example 5.

Is consolidation required for the environmental part of the LCID output?

With regard to environmental hazards, consolidation of measures as described in the previous paragraph for Human Health aspects is not relevant to the environmental output of the LCID. As laid out in the methodology, OCs and RMMs prescribed for the Lead Component will be transferred – with no further modification – to the SDS of the mixture. Hence, a consolidation step is not applicable. The (potential) impact of other components hazardous to the environment is covered via the adaption of the resulting M_{safe}. Be aware that the straight transfer of measures and conditions from (Lead) components to the mixture might possibly lead to a situation where RMMs specified for the Lead Component do not sufficiently cover the required reduction of emissions for additively acting substances, e.g. when different exposure routes (wastewater vs. air) are affected. It is therefore crucial to thoroughly perform the factual review as described in steps E16 and E17 of the LCID methodology.

How to handle if the suppliers of the components provide different identified uses

There might be some cases where the exposure scenarios of the Lead Components identified do not address all the contributing activities listed in the ESs for the other components of the mixture.

Example 4 includes such kind of consolidation: The Lead Components (dermal and inhalation) have different identified uses (PROCs 6 and 19 missing for the Lead Component inhalation). Therefore, the decision was taken to only communicate the intersecting set of contributing activities and PROCs for the mixture (see Ch. 5 of the example's introduction).

The ECHA Use Descriptor Guidance[23] has developed over time, the last update is from 2015. This still causes situations where formulators have to resolve deviations between the use descriptions in earlier versions and the current version when suppliers of components have made use of different guidance versions.

How to handle if different suppliers provide different safe conditions of use i.e., OCs and RMMs for the same substance/raw material.

Differing ESs might even be received for substances with the same substance profile that are registered via a joint registration by several manufacturers/importers. This happens e.g., if different assessment tools (e.g. ECETOC-TRA vs. Stoffenmanager) and/or setting parameters are used by registrants or suppliers for elaborating the CSR and the ESs. On the assumption that the different scenarios for the same use (including contributing scenarios) are applicable and valid for the same substance identity (and hazard profile), the formulator might make his choice on the most suitable and relevant safe use information to be included in the mixture SDS (and document reasoning): If the author of an (e)SDS has concrete knowledge on how the DU is using the product he can use the OCs and RMMs best fitting from eSDSs received. Otherwise he can either communicate the options side-by-side or decide to just include one set of information (e.g. use the option that allows the DU the highest degree of flexibility, the information with the best quality).[24]

4.2 Concentration based adjustment of data/information from ESs received

Can RMMs be adjusted to concentrations?

There will be cases where the RMMs from a supplier cover up to 100% of a lead component but the actual formulation will only contain a low percentage of it. An adjustment of RMMs might be appropriate in order to reduce the limitations for the DU without compromising on worker safety (i.e. equivalent level of protection ensured according to REACH Art. 37.4). Using exposure assessment tools/models, experts evaluate if the lower concentration of the substance in a mixture combined with the reduction of RMMs will lead to an exposure level that indicates safe use of the mixture (Risk Characterisation Ratio (RCR) < 1).

[23] Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.12 “Use description”, December 2025: http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197

[24] In Version 1.0 reference was made to FECC Guidance "Management of ES information in the ES”. This guidance is no longer available on the FECC website

4.3 Adaptation of data/information resulting from applying the LCID methodology

Can technical terminology or control measures be adapted to make them more relevant to the user audience?

Strictly speaking, legal requirements for SDS content are defined by Art. 31 of REACH and terminology resulting from applying available tools for drafting of ESs should be in line with these requirements. However, end-users often ask for advice in terminology they are familiar with. This is especially common with end-users outside industries with some specific knowledge about exposure assessment, exposure reduction technologies and measures (e.g. PPE) or training. Example 7 provides some exemplification of this approach. The work done so far on specific use descriptions and use maps as well as the wording and pictograms developed within the DUCC activities on SUMI address these needs.

Additionally, it needs to be highlighted that SDSs can help companies to comply with several pieces of legislation – not just REACH. In this regard, safe use recommendations should allow adaptation to a local situation by the recipient of the SDS. The optimal example is skin/hands protection, it needs to be addressed in the SDS/ES, but the most suitable material of gloves might not only depend on chemical properties of a mixture's ingredient substances, but also mechanical or heat demands might require consideration. For workplaces the employer has to perform a risk assessment[25] that takes all these different workplace aspects into account. Therefore, often such adaptation can only be made at almost the end of the supply chain.

So, it was identified that the adaptation of the terminology sometimes can become counterproductive, if a raw material formulator either provides too fine-tuned and hence specific, hence restrictive information or unintentionally loses level of detail when passing information to the downstream users.
Therefore, similarly to the decision on which format to use to communicate safe use information for a mixture, this depends on the target audience. Adaptation of the technical terminology can be beneficial, if the reader of the SDS is an end-user of the mixture. For the raw material suppliers, it is not only easier, but it is also more valuable to keep language as it is and provide this information unchanged to the next formulator.

In general, the terminology in exposure scenarios should be understandable to those expected to make use of it, i.e. OSH managers, environmental site managers and in certain sectors perhaps the foreman instructing his workers.

General remark not directly related to the project, but to the needs of those companies receiving safe use information for mixtures: The process of gaining more joint understanding of the interface of REACH and OSH (Occupational Safety and Health

[25] Council directive 89/391/EEC, Art. 6 Paragraph 3 a

Protection) requirements, synergies and most suitable sharing of tasks between REACH and OSH audiences is ongoing. One thing is already evident: The safe use information under REACH may not make OSH work superfluous as also other aspects beyond the hazards from substances have to be considered, e.g. local conditions, downfall, heat, etc.).

There are existing OSH requirements for the safe use of mixtures which have generic applicability and are not linked to substance specific hazards, e.g. for spray mist and dust. As a consequence, formulators have derived OCs and RMMs for all products which only depend on use conditions (e.g. effective exhaust ventilation for spraying, respiratory protection equipment for spraying and sanding, referred to in sector use maps). These generic conditions of use may be taken as granted for the substance specific assessment under REACH.

How to display/group information in such way that it suits the needs and experiences of the user audience

There are some examples available where software providers and/or companies have invested in work on advanced formats that allow to display or group safe use information in a way that users more easily find or understand what information is applicable for their use(s). These examples make starting points for further thoughts on best practices and options for defining potential approaches/rules and generally require adaptation of safe use information items received for the mixture's components.

However, to come to approaches deemed to be best practice and with potential for being used in an automated way, more reflection and broader review of their applicability for different cases is required.

Project examples 5, 6a and 7 provide some hints related to adaptation of technical language and display of relevant information.

4.4 Other aspects

The LCID methodology workflow as described in a Practical Guide foresees steps E16 and E17 to ensure that OCs/RMMs for Lead Components/Priority Substances (related to Human Health and Environmental Hazards) are efficient enough to cover other constituents and/or exposure pathways and, if any, substances with specific properties not reflected by classification. If applicable, OCs and RMMs identified in such considerations would overrule less stringent ones from step E15. For the OCs and RMMs derived based on steps E16 and/or E17 considerations for further consolidation, e.g. for providing understandable information not conflicting with other SDS items, according to the practices as described in chapter 4.1 should basically be also applicable.

The LCID methodology also points out triggers that require a case-by-case assessment (e.g. if interaction between components of the mixture is suspected; LCID step H2). Another practical issue might be a component not contributing to the classification of a

mixture with a low DNEL or other value received. This component would not be considered by the LCID methodology. A low DNEL might e.g. be based on very conservative assessment factors, or the non-classification of the component is incorrect. In such cases expert knowledge and judgement is required and safe use information for the mixture that might go beyond consolidation or adaptation as described in chapter 4.1 might be needed.

Another situation for expert judgement might be related to mixtures containing solid substances or low volatile liquid substances and where under the conditions of use aerosols, spray mists or spray droplets form. The LCID method allows factoring in of vapour pressure for proper weighting of a component where this intrinsic property drives the exposure (to vapours). However, if specific operational conditions trigger formation of aerosols, spray mists or spray droplets, the related exposure potential cannot be addressed by factoring in of vapour pressure. In these cases expert judgement might be needed to identify the lead component(s) in the mixture.

5. Conclusions/summary

As part of the implementation of the ENES Work Programme until 2020 initiative, further guidance on the application of the methods and tools for supply chain communication for mixtures was requested. To this end, this document's aims are to provide practical guidance and examples on how the results from the application of the Lead Component Identification (LCID) methodology might be communicated in the safety data sheet (SDS) of a mixture.

The LCID methodology, as such, is described in detail in a separate document (Practical Guide[26]). Focus here is on how the safe use information (i.e., operational conditions (OCs) and risk management measures (RMMs))[27] from the relevant components identified by the LCID methodology might be consolidated, placed and communicated via a SDS to Downstream Users (DUs).

Project examples

7 project examples are provided that represent 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
- representation from different industries (e.g. home care, coatings) and user groups (e.g. industrial/professional, formulator, end-user)

Table 1 in Chapter 2.3 gives an overview of the characteristics of the project examples. Details regarding considerations, guidance and recommendations in the decision-making steps of authoring the examples are provided in Chapter 3. The examples themselves are presented as an appendix to this report. Each case consists of an introduction (including user group audience, relevant LCID methodology input and output data, and case-specific remarks), and a display of the relevant SDS excerpts under discussion. The data resulting from applying the LCID methodology are highlighted by a green-coloured outline in the SDS excerpts.

Embedding or annexing of 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 into the main body of the SDS or by annexing the

[26] Practical Guide on LCID methodology: http://www.vci.de/vci-online/services/publikationen/broschueren-faltblaetter/vci-cefic-practical-guide-safe-use-of-mixtures-under-reach-lcid-method.jsp

[27] As the definition of "exposure scenario" refers to a substance (according to REACH Art. 3 No. 37) the term "safe use information" is used in this report when information for a mixture results from inclusion of component's exposure scenarios in the mixture's safety data sheet. This terminology is not limited to this report but it is common practice under the ENES work programme.

information in a format best suited to the recipient and author of the SDS. This can be obviously influenced by the authoring tool used and the target audience, but there are other factors worth considering in making such decisions.

One of the points of consideration is where the user is placed in the supply chain; this may influence the preference of how this information is conveyed. For example, formulators often prefer to receive relevant components' exposure scenarios in an annex to the SDS whereas end-users might prefer safe use information be embedded in the body of the SDS.

Furthermore, the number and variety of OCs and RMMs may influence the decision on placement of safe use information in the SDS (see Chapter 3.1.1). The more complex the details, the better option may be to incorporate these into an annex, for ease of comprehension.

In addition, a different approach on placement of safe use information might be based on the hazards associated with the mixture (see Chapter 3.1.2). While local effects such as eye corrosivity can generally be addressed by PPE for all uses, systemic effects are often more task-specific, so an annex may be the preferred option.

A flow chart (Figure 1) is provided that summarizes the key questions to decide if the safe use information for a mixture could be embedded in the core body of the SDS or better as an annex attached to the SDS. Overall, the main driver for the decision is the need for differentiating control measures across all relevant uses and/or contributing activities.

Format options

For displaying safe use information of a mixture two main format options are applicable:

- Embedded in the body of the SDS

  The content of the sections of the main body of the SDS is defined in Part B of REACH Annex II. In these sections, in addition to the safe handling recommendations for the mixture, differentiation can be made between single activities or a reference to an exemption for a specific activity is possible.

- Provided in an annex

  No mandatory format for providing safe use information of mixtures in an annex is stipulated under REACH. This report offers some examples of formats for providing safe use information in an annex for consideration. This includes the following types of annexes: similar to an exposure scenario (extracted from the CSR for a substance); similar to the Downstream Users of Chemicals Group (DUCC) template or a tabular format.

Consolidation of information

There will be cases when information received in the SDSs from suppliers for the relevant components (use descriptions, OCs and RMMs) might require consolidation to

avoid conflicting information or adaptation would make the resulting safe use information more user-targeted.

Basically, consolidation and adaptation of safe use information from the lead components ESs should aims to

- provide understandable, relevant and adequate information, corresponding to the hazards of the mixture and the use conditions
- avoid conflicting or misleading information regarding safe handling and exposure controls for the mixture

Whereas most often formulators might prefer non-consolidated safe use information coming from Lead Component ESs, end-users potentially might give preference to more consolidated safe use information or even further adaptation of such advice to their needs.

Chapter 4 gives general hints regarding consolidation and adaptation and refers to respective project examples. More advanced rules might be developed in future and would then allow more support for these tasks.

Standard phrases

The examples given use, to the extent possible, standard SDS phrases that are typically provided in SDS IT authoring systems for the SDS sections and the annex. In addition to ease of generation this also allows for ease of translation to other languages.

During the project, phrases for indicating whether safe use information is included in the SDS sections[28] or provided as an annex were derived and forwarded for consideration in the EuPhraC Phrase Catalogue[29].

[28] „Relevant exposure scenario information for the components of this mixture has been included in section 7 and/or 8 of this SDS and therefore no annex is provided." OR "Relevant exposure scenario information for the components of this mixture has been included in the annex attached to this SDS."

[29] EuPhraC Standard Phrases: http://www.esdscom.eu

6. Glossary

AC	Article Category
Additive effect	Any effect wherein two or more substances or actions used in combination produce a total effect, the same as the sum of the individual effects
ATE	Acute Toxicity Estimate
C_i	Concentration of the component i in the mixture
C_{LC}	Concentration of the Lead Component in the mixture
CLP Regulation	Regulation on Classification, Labelling and Packaging of substances and mixtures, Regulation EC No 1272/2008
CMR	Carcinogenic, Mutagenic or toxic for Reproduction (substances)
Conditions of use	Conditions of use are operational conditions (OC, e.g. duration of activity) and risk management measures (RMMs, e.g. local exhaust ventilation)
CS	Contributing Scenario
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
Distributor	Only stores and places on the market a substance according to REACH Art. 3 No. 14
DU	Downstream User according to REACH Art. 3 No. 13
ECETOC-TRA	Model for exposure estimation and risk description. TRA: “Targeted Risk Assessment”
ECHA	European Chemicals Agency
ED	Endocrine Disruptor
End-Use(r)	Final downstream use(r) in a supply chain
ES	Exposure Scenario
eSDS	Extended Safety Data Sheet
ERC	Environmental Release Category. Categories for release of chemical substances into the environment.
Exposure	Exponere (lat): to be set out; contact between a chemical substance or a physical or biological agent on the one hand and an organism or an environmental compartment on the other.
Formulator	Downstream user who formulates mixtures from substances or mixtures
GHS	Globally Harmonized System of Classification and Labelling. It is implemented in Europe by the CLP Regulation.

LC	Lead Component
LCCI	Lead Component Candidate Indicator
LCI	Lead Component Indicator
LCI_{α}	LCI for route of exposure α
LCI_{group}	Sum of the LCIs of the grouped components
LCI_{max}	Maximum LCI from the components of the LCI_{group}
LCID	Method to identify Lead Components in mixtures considering DNELs and PNECs available from registrations under REACH and classification of components according to CLP Regulation
LD_{50}	Lethal Dose resulting in 50% mortality of the experimental animals
LC_{50}	Lethal Concentration resulting in 50% mortality of the experimental animals
MAK	Maximum concentration of a chemical substance in the work place air which generally does not have known adverse health effects; in Germany: “Maximale Arbeitsplatzkonzentration”
MF	Modifying Factor
M-factor	A multiplying factor that gives increased weight to substances classified as hazardous to the environment
M_{safe} value	Maximum daily tonnage of the substance guaranteeing safe use for a specific application
Mode of action (MoA)	Mode of action (MOA) is a biologically plausible sequence of key events leading to an observed effect, supported by robust experimental observations and mechanistic data.
N/A	Not Available
NO(A)EL	No-Observed (Adverse) Effect Level
NO(A)EC	No-Observed (Adverse) Effect Concentration
OC	Operational Condition (of use) such as duration and frequency of substance use, application temperature, state of aggregation of the substance
OEL	Occupational Exposure Limit
PBT	Persistent, Bioaccumulative and Toxic (substance)
PC	Product Category
PEC	Predicted Environmental Concentration
PMT	Persistent, Mobile and Toxic
PNEC	Predicted No-Effect Concentration
PPE	Personal Protective Equipment
PROC	Process Category
RCR	Risk Characterisation Ratio

REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals. Regulation (EC) 1907/2006 that entered into force on 1 June 2007 in the European Union
RMM	Risk Management Measure (e.g. local exhaust, closed equipment, gloves of a certain specification, instructions).
SCED	Specific Consumer Exposure Determinant
SDS	Safety Data Sheet
Scaling	Here: Use of simple arithmetic operations, in order to be able to calculate with exposure estimates based on one's own specific input values
SpERC	Specific Environmental Release Category
STOT(-SE/RE)	Specific Organ Toxicity (SE: Single Exposure; RE: Repeated Exposure)
SU	Sector of Use
SUMI	Sector specific Safe Use of Mixtures Information for end-users
SVHC	Substance of Very High Concern
SWED	Sector-specific Workers Exposure Description
TLV	Threshold Limit Value
Use Descriptor System	System for the short description of uses. The abbreviations specified in this system can be used in the short title of an exposure scenario, in order to give a first indication, in which industries a substance is used, to which type of product it belongs, during which processes it is used and – if of importance – in which products it can appear later on.
Use map	Overview of uses containing the relevant use descriptors and inputs that can be used to assess worker, consumer and environmental exposure to a substance
vPvB	very Persistent and very Bioaccumulative (substance)
vPvM	Very Persistent and very Mobile