Second Workshop on REACH Review Action 3

Improving the workability and quality of extended Safety Data Sheets

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Background document for discussions
Method for extending the SDS for mixtures (Scoping document)

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1. Objective and Scope

Provide a methodology for formulators for including exposure scenarios, the related DNELs and PNECs and other relevant information from sections 1.2, 7 and 8 of the individual ingredient substance SDSs into the SDS for the mixture. If the ingredient is already a classified mixture, the method applies accordingly to the DNELs, PNECs and exposure scenarios for the hazardous ingredient substances in that mixture[1].

The methodology includes a generic workflow (tasks) and refers to a number of methods/tools to carry out the tasks. Where a method/tool is needed but not yet available to the broader community of formulators, this is flagged in the following document.

2. Requirements laid down in REACH

- Suppliers of classified mixtures shall provide the recipient with a SDS according to REACH Annex II
- The SDS shall enable:
    - users to take the necessary measures related to the protection of human health and the environment
    - employers to determine whether any hazardous chemical agents are present at the workplace and to assess any risk arising from their use
- Writer/Author of the SDS shall:
    - Take into account the specific needs and experience of the user audience (as far as they are known)
    - Use simple, clear and precise language
- An actor in the supply chain having prepared a CSR (according to Article 14 or 37) shall ensure that the SDS is consistent with that CSR, and attach the relevant exposure scenarios to the SDS (Article 31(2) and (7)). Note: This refers to substances (as such, in mixtures or in articles), but not to a CSR for the formulated mixture itself.
- A formulator shall include exposure scenarios and any other relevant information from the SDS supplied to him when compiling his own SDS for identified uses (Article 31(7)). The formulator must prepare a DU CSR for any use of a substance outside the conditions described in an exposure scenario communicated to him (Article 37(4)).
- In REACH, there is no explicit obligation for the mixture producer to assess the combined risk across the individual substances in the mixture, i.e. risks due to simultaneous exposure to substances that may cause additive effects. However there may be situations, where the formulator has to take into account additivity in order to come up with appropriate advice on exposure controls for the mixture SDS. In such case multiple, parallel exposure assessments can be carried out for the single ingredient substances, demonstrating control of risk by means of a combined risk characterisation ratio (to the extent that a same mode of action cannot be excluded). Note, under CLP, the whole mixture's hazards must be evaluated, taking into account additivity of effects.
- Relevant DNELs and PNECs are to be provided in Section 8.1 of the SDS for the ES attached (see Annex II point 8.1). Inclusion for DNEL/PNECs of individual substances into the SDS for a mixture would follow from the general inclusion obligation under

[1] Hazardous ingredient substance means in context of this guidance and individual single substance meeting any of the criteria for being classified hazardous or considered a PBT/vPvB. Where long-term systemic hazards have been identified for a substance (and corresponding a DNEL or PNEC is available for that substance), such DNEL/PNECs are to be included into SDS for mixtures, depending on the contribution of that substance to the hazard of the whole mixture. Assessment of this contribution goes beyond application of the CLP classification rules.

31(7).

The novelty introduced by REACH concerns two information elements that were not available to formulators generating their SDS for a mixture before REACH came into force:

- The SDS for substances includes no-effect levels for human health and the environment, enabling a quantitative risk characterisation for the ingredient substances, and thus support the determination of exposure levels that can be regarded "safe". The DNELs and PNECs can be understood as an information element complementing the hazard characteristics of the substance based on classification.
- The SDS for a substance includes use and activity-specific advice for the safe handling and exposure controls, often with some level of detail regarding the operational conditions and the required engineering controls for the inhalation route of exposure. This information is in particular relevant for the formulator for providing information under Sections 7.1 and 8.2.1 of the safety data sheet.

Under REACH, formulators are obliged to (i) identify whether their mixtures and the anticipated use conditions (including application equipment) are within the ES conditions communicated to them and (ii) include the relevant ES information into their own SDS. The relevance of the information depends on the hazards of the whole mixture (resulting from the hazards of the single components in combination with each other), the anticipated activities with the mixture, the related operational conditions and the needs and experience of the user audience. Inclusion of ES information shall enable the user of the mixture to take necessary measures related to protection of human health and environment.

In conclusion: The formulator must consider foreseeable use conditions and the related exposure/risks potential when preparing the SDS for the mixture. Though not stated explicitly in REACH nor in Annex II, without some kind of exposure assessment [considerations] for their products, the formulators are not able to meet the requirements of Annex II.

3. Methodology to generate mixture SDS

The methodology for extending the SDS for a mixture consists of a number of complementary elements. Some elements are to be applied by default, others may or may not be applied as standalone or in combination with each other.

3.1. Determine target audience

Determining the target audience of the mixture SDS is a pre-requisite to take into account the needs and experience of the SDS recipient. This should include as a minimum the following aspects:

- Is the recipient a company producing mixtures, which can therefore be expected to carry out own assessments regarding the hazards of their mixture and the corresponding safe use advice to users?
- Is the mixture used for various purposes in various sectors and is it therefore appropriate to provide differentiated safe use information for the different uses and audiences (e.g. in the form of Annexes)?
- Is a significant fraction of the user community micro-companies that need concrete and reliable use instruction in a language they can understand (rather than reminders on the assessments they need to carry out themselves)?

Based on the target audience characteristics, the formulator should choose an

appropriate way of communicating the safe use advice to them.

3.2. Characterise the use of the mixture

A formulator may carry out the following steps: Determine the category of mixture and the anticipated activities, based on the REACH use description Guidance R.12. Include into this analysis also the basic operational conditions of use of the mixture (temperature, aerosol/dust forming conditions, availability of general ventilation and engineering controls) provided by the supplier of the substances' exposure scenarios. If a sector use-map exists, map your portfolio of mixtures to the use-map of your sector. Identify whether the use of your mixtures is covered by the titles[2] of the exposure scenarios received. Note: If a component for the mixture is a mixture itself, the titles [identifiers] of the included exposure scenarios will be reported in <*to be worked out*>. Based on this comparison, establish whether the use of the mixture is covered in the registrations of its components, or whether the formulator needs to carry out an own CSR.

3.3. Determine lead components

3.3.1. Introduction

The classification rules for mixtures are a well-established method to determine the hazard of a mixture based on the classification[3] of the ingredient substances. The resulting classification of the mixture triggers the measures to prevent or control exposure. The classified ingredient substances contributing to the classification of the mixtures are to be identified in section 3 of the SDS, and the corresponding DNELs/PNECs shall be included in section 8.1.

3.3.2. LCID method[4]

The Lead Component Identification Method (LCID) aims to focus the inclusion of exposure scenarios and DNEL/PNECs to those ingredient substances [components], driving the risk when using the mixture, based on concentration, vapour pressure, degradability and DNEL/PNECs. This complements the mixture classification with quantitative considerations on exposure potential and provides a basis for determining the relevant information from the ingredient substance SDSs, when compiling the SDS for the mixture. In recent years, the LCID has been tested and the outcome exemplified under the umbrella of ENES. It can be used as a qualitative method to support the inclusion of received exposure scenarios into the safety data sheet of mixtures (see section 3.4).

3.3.3. Consistency check for mixture classification

The classification of a substance indicates the type and extent of hazard in relation to a list of defined endpoints. For long-term systemic toxicity, in addition, often a DNEL exists, based on which the severity of the hazard can be more precisely characterised, and a safe exposure level determined. As a consequence, based on available DNELs, it is possible to determine more accurately (based on exposure and risk characterisation) at

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[2] The title or any other identifier of exposure scenarios (e.g. use code) reflecting the uses identified and assessed by the registrant/supplier.

[3] In the context of this document classified substance means a substance meeting the criteria for being classified hazardous or considered a PBT, based on the registrants' assessment, unless a harmonised classification exists.

[4] 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

which concentration level a component in a mixture needs to be taken into account for risk management.

The following section describes a few guiding principles on how a formulator can check the consistency between the CLP classification and the REACH DNEL information, and what to do, if a mismatch occurs.

Role of DNELs when ingredient substance is classified for systemic hazards

To be worked out

Role of DNELs when ingredient substance does not lead to classification of mixture

To be worked out

Analogue considerations may apply regarding the relationship between environmental mixture classification and the PNECs of single ingredient substances.

3.4. Select safe use information for the mixture (qualitative method)

3.4.1. Introduction

The qualitative method selects relevant information from the extended SDS received for the lead components of the mixture or from sector use-maps (if available). The methods have been tested for workability in a CEFIC/DUCC lead project and a VCI/CEFIC lead project. The test confirmed the efficiency gains possible, and ECHA believes that the methods have the potential to improve workability and quality of extended safety data sheets. The SUMI selection method (based on use maps) should in ECHA's view be the default method, and the LCID adds most value where use-maps are not (yet) available or registrants' do not apply the use-map information available.

3.4.2. SUMI selection method

The method is part of the downstream sector use map approach. The safe use information for mixtures is compiled from the conditions of use described in the use-map (potentially up to three SUMI per mixture type to reflect risk management levels needed for different hazard levels of the same type of mixtures). The SUMI information is differentiated according to contributing activities with the mixture (to the extent different conditions apply to the different activities.

When receiving exposure scenarios based on a sector use map, these already contain codes based on which the formulator can select the right SUMI, depending on the concentration of the different ingredient substances in his mixture. Thus, the exposure scenarios are not used to **generate** information for the mixture but to **select** pre-defined information, corresponding to the content of the ES.

3.4.3. LCID based inclusion of exposure scenarios

Select safe use information for the mixture from the lead component(s)' ES information
Carry out consolidation and consistency check between

- the lead components (when the lead component(s)are different for inhalation,

dermal and the environmental route(s) of exposure
- the safe use information in Sections 7 and 8 of the of the SDS

For further refer to the guidance document (link see footnote 4).

3.5. Generate safe use information for mixture (quantitative methods)

3.5.1. Introduction

Carry out exposure estimation and a quantitative risk characterisation (alternatively to the qualitative selection method or complementary when OC/RMM are for example to be adjusted to lower concentration in the actual use) to determine the appropriate safe use information for the mixture. Such quantitative assessment may support the:

- processing of received exposure scenarios which the supplier has generated based on a sector use-map
- DU CSR for single components of the mixture
- multi-component safety assessment for mixture with combined RCR across the components

3.5.2. Adjustment of use conditions in the framework of sector use maps

SWED/SUMI adjustment and demonstration that the modification leads to an equivalent level of protection, compared to the ES received. Such assessment may be in particular required when registrants have based their assessment on a sector use map, but the highest safe concentration of a substance is too low compared to what is needed for the technical performance of the mixture. Based on the ECETOC TRA algorithm, the formulator may for example demonstrate that increasing the concentration can be compensated by enhanced ventilation conditions or reduced handling time. The same approach may work vice versa, when the formulator actually uses the substance in a lower concentration, and it may be reasonable to relax the ventilation conditions accordingly.

Note: It needs to be clarified where such adjustments at single formulator level cross the border to a DU CSR.

3.5.3. Downstream user CSR

Such assessment may be in particular required when the formulator's mixtures and the associated contributing activities are not addressed at all in the SDS of an ingredient substance (no exposure scenario corresponding to the mixture type available, contributing activities missing in the ES). Another case for DU CSR would occur where the formulator's product is clearly used outside the conditions communicated in the registrant's ES and no sector use map exists as a framework for adjustments. The option of a DU CSR is also available when the formulating company decides that it is more efficient to carry out the CSR themselves for their mixtures and clients from the beginning, rather than to process the exposure scenarios for the mixture components as received from suppliers.

3.5.4. Combined risk across components in the mixture

Multi-component safety assessment for a mixture with a combined RCR across the ingredient substances may be carried out when it cannot be excluded that one or more different ingredients in a mixture affect the same target organ (mode of action). Such an assessment is independent of 3.5.2 and 3.5.3 above, and does not correspond to the DU duties under Article 37 of REACH. It is rather the analogue to the mixture classification rules in the case of additivity, and addresses in particular the simultaneous presence of substances with low no-effect levels with the potential to be inhaled by workers (due to high vapour pressure and/or aerosol/dust forming conditions). The formulator may need to carry out such an assessment to then recommend the appropriate exposure control measures for communication to his customers.