Downstream Users of Chemicals Co-ordination group

How exposure scenario information on substances can be converted into information for the safe use of mixtures[1]

The concept of Exposure Scenarios (ESs), strictly speaking and as defined in the REACH legal text, **applies only to substances** and not to mixtures[2].

In the case of mixtures for which a safety data sheet (SDS) is legally required and that contain one or more registered substances for which an extended SDS has been received, downstream users (DUs) must provide their customers with information on the hazards of their mixtures and conditions of safe use of the mixtures, including Risk Management Measures advice[3].

The question of when[4] and how to update SDSs of mixtures sold by DUCC members to reflect information from ESs of substances (or "intermediary mixtures", as applicable) purchased is frequently asked.

This DUCC paper describes potential options that DUs may choose to convert the information received on individual substances (or "intermediary mixtures", as applicable) into information for the safe use of mixtures.

This topic is being discussed within the Exchange Network on Exposure Scenarios (ENES)[5], a collaborative network launched by ECHA which aims to identify good practices on preparing and implementing exposure scenarios and which is composed of ECHA, Member State Competent Authorities and industry representatives.

0. Introduction

DUCC members – downstream users under REACH – typically formulate mixtures that are placed on the market as such and used either by consumers, by professionals or by industrial users. In most cases, the use of DUCC members' mixtures corresponds to the last stage in the life cycle tree of the substance ('end-use mixtures'). There are also DUCC members who formulate 'intermediary mixtures' to be used downstream as raw materials to formulate 'second-level' mixtures.

This paper assumes that ESs of registered substances used in the mixture are available to the formulating company.

For **mixtures meeting the criteria for classification** in accordance with Directive 1999/45/EC or Regulation (EC) No 1272/2008, hereunder referred to as "classified", and placed on the market, **a SDS must be supplied**. The general existing practice is that this same SDS is typically used at the company manufacturing premises, *e.g.* for protection of workers during storage or packaging operations.

[1] This will be referred to as "Exposure scenario related information"
[2] ECHA "Guidance on the compilation of safety data sheets" (Version 1.1. December 2011) – p. 10, footnote 15; p. 25, footnote 28.
[3] ECHA Practical Guide "How downstream users can handle exposure scenarios" (p. 31) and ECHA "Guidance on the compilation of safety data sheets" (Version 1.1. December 2011, section 3.23, pp. 24-25).
[4] DUCC document: Revision Management of Safety Data Sheets for mixtures complying with REACH and CLP Regulations.
[5] http://echa.europa.eu/en/about-us/exchange-network-on-exposure-scenarios

1. Information for the safe use of mixtures

In determining the duties and options for DUs in relation to mixture SDSs, the following situations have been considered:

a. Formulation[6] of mixtures by DUCC members

This use takes place at DUCC members' formulating premises and is thus always an **industrial use**.

DUCC members must check whether the use corresponding to the formulation of their mixtures is covered in the incoming SDSs/ESs of the substances (and/or "intermediary mixtures", as applicable) and they have to comply with Operational Conditions/Risk Management Measures (OC/RMM) prescribed in the ESs (or find alternative mechanisms to comply)[7].

As long as **the mixture is not placed on the market**, there is no legal requirement to develop a SDS for the formulated mixture[8]. However, workers safety legislation[9] requires that risk assessment is performed and that handling and safety information is provided to workers. For practical reasons, safety information for workers is often provided in the form of a SDS for the mixture, regardless of any legal requirement to produce a SDS.

↳There is no need to develop ES-related information for the safe (internal) use of classified mixtures not placed on the market. Safety information must be communicated but workers' safety legislation governs this use and requires neither that the information be communicated via an SDS nor the creation of an annex to the SDS.

b. Placing on the market of mixtures intended for professional or industrial users

DUCC members need to check whether the OC/RMM related to the intended uses of the mixture and to the uses that they have been made aware of are covered in the incoming SDSs/ESs of the substances (and/or "intermediary mixtures", as applicable).

In addition, the REACH legal text requires the formulator to forward relevant information on toxicity/safety for the substance(s) in the mixture[10]. For classified mixtures, it is **mandatory to provide SDSs to professional and industrial users**. Relevant information contained in incoming ESs of substances (or "intermediary mixtures", as applicable) must be reflected in the SDSs of mixtures, i.e. must be converted into information for the safe use of mixtures.

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[6] SU10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys); ECHA Guidance on Information Requirements and Chemical Safety Assessment, chapter R.12: Use Descriptor System.

[7] Art 37(5).

[8] Art 31(1) refers to suppliers, which is defined in relation to placing on the market: Art (3)(32).

[9] Framework Directive 89/391 on Occupational Health and Safety and related Directives.

[10] Art. 37(5) requires that the DU, where suitable, recommend appropriate measures to adequately control risks identified in the SDS supplied to him (or his own CSR). Art 31(7) on SDS requires the DU to include relevant exposure scenarios, and use other relevant information from the incoming SDS in their own SDS.

To meet this requirement, three options are often proposed in practice[11]. The choice on the most suitable option will also depend on whether the formulator is formulating an "intermediary mixture" or an "end-use mixture":

	Description	Preferred option when formulating
Option 1	Forward the ES of the relevant substance(s)	Intermediary mixture
Option 2	Consolidate ES of relevant substances contained in the mixture into an annex to the SDS of the mixture	Intermediary mixture
Option 3	Integrate the information on OC/RMM in the main body of the SDS of the mixture (sections 7, 8 and/or 13)	End-use mixture

It may be possible under each option to reduce the number of substance ESs to be considered to the 'risk-leading' ones by applying the DPD+[12], the CCA[13] or other similar methods.

Options 1 and 2 are considered as preferred for "intermediary mixtures" because they enable the next DU to more easily aggregate ES-related information from his different raw materials (substances or "intermediary mixtures", as applicable).

Option 3 seems to be the option that minimises the effort for the end-user to handle the received information in the mixture SDS, although this does not necessarily limit the effort for the formulator who prepares the SDS.

When an ES and/or annex is attached (options 1 and 2) consistency between the main body of the SDS and the ES and/or annex must be ensured.

For options 2 and 3, it is important to maintain the link between a given substance in the mixture and the corresponding ES information (especially in the case of "intermediary mixtures") to avoid losing important information through the supply chain.

↳Professional and industrial end-users do not have SDS-sending duties themselves. Integrating incoming ES information into the main body of the SDS as per option 3 is a valid and practical approach that provides relevant information in a concise manner to workers, and builds on existing practices. Alternatively options 1 and 2 can be applied as appropriate. The mixture supplier can choose on a case-by-case basis.

***Note**: In case the formulator has developed his own Downstream User Chemical Safety Report (DU CSR) in accordance with Article 37(4) for a substance contained in his mixture (use(s) not covered in the upstream supplier's ES), he must annex the "substance-ES" to the SDS of the mixture he is placing on the market, if relevant to the recipient of the SDS.*

Further assessment on how these two requirements can work in practice is needed.

[11] ECHA "Guidance for downstream users" and Cefic document "REACH Practical Guide Part III: Mixtures"
[12] Cefic document "ES for preparations (the 'DPD+' approach)"
[13] Critical Component Approach

c. End-use mixtures intended for consumers (general public)[14] and available in retail

SDSs for classified mixtures do not need to be supplied to members of the general public[15] if sufficient information is provided to enable safe use by consumers, unless requested by a DU or a distributor. The main means to communicate **safe use information to consumers** is the product **label**.

In addition, it is common practice, although not a legal requirement, to supply SDSs to **retailers** (they are distributors), and they often request them. Whilst retailers are not normally exposed to the chemicals contained in the end-use mixtures, as they only store the products and manipulate the packages, they need to know what to do in case of accidental spill/release. This is addressed in the main body of the SDS. ESs that cover the use and exposure of the chemical substance (or mixture) by consumers are not relevant for retailers and thus do not have to be communicated to them.

↳ For mixtures intended for consumer use, there is no need to include ES-related information in the SDSs supplied to retailers. The labels and the product design (composition, packaging, dosage, viscosity, etc) should be consistent with OC/RMM received in incoming ESs.

d. The specific case of placing on the market of samples of mixtures

In line with SDSs requirements, the **sending of samples** for classified mixtures is considered to be placing on the market and, thus, a SDS must be supplied.

For Research & Development samples (e.g. new mixture or new use), due to the very nature of R&D, the use and the conditions of use of that particular mixture provided as a sample may not be known or identified yet (it could depend on technical performance, consumer acceptance, etc.). In view of that, and by analogy to Art 37(4)(f), it would be difficult, if not impossible, to develop ES-related information.

For known uses, case (b) may apply as before.

↳ For R&D samples, ES do not need to be provided, as long as the requirements for the protection of human health and the environment are in place.

e. Is ES-related information required for non-classified mixtures placed on the market?

For **non-classified mixtures**, another general existing practice is to typically provide SDSs – although **not legally required**, except under certain conditions[16] and where the

[14] As per Article 2(6) certain mixtures in the finished state, intended for the final user, are exempted from the obligation of Title IV of REACH – Information in the supply chain.
[15] Art. 31(4).
[16] Art. 31(3) - When the mixture contains: a) in an individual concentration of ≥ 1 % by weight for non-gaseous mixtures and ≥ 0,2 % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or, b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous mixtures at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or, a substance for which there are Community workplace exposure limits.

SDS is specifically requested by a professional user. In these cases where a SDS is not legally required, there is then no legal requirement to convert any information based on the ESs of the incoming individual substances (and/or "intermediary" mixtures, as applicable) into the (non-classified mixture) SDS.

↳For the cases where a SDS can be requested for a non-classified mixture, it is not required to annex ES-related information to the SDS.

2. Conclusion

As defined in the REACH legal text, the concept of exposure scenario (ES) is only applicable to substances.

A Safety Data Sheet must be supplied for mixtures meeting the criteria for classification in accordance with Directive 1999/45/EC or Regulation (EC) No 1272/2008, hereunder referred to as "classified" and placed on the market.

When compiling their own SDS, formulators will need to extract and forward relevant information from substance ES (and/or "intermediary mixtures", as applicable).

In practice this duty will differ depending on the formulation situation:

During the formulation stage, the safe use of mixtures which are not placed on the market is governed by workers' safety legislation which does not require the development of a SDS nor the creation of an annex.

For "intermediary mixtures" (used as raw materials in other mixtures), from a practical point of view, it would be preferred to have ES-related information annexed to the SDS.

For end-use mixtures intended for professional or industrial users, ES-related information of incoming substances (and/or "intermediary mixtures", as applicable) can be integrated in the main body of the SDS.

In the case of end-use mixtures intended for consumers and available to retailers, sufficient information on safe use will be communicated via the label. It is common practice to supply SDS to retailers who will not need an ES because information for their safe use is provided in the main body of the SDS.

For R&D samples of mixtures an ES does not need to be provided.

In some cases a SDS must be provided for non-classified mixtures but no ES needs to be developed.

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