Downstream Users of Chemicals Co-ordination group

Sector-specific approaches towards developing and communicating information for the safe use of mixtures

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DUCC

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Foreword

This explanatory document was developed by **DUCC member associations** representing companies that use chemicals to formulate mixtures as finished products for end users, including professional and industrial users.

This explanatory document is issued by the DUCC[1] Mixtures Task Force (participant DUCC members: A.I.S.E., CEPE, EFCC, FEA, Fecc and FEICA), which developed a communication format in the context of the following two actions of the CSR/ES Roadmap[2]:

- Action 4.4: Further develop the **methodology** to link the **substance-related** safety advice in the exposure scenarios with the communication on safe use of (substances in) **mixtures**.
- Action 5.1: Analyse the **information needs** of the different **end-user** groups and **improve** the **presentation of information** on **safe use of mixtures** in the safety data sheet (either in exposure scenarios or in the main body of the document).

DUCC members developed 'bottom-up' approaches for deriving information on the safe use of mixtures, one of the main elements of such approaches being the SUMIs – Safe Use of Mixtures Information. The SUMIs are intended to include simplified and tailored information on the safe use of mixtures, which will be appended to or incorporated in a Safety Data Sheet. The other common element of the approaches is the SWEDs – sector-specific Workers Exposure Descriptions, which are the basis of the SUMIs content. A template for the SWEDs is being discussed under the following action of the CSR/ES Roadmap:

- Action 2.3.A.: Exposure assessment inputs for workers

The 'bottom-up' terminology has been initially applied to the DUCC project to distinguish it from the 'top-down' approach that was being initiated by suppliers' sector associations, namely Cefic and VCI. Whilst the 'bottom-up' concept has as a starting point the information on the uses of the mixtures, the 'top-down' approach starting point is the information from the substances that constitute the mixture, more specifically, the substances that are seen as contributing more to the exposure, for each endpoint. This type of approach is considered by the project group to be less practical for mixtures for end-users.

During the development of the DUCC project it was understood that the focus is more on developing 'communication formats' to be used for the communication on safe use of mixtures, both upstream (SWEDs) and downstream (SUMIs) within the existing boundaries of REACH.

This document provides some background information about the concept of the 'bottom-up' approach, focusing on the SUMIs and its objectives, providing as well a template. Sectors who may wish to develop SUMIs can find useful considerations about the concept. The document assumes that the user has some knowledge about supply chain communication under REACH, sector use mapping tables, exposure assessment and exposure scenarios.

[1] For a glossary of terms and acronyms, see annex 5.
[2] CSR/ES Roadmap website

1. Overview of safe use communication for mixtures

The requirement to communicate an Exposure Scenario (ES) down the supply chain, strictly speaking and as defined in the REACH legal text, applies only to substances and not to mixtures[3].

In the case of mixtures for which a safety data sheet (SDS) is legally required, i.e. mixtures meeting the criteria for classification in accordance with CLP Regulation (EC) No 1272/2008, hereunder referred to as "classified", and that contain one or more registered substances for which an extended SDS has been received, downstream users (DUs) must provide their customers (professional or industrial end-users) with information on the hazards of their mixtures and conditions of safe use of the mixtures, including advice on Risk Management Measures (RMM) and Operational Conditions (OC).

According to REACH, the formulators 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[4];
- forward relevant information on safe use for the substances contributing to the classification of the mixture. As mentioned above, for classified mixtures, it is **mandatory to provide SDSs to professional and industrial users**. Relevant information contained in incoming ESs of substances must be reflected in the SDSs of mixtures, i.e. must be converted into information for the safe use of mixtures[5].

To meet the latter requirement, three options are proposed in practice[6]:

Option 1	Integrate the information into the main body of the SDS
Option 2	Append safe use information for the mixture to the SDS
Option 3	Attach the relevant exposure scenarios for the substances in the mixture as an annex

The formulator will choose, on a case-by-case basis, which option is the best. The process should be as efficient as possible, proportionate to the risk and relevant and understandable to the recipients.

For more information on these options, please check the DUCC paper on "How exposure scenario information on substances can be converted into information for the **safe use of mixtures**".

[3] ECHA "Guidance on the compilation of safety data sheets" (Version 3.1, November 2015, p. 26, footnote 29).
[4] Art. 37 (5): "Any downstream user shall identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified in any of the following: (a) the safety data sheet(s) supplied to him; (b) his own chemical safety assessment; (c) any information on risk management measures supplied to him in accordance with Article 32."
[5] Art. 31 (7): "Any downstream user 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."
[6] ECHA "Guidance for downstream users" (version 2.1., October 2014, p. 85), ECHA "Guidance on the compilation of safety data sheets" (Version 3.1, November 2015, section 2.23., pp. 26-27) and Cefic "REACH Practical Guide on Exposure Assessment and Communication in the Supply Chains, Part III: Mixtures under REACH" (March 2010, pp. 14-15)

1.1. The DUCC 'bottom-up' approaches for the safe use of mixtures, including the SWEDs and the SUMIs

DUCC members have started this project with the following objectives:

- To help their member companies in complying with their obligation to provide safe use information for classified mixtures (as explained above)
- To develop meaningful, tailored information for professional and industrial end-users of mixtures, by ensuring consistent translation of the substances' ESs
- To cover the majority of uses within a sector
- To simplify communication with raw material suppliers

Sector Use Maps and SWEDs – sector-specific Workers Exposure Description

Many formulators are represented within a sector organisation, which in many cases facilitates communication along the REACH supply chain by analysing typical end-uses within their sector. They can therefore create documents describing the 'average' and 'standard' conditions for each relevant end-use within the sector. The documents that contain sets of information describing the relevant uses for the sector are the so called '**use mapping tables**' or '**sector use maps**'. Within these documents, the uses are described by:

- the use descriptors[7],
- relevant Operational Conditions (OC) and Risk Management Measures (RMM) (duration, PPE, …)
- as well as, any additional information that is found to be relevant[8]

The 'sector use maps' are a means to communicate to the registrants about the conditions under which those typical (end-) uses take place. The registrants can make use of that information to:

(i) cover the majority of (end-) uses of mixtures from a sector in their Chemical Safety Report, ensuring representativeness

(ii) perform the Chemical Safety Assessment, with relevant and realistic information provided by the sector.

The 'sector use maps' typically cover three aspects: the environmental, worker and consumer exposure. Similarly to the overall 'sector use maps' template, three individual templates exist (or are under finalization at the time of writing) for each of these three components of the 'sector use maps' that are known as 'exposure assessment inputs'. This project is focusing on the workers exposure for which the corresponding exposure assessment input are the SWEDs – Sector-specific Worker Exposure Description[9]. The other exposure assessment inputs are the SpERCS – specific Environmental Release

[7] ECHA Guidance on Use descriptor system (Chapter R.12)

[8] It shall be noted that, at the time of writing of this document, the template for the 'sector use maps' is also under revision as part of actions 2.1 and 2.7. of the CSR/ES Roadmap. The new template will be called "improved use maps".

[9] The SWEDs are the scope of Action 2.3.A. of the CSR/ES Roadmap, please consult the dedicated website for updated information.

Categories, for the environment and the SCEDs – specific Consumer Exposure Determinants, for the consumer.

The sectors involved in this project have created their SWEDs, containing the relevant information in terms of workers exposure, which includes also some boundaries – usually the OC/RMM, which can be complemented with other additional quantitative values, such as maximum concentration for relevant substances, minimum tolerable DNELs, etc… This will depend on the specific situation of each sector.

The SWEDs can be used in different ways:

- by the registrant: for the workers chemical safety assessment. In this case, the registrant can include a reference to the SWED that he has used in his CSR and later on the ES of the substance – if so, the formulator will have his task facilitated;
- by the formulator:
    - to 'validate', i.e. to compare with the incoming exposure scenarios for the substances in the mixture. If the SWED selected by the formulator covers all the conditions of use described in the exposure scenarios of all the substances present in the mixture he will sell, he can pick the corresponding SUMI and append it to the SDS of the mixture;
    - to send it to the supplier, in case he cannot validate any SWED against the ES of the substance(s). The formulator asks the supplier to consider updating his CSR and to cover the conditions described in the SWED;
    - to perform his own CSA[10], in case he cannot validate any SWED against the ES of the substance(s). Although the SWEDs are defined for typical uses of mixtures, the information they contain is appropriate to perform a CSA for a substance. The ES resulting from the DU CSA will then reflect the conditions described in the SWED.

It has already been explained that different sectors can include different boundaries in their SWEDs, depending on the information that is known to the sector and also depending on the parameters that are found to be more significant to describe the uses of their mixtures.
There are other possible differences between SWEDs of different sectors that are worth mentioning:

- the SWEDs can be created at use or contributing activity level, i.e. they can cover the whole process that a worker has to perform or they can cover only the individual activities, i.e. only the transfer, only the mixing, only the brushing, etc.
- the SWEDs can be created for different level of hazards of the same type of product, e.g. a mixture can have different concentrations of a certain substance and depending on that the operational conditions and risk management measures may differ.

Further detail on these differences will be provided by the sectors, once their SWEDs/SUMIs are published.

[10] For more information on how to perform a DU CSA please check the ECHA "Practical Guide 17: How to prepare a Downstream User Chemical Safety Report".

The SUMIs – Safe Use of Mixture Information

For each SWED that has been developed a corresponding SUMI has been created (1:1 relation). The SUMIs correspond to option 2, mentioned above in section 1[11].

The SUMIs follow a format (see Annex 1) and include only the information from the SWEDs that is relevant to the end-user, in a language that is understandable to him. The sector associations will make all these documents available on their website.

The SUMIs include a mandatory/common part and optional chapters, to be adapted to the needs of each sector. The common chapters are:

- Title
- General description of the process covered
- Operational Conditions
- Risk Management Measures
- Disclaimer

The optional chapters are:

- Additional good practice advice
- Additional information depending on product composition

As for the SWEDs, the SUMIs are use-oriented. This means that one SUMI can be used for multiple products.

On the other hand, more than one SUMI can be integrated within or appended to the SDS. This is due to the fact explained above that some SWEDs will be developed for the whole use and other SWEDs will be developed for a single activity. Another reason could be that the same product can be used in different ways, e.g. a paint can be used by spraying or rolling/brushing.

It is important to note that the SUMIs don't replace the SDS. As mentioned above, the SUMIs are use-oriented and all the product-specific information is included in the SDS (classification, specifications of PPE, …) – this is one of the main aspects highlighted in the disclaimer included in each SUMI.

With time, once the supply chain starts integrating the SWEDs in the assessment processes, SUMIs are expected to start being received and end-users can expect to understand and process ES-related information more easily.

1.2. How can the formulators use the SWEDs/SUMIs that have been developed by the sector associations?

The first step for the formulator is to assess if his mixture is classified. For non-classified mixtures it is not legally required to provide SDS, except under certain conditions[12]. There is nevertheless in some sectors

[11] Some DUCC members will prefer to follow option 1, i.e. to include the relevant safe use information in the main body of the SDS, but this project is currently focusing in option 2, i.e. to attach to the SDS the relevant safe use information.

an existing practice to typically provide SDSs, but in such cases a SUMI will not be expected. If the formulator decides not to provide an SDS because the mixture is not classified, he should keep all justifying documentation.

If the mixture is classified, the formulator can look for a sectorial "bottom-up" approach. If there is none, the formulator can apply the Cefic/VCI LCId methodology[13].

The figure below is a schematic overview of these first steps:

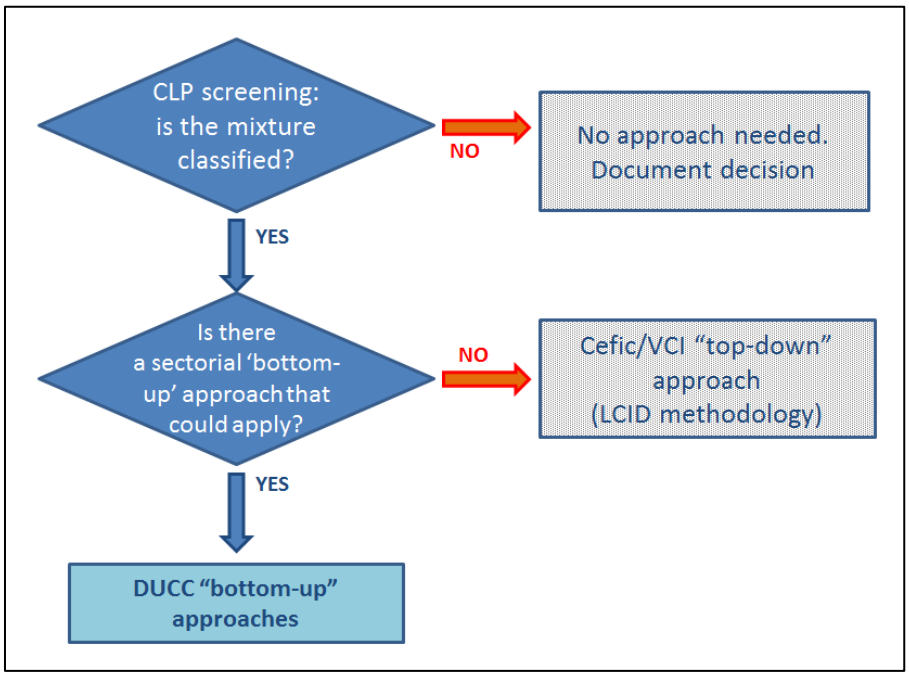

Figure 1 – Overview of the decision process on the need for the formulator to develop safe use mixture information and, if so, choosing between 'bottom-up' or 'top-down' approach.

Once the formulator finds the appropriate sectorial documentation, he will need to select the SWED which reflects how his mixture is to be used by customers, and then validate the SWED against the exposure scenarios he has received for the substances included in his mixture. This will consist of cross-checking the operational conditions and risk management measures, as a minimum. Depending on each sector, other kind of checks may be needed: maximum concentration, minimum tolerable DNEL, etc. these will be specific requirements that are found needed by each sector and explanations will be provided on a case-by-case basis. Once the formulator establishes that a SWED covers all the conditions described in the exposure scenarios of the substances in his mixture, he just needs to pick the corresponding SUMI and append it to his SDS.

[12] 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.

[13] For more information please check the Cefic REACH Guidance and Tools website.

In case the formulator finds that a SWED does not cover all the conditions described in the exposure scenarios of the substances, he has several options:

- To send the SWED information back to his supplier and request supplier to cover that use, i.e. to perform a new chemical safety assessment using the information contained in the SWED.
- To perform a downstream user chemical assessment using the information contained in the SWED. As a result he will obtain an exposure scenario for a substance, for the use downstream – according to the REACH legal text this exposure scenario has to be attached to the SDS of the mixture[14].
- To apply the Cefic/VCI LCId methodology.

The scheme below provides an overview of the processes described above:

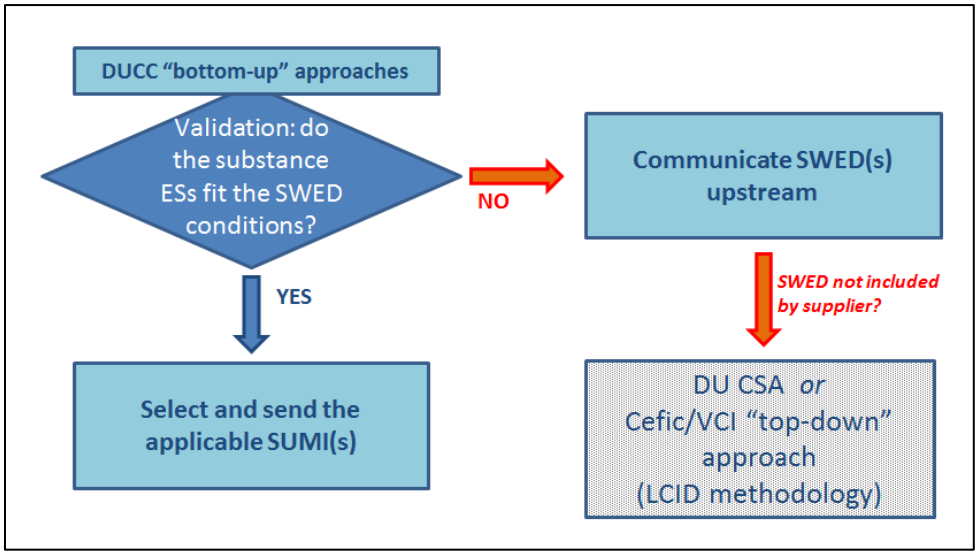

Figure 2 – overview of the steps between validating a SWED and sending the corresponding SUMI, and what to do if no SWED can be validated

[14] By the time of writing of this document no extensive discussion on the relation between a SUMI and an exposure scenario for a substance has taken place.

In essence:

SWEDs	SUMIs
Communication format for upstream communication Contain the input parameters for a Chemical Safety Assessment – Workers Exposure (provide the exposure determinants)	Communication format for downstream communication The output of the sectorial 'bottom-up' approach, tailored-made for the end user
Applicable to	
Mixtures (uses of)	Mixtures (uses of)
Content based on	
Sectorial information about workers use of the mixtures / sector use maps	SWEDs
Used by	
Registrants Formulators	Formulators End-users
Used for	
Chemical Safety Assessment – workers' exposure assessment (by registrants) Validation of the incoming ES for substances – to check if the conditions described in the ES for each substance in the mixture are covered by the conditions described in the SWEDs (by formulators)	Communication downstream – append to or integrate the SUMIs within the SDS of the mixture (by formulators) Providing safe use information – professional and industrial end-users (workers) to follow the conditions described
Where to be found	
On the sector website In the Cefic "Overview table of the associations activities"[15]	On the sector website In the Cefic "Overview table of the associations activities"[16]
Other	
• 'Specific' to a sector • They are not substance-based • They may be complemented with a SpERC for full description of the use, since they don't address the environmental exposure	• 'Specific' to a sector • They are not substance-based • They need to be supplied together with a Safety Data Sheet

1.3. How will the supply chain communication work with the integration of the concept of SWEDs and SUMIs?

1. The formulators' sector associations create the SWEDs and SUMIs, based on information they hold/receive/will collect from their end-users. The SWEDs will be part of the sector use maps.

[15] More information in the Cefic REACH Guidance and Tools website.
[16] Idem

2. The registrant uses the information from the SWEDs when he performs the workers' chemical safety assessment.
3. The registrant sends the SDS for the substance and ideally includes a reference to the SWEDs that he has used, in the relevant exposure scenarios.
4. The formulator receives the exposure scenarios for the substances that he will include in the mixture.
5. The formulator validates the exposure scenarios received: he checks, for each substance included in the mixture, that the conditions described in the exposure scenario are covered by his selected SWED.
6. Once the formulator establishes that the SWED covers all the conditions of use described in the exposure scenarios of all the substances present in the mixture he is formulating: he picks the corresponding SUMI and appends it to the SDS of the mixture.
7. The end-user receives a SUMI attached to the SDS of a mixture.

Below a visual scheme is included on the use/link of SWEDs and SUMIs in the supply chain:

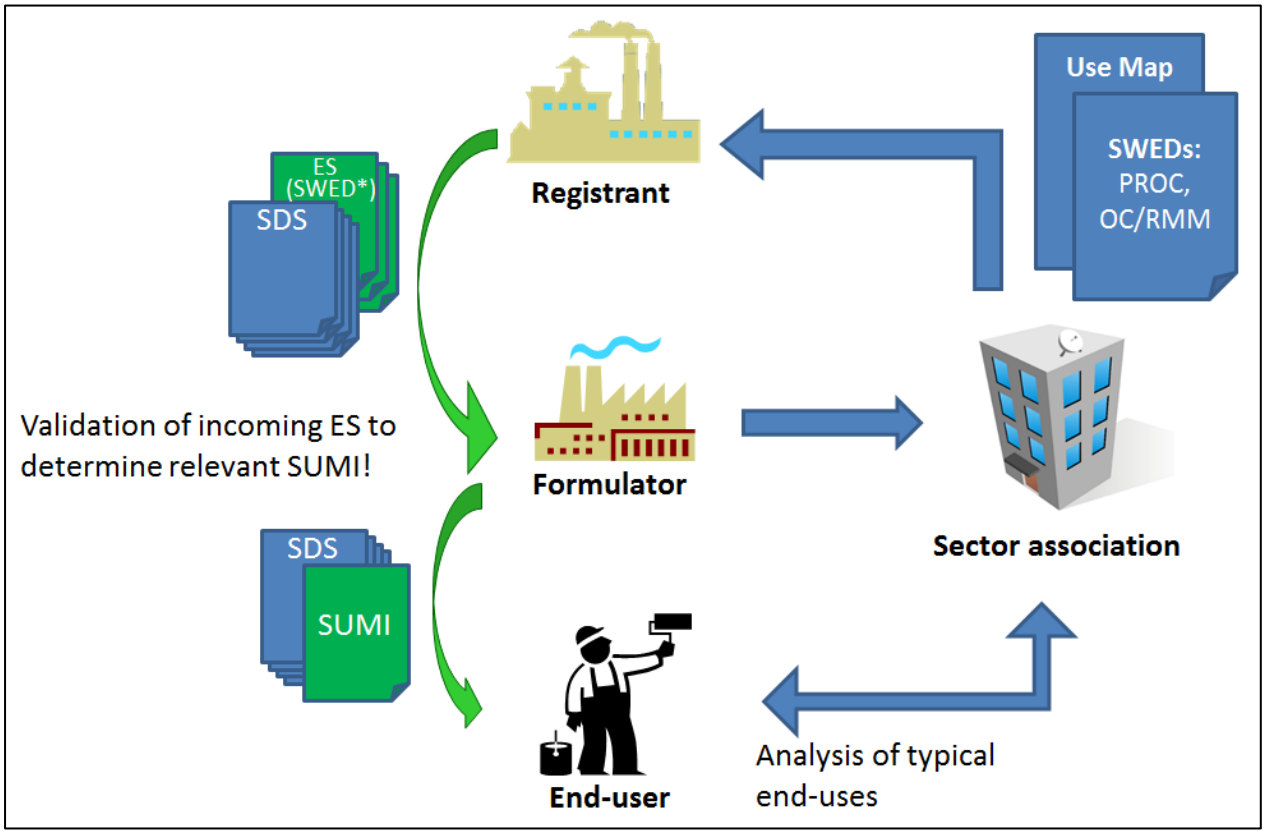

Figure 3 – How the communication in the supply chain will work once the SWEDs and SUMIs are implemented

2. Concluding remarks

2.1. Main advantages of the SWEDs and SUMIs

The SWEDs, if taken up by the registrant, will allow:

- Consistency of the safe use information that is communicated downstream.
- Additionally, if the registrants include the reference of the SWED that they have used, the formulator will more easily do the 'validation' step.
- To reduce situations where the registrant proposes conditions that are not appropriate in practice, because the OC/RMM mentioned in the SWEDs are relevant for the end-user.

The use of the SUMIs in the SDS of mixtures allows that:

- End-users will understand better the information received
- End-users will receive the information that is relevant for their tasks
- End-users will become familiar with the template
- The information will be presented in a harmonised way, allowing the future integration in the ESCom Standard Phrase catalogue[17]
- Translation of SUMIs in the future is facilitated

Both elements ensure:

- Representativeness / Realistic and meaningful information: the information has been prepared by sectors who are in the possession of information regarding the market and (end-) use of the mixtures
- Standardisation and Harmonisation: if the same templates are used the collection and use of information is facilitated
- Simplicity: the end-users will better understand and more easily put in place the information they receive

2.2. Boundaries in the use of the SWED/SUMI approach

The sectorial approaches based on SWEDs/SUMIs are meant to help formulators in complying with their obligations for communicating safe use of mixtures. They don't cover the obligation of the formulator to check if his conditions of use of a substance are covered.
It is also important to note that the SWED/SUMI approach is focusing on the workers exposure assessment and therefore is addressing the case of mixtures classified for health hazards. There may be mixtures that are also classified for the environment, and the SWED/SUMI approach may need to be complemented by the use of a SpERC. Some of the DUCC sectors may choose to include in the SUMI some (additional) information related to environmental considerations, but there hasn't been an extensive discussion at DUCC level on how to relate a SWED/SUMI to a SpERC.

[17] For more information on ESCom please check the Cefic dedicated website.

2.3 Next steps

Following the publication of the SWEDs/SUMIs by the DUCC members, the sectors will work on:

- Development of Chesar input files,
- Selection of relevant phrases to be proposed for the ESCom phrase catalogue.

Both actions are expected to be developed in the course of 2016.

Annex 1 – SUMI template

SUMI **Safe Use of Mixtures Information for end-users**	**[Sector/Company logo]**

Title: [Text][18]

This document is intended to communicate the conditions of safe use for the product and should always be read in combination with the product's Safety Data Sheet and labels.

General description of the process covered

[Text]

This section may include a reference to the Use descriptors (SU, PROC / PC and ERC, if applicable) or include a sentence like: "This safe use information is linked to SWED_sector_code_..." (a link to the SWED would ideally be included).

Obs: we acknowledge that this information may not be relevant for the end user but rather for the enforcement/competent authorities, so each sector should take a decision on its relevancy.

Operational Conditions

[Text] or

Maximum duration	[Text]
Range of application / Process conditions	[Text]
Air exchange rate	[Text]
Others	[Text]
(…)	[Text]

This section should consist of text or a table including all the 'restrictions' that the end-user needs to follow, taken from the exposure assessment (e.g. ECETOC TRA), such as the

[18] Include the version number in the SUMI (e.g. in the header, footer, …). Obs: the names/version numbers of the SWEDs and SUMIs will be similar to demonstrate the link.

parameters included above. This section should also include environmental considerations, if relevant.

Risk Management Measures

[Text + "See chapter 8 of this Safety Data Sheet for specifications"]

This section can include relevant pictograms and environmental considerations, if relevant.

Optional chapters

Additional good practice advice

[Text]

This section should include, when relevant, good practice recommendations/information, comprising e.g. relevant pictograms. It may refer to environmental considerations as well.

Additional information depending on product composition

[Text]

This section should include references to other relevant sections of the SDS.

Eg. The case of GEIS from A.I.S.E. in case of presence of certain allergenic substances; presence of certain hardeners for CEPE, etc…

Disclaimer

[Text]

Below is just a generic example, for each sector to adapt.

This is a generic document for communicating conditions of safe use of a product. This document relates only to conditions of safe use and is not specific to a product. It is the responsibility of the formulator to link this SUMI to a specific product that he is selling.

If a SUMI code is mentioned in Section 1 of the SDS of a product, the formulator of that product declares that all substances in the mixture are present in such concentration, that the use of the product within the conditions of the SUMI is safe. When available, this safe use is ensured by evaluating the results of the chemical safety assessments as performed by the raw material suppliers. When no chemical safety assessment has been carried out by the supplier for an ingredient that contributes to the classification of the mixture, the formulator has performed a safety assessment himself.

Following Occupational Health legislation, the employer of workers that use products that are assessed as safe following SUMI conditions remains responsible for communicating relevant use information to employees. When developing workplace instructions for employees, SUMI Sheets should always be considered in combination with the SDS and the label of the product.

[Sector name] is under no conditions liable for any damage, no matter of what kind, which is the direct or indirect consequence of acts and/or decisions (partly) based on the contents of this document.

Annex 2 – General instructions for sectors to fill the SUMI template

1. The version number of the SUMI is to be included in the document, e.g. either in the header or footer.
2. Each sector to decide if the use descriptor codes need to be included. As an alternative a link to the corresponding SWED can be given (in this case the SWED will contain the use descriptors).
3. The fields where "[text]" or other text inside square brackets appears is to be replaced by the relevant content.
4. The text in blue font is to be removed. It serves as orientation and exemplification.
5. The optional chapters are for each sector to decide whether they are relevant.
6. The disclaimer is to be adapted by each sector.

Annex 3 – Additional supporting material

DUCC Sectorial 'bottom-up' approaches

- Presentation at ENES 9 – Sector-specific approaches for deriving information towards developing and communicating safe-use of mixtures
- Presentation at ENES 8 – Downstream user sectors: Safe Use of Mixtures Information (SUMIs). State of play and next steps
- Presentation at ENES 7 – Sector approaches to generating safe use information (the "bottom-up" approach): Update on latest developments and next steps

Cefic/VCI LCId methodology

- Presentation at ENES 9 – to be updated soon: http://echa.europa.eu/en/view-article/-/journal_content/title/ninth-meeting-of-the-exchange-network-on-exposure-scenarios-enes-
- Presentation at ENES 8 – Practical Guide for Mixtures and LCID Methodology .Progress report
- Presentation at ENES 7 – The Lead Component Identification Methodology (the "top-down" approach) explained: Workflow and practical guidelines

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Annex 5 – Acronyms

A.I.S.E.	International Association for Soaps, Detergents and Maintenance Products
Cefic	The European Chemical Industry Council
CEPE	European Council of the Paint, Printing Ink and Artists' Colors Industry
Chesar	Chemical Safety Assessment and Reporting tool
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
DU	Downstream User
DUCC	Downstream Users of Chemicals Co-ordination group
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EFCC	The European Federation for Construction Chemicals
ENES	Exchange Network on Exposure Scenarios
ERC	Environmental Release Category
ES	Exposure Scenario
ESCom	Exposure Scenarios for Communication
FEA	European Aerosol Federation
Fecc	European Association of Chemical Distributors
FEICA	Association of European Adhesive and Sealant Industry
GEIS	Generic Exposure Information Sheet
LCId	Lead Component Identification (Methodology)
OC	Operational Conditions
PC	Product Category
PPE	Personal Protective Equipment
PROC	Process Category
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (EC) No 1907/2006
RMM	Risk Management Measures
SCED	Specific Consumer Exposure Determinant
SDS	Safety Data Sheet
SpERCs	Specific Environmental Release Categories
SU	Sector of Use
SUMI	Safe Use of Mixtures Information
SWED	Sector-specific Workers Exposure Description
TRA	Targeted Risk Assessment (Tool)
VCI	Verband der Chemischen Industrie e. V. (the German chemical industry association)