Safe use information for mixtures:
A ‘bottom-up’ approach

• REACH requires downstream users (formulators) to check that exposure scenarios they receive for substances cover all relevant uses, and to
  – adopt the Operational Conditions and Risk Management Measures relevant for their own use(s) → session later on workplace safety assessment
  – pass on relevant information to the next actor in the supply chain to their customers

• Formulators need to decide how to convert/consolidate exposure scenario information on substances into safe use information for their mixtures

• A sectorial ‘bottom-up’ approach is suitable for end-use mixtures with clearly defined markets and uses
  – DU sector organisations are well placed to identify the typical uses of their products, with standardized conditions of use
SUMI selection methods

The elements

**SWED**

Sector-specific Worker Exposure Description

- Describe the typical use conditions of mixtures by workers
- Are an element of the use maps
- Template is published
- It comprises input information for registrants to perform a CSA - Workers’ Exposure (i.e. provides the exposure determinants)

**Formulator**

1. To check SWEDs vs. incoming ES for substances
2. To communicate downstream the appropriate SUMI

- Based on SWED → the output of the assessment, containing simple advice to the professional or industrial end-user
- One SWED ⇔ One SUMI
- Are use oriented and not specific for a product
- To be integrated within or appended to the SDS of mixtures (1- or 2-pager)

**SUMI**

Safe Use of Mixtures Information

SUMI selection methods

In operation

Pre-defined, standardized sets of information containing the relevant Operational Conditions & Risk Management Measures for the majority of uses of the mixtures that are relevant for the sector

End users industrial

End users professional

Safe use information pre-defined by the sector, in easy-to-understand language for industrial and professional end-users
**SUMI - The template**

<table>
<thead>
<tr>
<th>Mandatory SUMI content</th>
<th>Optional SUMI content</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SUMI:</strong> Safe Use of Mixtures Information for end-users</td>
<td><strong>Good practice advice</strong></td>
</tr>
<tr>
<td><strong>Sector_SUMI_code:</strong> Title of SUMI</td>
<td>If relevant, applicable (sector-specific) good practice advice</td>
</tr>
<tr>
<td>General description of process covered</td>
<td>Use of pictograms when available</td>
</tr>
<tr>
<td><em>May include use descriptor codes or reference to SWED</em></td>
<td>Additional information on product composition</td>
</tr>
<tr>
<td><strong>Operational Conditions</strong></td>
<td>To include references to other relevant sections of SDS or product label</td>
</tr>
<tr>
<td>Maximum duration:</td>
<td></td>
</tr>
<tr>
<td>xx min.</td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
</tr>
<tr>
<td>xxx</td>
<td></td>
</tr>
<tr>
<td><strong>Risk Management Measures</strong></td>
<td></td>
</tr>
<tr>
<td>Required RMMs, use of pictograms</td>
<td></td>
</tr>
<tr>
<td>Reference to Section 8 of SDS for RMM specifications</td>
<td></td>
</tr>
<tr>
<td>If applicable: any environmental measures</td>
<td></td>
</tr>
<tr>
<td><strong>Disclaimer</strong></td>
<td></td>
</tr>
<tr>
<td>Disclaimer on boundaries of SUMI use</td>
<td></td>
</tr>
<tr>
<td>Sector_SUMI_code / version number</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE: This format can be adapted by companies. Published on DUCC website.

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**SUMIs**

Some considerations on their use

- Sending information on safe use is mandatory for **hazardous** mixtures (REACH Art. 31(7))
  - Therefore SUMIs would be expected for classified products only

- SUMIs **do not** replace SDS!
  - The SDS includes **product-specific** information (classification, specifications of Personal Protective Equipment, ...) and SUMI is for the use

- Sometimes **more than one SUMI** can be integrated within or appended to the SDS
  - Depending on the way that typical uses are defined by the sectors, and/or the uses that are relevant for a customer

- SUMIs should be **translated** into all relevant languages (made available by sectors)
  - Since they form an integral part of the mixture SDS
SUMI selection methods
The process – in brief

SUMI selection methods
The process

- Each sector defines the ‘applicability domain’ for its SWEDs and SUMIs
  - Qualitatively, e.g. by specifying the product types or hazard classifications to which each applies; or
  - Quantitatively, by calculating expected exposures (e.g. using ECETOC TRA)

- The formulator has to:
  1. Identify the SWED+SUMI that most appropriately reflects his customer’s use
  2. Carry out a ‘validation’ step for each relevant* substance in the mixture
     - Check received substance ES against the OCs and RMMs in the SWED/SUMI, to ensure the second are at least equal to the first
     - In some sectors a quantitative screening option is also available, to check if use is safe (RCR < 1) by comparing substance DNEL vs. calculated exposures

* Typically validation will not be required for every substance in the mixture, but only for those determining the risk / contributing to the classification of the mixture

Validation will be supported by electronic tools in future (e.g. ESCom)
SUMI selection methods

Key aspects

• Prepared by sector associations
  – The concept was developed by DUCC members, but other DU sectors can also consider developing their own SWEDs and SUMIs

• Currently focused on human health for workers
  – A similar approach for environmental information is in development

• Developed to cover the majority of typical uses in a sector (‘80:20 rule’)
  – Formulators have a range of options if a standard SUMI cannot be selected/validated, e.g.
    • Provide SWEDs to supplier and request updating of CSR and ES
    • Customize SWED and SUMI to reflect customer’s use
    • Apply a ‘top-down’ method, such as LCID
    • Carry out a DU CSA
    • Change supplier or substitute the substance

SUMI selection methods

In a nutshell

• Support formulators in complying with their obligations under REACH

• Help to improve communication in the supply chain and the safe use of chemical mixtures by end users

• An explanatory document is available on the DUCC website at http://www.ducc.eu/Publications.aspx

• Information can also be found on ECHA’s webpages at https://echa.europa.eu/communication-in-the-supply-chain