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FEICA Use Map Guidance

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1. Introduction

The REACH Regulation EC 1907/2006 requires in Article 14 to include with the registration of substances a chemical safety assessment on the whole life cycle of a chemical. The result of such an assessment is communicated downstream via exposure scenarios (ES) attached to the safety data sheet (SDS) of the substance. Downstream users such as formulators or users of adhesives and sealants, are required in Article 37 of the same regulation to take this information on safe use into account in their own documents and adjust their own use conditions accordingly. They also have a right to communicate their use conditions upstream and request an assessment from the registrant of the substance.

To assist this process several downstream user associations under the umbrella of DUCG (Downstream Users of Chemicals Coordination Group) have summarised their typical uses by including state-of-the-art use conditions of main applications in so-called use maps. Here, some specific guidance is given to registrants of substances, when doing the risk assessment under REACH, and to formulators of adhesives and sealants, when updating the safety data sheets of their products. The use maps describe main downstream uses of substances in formulation and end use schematically by applying the language of the REACH Use Descriptor system (cf. REACH Guidance R.12).

This guidance is not intended to describe the full use map concept but rather the specifics of applying the FEICA use map. Consistently applying the use map to substances used in a sector allows formulators to consistently assess their products intended to be applied for these uses. Generation of consistent mixture information is very difficult or not at all possible with the divergent information received from assessments referring only to individual substances or substance groups (GES-based).

In addition, default safe use information on mixtures (SUMI) related to the use map has been made available to be used by the formulator in its downstream communication.

1.1 Concept of Use Maps (aka SUMI Selection Method)

The FEICA Use Map consists of 4 elements:

- Use map document
 - Describes the typical uses of adhesives and sealants (A&S) with a description, some typical examples and related chemical technologies.
 - Relates these typical uses to the terminology used in risk assessments under REACH, specifically the use descriptor system of ECETOC TRA, which is described in ECHA's guidance on IR&CSA R12 in detail.
 - One formulation use (included for completeness only, SWED / SUMI do not apply)
 - Seven industrial uses
 - Seven professional uses
 - Four types of consumer adhesives and sealants
- SWEDs
 - Describe the 14 industrial and professional uses of the use map in detail, including the state-of-the-art risk management measures.
 - Relate the steps of product application (= contributing scenarios) to the input parameters for computer-based exposure estimation tools.
 - Eleven industrial SWEDs

- Eight professional SWEDs
- SPERCs
 - Describe the conditions of A&S manufacture and application with regard to potential environmental releases of their constituents.
 - Background documents describe the justification for the chosen data.
 - Thirteen SPERCs differentiated between
 - water-borne and solvent-borne/less adhesives and sealants
 - volatile (b.p. < 250 °C) and non-volatile (b.p. > 250 °C) substances
 - industrial (site specific) and professional/consumer (wide-dispersive) uses
 - indoor and outdoor uses
 - Beyond these differentiations SPERCs are common to the uses described here.
 - SPERC values serve as parameters for EUSES based assessments.
- SCEDs
 - Four SCEDs for different types of A&S describe the typical conditions in consumer use.
 - A survey of consumer habits in the use of A&S was conducted by FEICA to create a basis for the SCED data.
 - SCED values serve as parameters for CONSEXPO based assessments.

In addition to the use map as described above, FEICA has published 19 SUMIs, which contain safe use instructions on the basis of a quantitative risk assessment under REACH. Each SUMI relates 1:1 to a SWED. If a SWED has been assessed as safe for all substances in an A&S product, the corresponding SUMI can be attached to the SDS of this product for communication further downstream to end users. See also the DUCC document 'How to use SUMIs: Operational framework' for further details.

1.2 Available Resources

1. Use map library of ECHA (see references)
 - Use maps of many downstream sectors
 - Use map and all supporting documents (SWED, SPERC, SCED)
 - Available in MS Office format and as CHESAR upload file
 - SPERC factsheets and background documents
 - History of changes
2. FEICA website (see references)
 - Same files as in ECHA's use map library
 - SUMI files for formulators
3. ECHA guidance on IR&CSA (see references)
 - Specifically, chapters R12–R16
 - Detailed information on how to perform the CSA
4. Exposure assessment tools
 - CHESAR (<https://chesar.echa.europa.eu/>)
 - Trexmo
<https://www.seco.admin.ch/seco/de/home/Arbeit/Arbeitsbedingungen/Chemikalien-und-Arbeit/Exposition/TREXMO.html>
 - ART (<https://www.advancedreachtool.com/>)
 - Stoffenmanager (<https://stoffenmanager.com/>)
 - EUSES (<https://echa.europa.eu/de/support/dossier-submission-tools/euses>)
 - ECETOC TRA (<http://www.ecetoc.org/tools/targeted-risk-assessment-tra/>)

- EMKG (https://www.baua.de/DE/Themen/Arbeitsgestaltung-im-Betrieb/Gefahrstoffe/EMKG/Einfaches-Massnahmenkonzept-EMKG_node.html)
- MEASE (<https://www.ebrc.de/industrial-chemicals-reach/projects-and-references/mease.php>)
- ConsExpo (<https://www.rivm.nl/en/consexpo>)

2. Guidance for Registrants

2.1 Purpose of the Use Map

For registrants the use map provides a translation of the typical uses in a sector into the language and parameters needed for a chemical safety assessment (CSA) under REACH with computer modelling tools such as ECETOC TRA, Advanced REACH Tool (ART) or others. With the provision of all these uses including all parameters and RMMs in one upload file for CHESAR, the use map also simplifies the assessment process significantly if this tool is used. The communication between a registrant and its individual customers will be markedly reduced when a use map is applied in the first place. By consistently assessing substances with these same parameters, the formulator of a mixture for a specific use can conclude the safety information he has to provide to his customers.

2.2 Selection of Uses

The FEICA use map covers the majority of typical uses for sealants and adhesives in industrial and professional as well as consumer settings. However, there exist also niche applications in the sector which will continue to require individual communication along the supply chain.

As a general rule all uses of the use map should be assessed for a substance that is sold widely in this sector. If the substance is more specific and used by only a few customers, it might be advantageous to discuss the relevant uses from the use map beforehand with these customers. In some cases, the substance properties may eliminate some uses. One obvious example is solvents, which will never be used in a powder product. Another example is a substance not suitable in water-based products.

The formulation life cycle stage is mentioned in the use map but without the detailed SWED information. Only the relevant PROCs for worker assessment are listed, and the assessment is expected to be done following the general ECHA guidelines with the results being communicated as standard exposure scenarios. SPERCs, however, are available also at the formulation stage to allow for more specific environmental assessments.

2.3 Environmental Assessment

While the individual uses are specific for the worker assessment, they all correspond to the same set of SPERCs for the environmental assessment within the industrial and widespread uses, respectively. Because a product may contain volatile and non-volatile substances, the appropriate SPERC is chosen on the substance level based on their properties, e.g., for non-volatile substances with a boiling point above 250 °C. If the assessed substance has a boiling point above 250 °C, then the SPERCs for volatile substances (i.e., for substances below 250 °C) must be removed from the assessment. The case is less obvious for the SPERCs differentiated between water-borne and solvent-borne adhesives. This differentiation depends mostly on the adhesive or sealant and much less on the substance. Therefore, it is recommended to assess both versions when a corresponding use for the worker/consumer is assessed.

For tonnages, each relevant SPERC should be once assessed with the full registered tonnage of the substance or – if known – the tonnage sold in the adhesive and sealant sector. From a registrant's perspective, a split of tonnage per individual use of the FEICA use map cannot be reasonably assumed. Therefore, the background document on SPERCs contains information on indicative tonnages in the adhesive industry. They can be used as a conservative starting point for an

assessment. If required, the tonnage for the industrial site assessments may be further reduced to achieve an RCR below 1. In any case the safe quantity per local site should be reported as Msafe.

2.4 Performing the Risk Assessment with CHESAR

The CHESAR tool, together with its full documentation including the way to apply a use map is available on ECHA's website (<https://chesar.echa.europa.eu>). This is not repeated here.

If CHESAR is used for the risk assessment, the import of the FEICA use map file in CHESAR format is strongly recommended. After uploading, the uses have to be supplemented with some substance-specific data, e.g., tonnages (see above). If the relevant information is available, some uses may now be deleted from the assessment (see above), and the ERCs (SPERCs) that are not relevant for this substance must be deleted. SWEDs shall be kept as provided.

In a first run the 3 quantitative assessments of ECETOC TRA for workers and for consumers and EUSES for the environment are run on the Use Map. Additionally, for qualitative assessments the justification needs to be added manually. If all assessments return a green check mark, the task is completed. For those not yet green, the concentration of the substance in the mixture may be reduced in iterations until the RCR gets below 1. No other assessment parameter may be changed, and in CHESAR these are also blocked. If RCR < 1 cannot be achieved this way or if the concentration of the substance becomes unrealistically low, a tier 2 assessment or the use of measured data is required. See the next chapter for this. The way to integrate the results of an outside assessment back into CHESAR is described in ECHA's guidance.

As a last resort the conditions can be switched from SWED based to 'Manual selection'. This will break the link with the Use Map and result in an individual assessment for this substance. As a consequence, the formulator will no longer be able to communicate a FEICA SUMI to his customers.

In cases where the tier 1 assessment fails to prove safe use, it is recommended that FEICA be contacted for discussion on the best way forward.

2.5 Performing the Risk Assessment with Tools Other than CHESAR

To our knowledge, CHESAR is currently the only tool that allows upload of a complete use map. In all other tools the individual data and parameters given in the MS Excel tables for use maps and SWEDs or PDF files for SCEDs and SPERCs need to be typed in or selected accordingly. It is important not to deviate from the conditions given in these files because this would break the link with the use map and the SUMIs for downstream communication.

2.6 Communication with FEICA Formulators

Formulators are using the FEICA use map to assign their products to specific uses beforehand on the basis of the conditions described in the use map and its supporting documents. They then need to know whether the substances in this product are safe under the use map conditions. Communication of number and name of the respective SWED, SPERC or SCED together with the maximum safe concentration or, in case of environmental assessments, the maximum safe tonnage (Msafe) is sufficient because all the conditions of these use map elements have been checked beforehand. In exposure scenarios generated by CHESAR, these data are given in the header of the exposure scenario followed by the details, which are a repetition of the use map data. For exposure scenarios generated outside of CHESAR, the same approach is recommended.

The most important point here has been mentioned already above in the chapters on assessment: Only if the conditions have not been changed from the given parameters can a SWED, SPERC or SCED be communicated down the supply chain. Modified assessments shall be communicated as standard exposure scenarios without reference to these use map elements.

2.7 Specific Considerations

Most sealants and adhesives are applied at ambient temperature. In the use map this has been set to 30°C for cases where a number is required by the tool. If the tool allows ambient temperature, this should be used instead.

If a parameter from the Use-map files is not available in the applied tool, then the closest condition in the direction of the worst case can be used. E.g., if 95% effectiveness for an RMM is not available, it can be set to 90%.

Dustiness is not specified in the Use Map because it is a substance property. In cases of adhesives and sealants provided in solid form (usually powders), the Use Map provides the physical form 'Solid (unspecified dustiness)'. This can be adjusted to the substance assessed, where applicable.

3. Guidance for Formulators of Adhesives and Sealants

3.1 General Step by Step Procedure

1. Independent of any substance, the formulator has first to study the FEICA use map Excel file and to assign to each of his products the use(s) for which the product is intended. For this task specifically the description of use in column G and the additional information in the last 2 (consumers) or 3 (industrial and professional workers) columns are useful.
2. Once all this has been established, the related SWED, SCED and SPERC codes must be noted for each product.
3. Next it needs to be checked whether the conditions of use that FEICA has assigned to the SWEDs also apply for the application of the own product. In the SWED Excel table it is necessary to run down all the rows for each SWED and verify that the information applies also to the given product. This step is not necessary for SPERCs and SCEDs.
This three-step preparatory work must be done for all hazardous products in the portfolio.
4. Now the substance exposure scenarios of each hazardous ingredient come into play. If the SWEDs, SPERCs and SCEDs defined above are assessed and their codes listed, the substance is safe in the product
 - a. for SWEDs up to the lowest concentration given for each of the SWED codes, and
 - b. generally, for end-use SPERCs and for consumer SCEDs.
5. The SUMI(s) corresponding to the SWED(s) can be attached to the safety data sheet.

Because this whole process is basically a check mark procedure, it can be easily implemented in software for automated processing.

Step 1

Assume a 1-component solvent-free adhesive that is sold in drums to industrial customers for automated application and in cartridges to professional customers for indoor repair jobs. The industrial customer may also have repair facilities and a small volume series where it is using cartridges. The adhesive in all cases is applied as a bead, which is compressed when the two parts are joined and thereby enclosed between the parts. All operations are performed at room temperature.

When this information is compared with the descriptions in the FEICA use map, the following industrial uses apply:

- FEICA_IS_004 (Industrial application of reactive adhesives)
- FEICA_IS_006 (Industrial small-scale application of adhesives)

For professionals the following use fits best:

- FEICA_PW_006 (Professional small-scale application of reactive adhesives and sealants)

Step 2

In our case an ingredient of this adhesive must be assessed against these SWEDs:

From use FEICA_IS_004 FEICA SWED IS_8b_i-a
 FEICA SWED IS_10_i-a

From use FEICA_IS_006 FEICA SWED IS_10_i-d
 From use FEICA_PW_006 FEICA SWED PW_10_i-a

For assessment of volatile substances (b.p. > 250 °C) these SPERCs:

From the industrial uses FEICA SPERC 4.2b
 From the professional use FEICA SPERC 8a.3

For assessment of non-volatile substances (b.p. < 250 °C) these SPERCs:

From the industrial uses FEICA SPERC 5.1a
 From the professional use FEICA SPERC 8c.3

Step 3

Now open the FEICA SWED table and check whether all conditions (e.g., temperature, task duration or protective equipment in use) in the column for FEICA SWED IS_8b_i-a can be met in the typical application of the given product or are exceeded towards higher protection. If this should not be the case, it is necessary to go back to step 1 and find a more suitable FEICA use, or ultimately the product must be assessed outside of the FEICA use map.

Repeat this for all 4 SWEDs that have been identified in step 2.

Step 4

Ideally all hazardous raw materials used in the given product have their exposure scenarios assessed on the basis of the FEICA use map. It is necessary only to find the FEICA uses identified in step 1 in the Annex to the SDS and check them for the presence of the SWEDs and SPERCs as identified in step 2. An exposure scenario generated by CHESAR (version 3.5 and higher) does indicate the SWEDs and SPERCs in its title section, e.g.:

17. ES 17: Widespread use by professional workers; Adhesives, Sealants (PC 1); small scale application of reactive adhesives and sealants¶

17.1. Title section¶

ES name: *Professional small scale application of reactive adhesives and sealants*¶

Product category: Adhesives, Sealants (PC 1)¶

Environment □	□	SPERC□	⌘
1: <i>Widespread use of volatile substances in adhesives / sealants - indoor</i> □	ERC 8a□	FEICA SPERC 8a.3.v3□	⌘
2: <i>Widespread use of volatile substances in adhesives / sealants and construction chemical products - outdoor</i> □	ERC 8d□	FEICA / EFCC SPERC 8d.1a.v2□	⌘
Worker □	□	SWED□	⌘
3: <i>Professional small scale indoor use of adhesives, sealants or primers by low energy spreading</i> □	PROC 10□	FEICA SWED PW_10_i-a□	⌘
4: <i>Professional small scale outdoor use of adhesives, sealants or primers by low energy spreading</i> □	PROC 10□	FEICA SWED PW_10_o-a□	⌘

In this example we have a volatile substance, and FEICA SPERC 8a.3 was assessed. Also, FEICA SWED PW_10_i-a was assessed. For a SWED it is necessary to check the maximum allowed concentration in the details of the exposure scenario and verify that the concentration of the

ingredient in the adhesive does not exceed this maximum. For the SPERCs the presence of an assessment with RCR <1 is sufficient.

This must be repeated for all the identified uses.

Step 5

Finally, the FEICA SUMIs are selected and attached as an annex to the SDS. Alternatively, the content of the SUMI can be included in the main body of the SDS.

FEICA SWED IS_8b_i-a	->	FEICA SUMI IS_8b-a
FEICA SWED IS_10_i-a	->	FEICA SUMI IS_10_i-a
FEICA SWED IS_10_i-d	->	FEICA SUMI IS_10_i-d
FEICA SWED PW_10_i-a	->	FEICA SUMI PW_10_i-a

3.2 Environmental Assessment (SPERC)

For environmental assessments it is necessary to differentiate mainly between widespread and site-specific uses. Widespread use is characteristic for professional and consumer uses. Their safe use assessment is based on generic tonnages from the registrant. Site-specific uses, like formulation and Industrial uses, on the other hand, follow specific assessments. Here, the releases of substances into the environment are generally concentrated to a few spots in a region and tolerable levels are assessed at a local level.

While the safe use during formulation can be derived directly from the registrant's information (eSDS), the safe use information for end uses is derived from a summary of several substance-specific use assessments. In all cases FEICA introduces a simple and straight forward way to assess and communicate the safe use of either substances (formulation) or mixtures (end uses), respectively.

Environmental requirements for formulators:

- For substances the maximum tolerable quantity shall be communicated from the registrant. In such cases the environmental contributing scenario in the eSDS should list the individual SPERCs that were applied and a tonnage value that is specified as M_{safe}. This substance use amount (in kg/d) is the maximum tonnage that can be used safely at a local level according to the practice as described by the SPERC factsheet. The formulator who receives the M_{safe} value from his registrant must ensure that this use amount shall not be exceeded during formulation of the respective end products.

Environmental requirements for professional and consumer uses

- In professional and consumer uses the potential environmental releases occur evenly across large areas. Therefore, an assessment of the overall tonnage following the SPERC parameters can sufficiently indicate the safe use per region. In FEICA's widespread SPERCs, the end users do not need to consider any specific precautions beyond the general good practice of chemical handling, e.g., disposal according to waste regulations. Therefore, once the product ingredients have been assessed for the corresponding use in the use map, a safe use is considered for the product by default.

Environmental requirements for industrial uses

- In a way similar to that of the formulation assessment, the industrial use of substances is based on site-specific assessments that may ultimately lead to different M_{safe} values per product ingredient. However, a product that contains several ingredients with different M_{safe} values is complex to communicate downstream to industrial users. An industrial end user would not be able to make a comparison with real site tonnages, e.g., where substances may be applied by different products at the same time. Therefore, FEICA conducted a study with conservative use assumptions on the environmentally most hazardous substances applied in industrial use. In this study, 23 commonly used ingredients were assessed according to the default SPERC scenarios to be safe for the environment. Because the substances were collected for the most severe hazard profile, the assessed information can be used as a read for other substances. Hence SUMIs based on this study are provided to formulators to guide the safe use of their products by their industrial end users.

3.3 Uses for Industrial and Professional Workers (SWED)

If the workers' assessment is based on a FEICA SWED for all ingredients that are classified under CLP, the corresponding SUMI is simply assigned and attached to the product's SDS. Should some of the hazardous ingredients not be covered by SWED-based assessments but rather by an individual assessment of the registrant, three options remain:

- If the individual parameters of the exposure scenario match those of the SWED or are less stringent, the SUMI can then still be used.
- A SWED-based assessment should be requested from the supplier of this substance. If it does not provide one, a use-map-based approach is not possible.
- Another option involves the ECHA guidance for downstream users.

3.4 Consumer Uses (SCED)

Consumers receive relevant information only through the label without an SDS. Therefore, SUMIs do not apply here. If the following requirements are fulfilled, the product can be sold for consumer use:

- the type of adhesive (product category PC1_01/02/03 or 04) is assessed in an exposure scenario for each (hazardous) substance in the consumer product
 - for consumer use, preferably but not necessarily based on a FEICA SCED,
 - for the environment, preferably based on a FEICA SPERC

This is without prejudice to any other applicable consumer regulation or requirement.

3.5 Communication to End Users (SUMI)

Purpose of the SUMI

A SUMI (Safe Use of Mixture Information) allows a formulator to communicate safe use information for the mixture to the end user. A SUMI is oriented on use and it is not specific for a product; it is linked to a SWED. It is not applicable outside of the context of REACH risk assessments.

SUMIs provide the 'product's safe use information' in a simplified and tailored manner to better understand and adopt any necessary measures. Therefore, information from the SUMIs can be used by employers to develop the workplace instructions as it complements the occupational safety and health requirements and also the information provided on the product's label and Safety Data

Sheet (SDS). However, the employer remains responsible for communicating any other relevant safety information to its employees.

The SUMI must be appended to the SDS or can be integrated within the main body of the SDS. A SUMI contains:

- A general description of the process covered
- Operational conditions
- Risk management measures
- Additional good practice advice
- The disclaimer

Where can a SUMI be used?

Information for safe use of a mixture is mandatory when an SDS is required. A SUMI is intended only for classified products; it is not required for:

- Non-classified products, including products not classified but with supplemental labeling information like an EUH phrase
- Products classified only for physical effects

SUMIs are not intended for safe use communication of mixtures in the middle of the supply chain, where the mixture is used in the formulation of another mixture. The applicable exposure scenarios of the relevant substances in the mixture, preferably based on SWEDs, might be a better option in this case.

SUMI vs SDS

A SUMI does not replace an SDS. The SDS contains product specific information (classification, physico-chemical data, specification on PPE...) while a SUMI is specific to a use.

In some cases, more than one SUMI can be integrated into or attached to an SDS.

The SUMI must be provided in the same language as the SDS.

4. References

ECHA Use-map Library

<https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library>

DUCC documents on use maps and SUMIs

<https://www.ducc.eu/Publications.aspx>

FEICA Industry Guidelines

<https://www.feica.eu/information-center/industry-guidelines>

ECHA Guidance on Information Requirements and Chemical Safety Assessment

<https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

ECETOC 2014. ECETOC Targeted Risk Assessment Tool Update to TRAv3.1
(<http://www.ecetoc.org/tools/targeted-risk-assessment-tra/>)

FEICA (2016) FEICA Guidance Paper - FEICA Specific Consumer Exposure Determinants (SCEDs)
(<http://www.feica.eu/cust/documentrequest.aspx?DocID=1405>)

5. Contact

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