FEICA The European voice of the **adhesive** and **sealant industry**

Brussels, January 2018

FEICA Specific Consumer Exposure Determinants (SCEDs)

FEICA, the Association of the European Adhesive & Sealant Industry, is a multinational association representing the European Adhesive and Sealant Industry. With the support of its national associations and several direct and affiliated members, FEICA coordinates, represents and advocates the common interests of our industry throughout Europe. In this regard, FEICA aims at establishing to establish a constructive dialogue with legislators in order to act as a reliable partner and create a mutually beneficial economic and legislative environment.

Contents

NOTE: This document, published in 2018, adapts the field "Frequency over a year" - as agreed by the DUCC/Concawe TF[1] to reflect the numerical value instead of the former frequency bands (i.e. the drop-down menu). This minor change aims to provide SCEDs users more detailed information on annual use frequency and also flexibility on their risk assessment methodologies. The references to the additional SCEDs for children glue have been deleted, as this this work has not been started.

[1] Revised SCED template

1. Introduction

Under REACH, companies have the responsibility of both collecting information on the substances they manufacture, and making an assessment of the hazards and potential risks from such substances. Therefore, in order to assess the exposure to the chemicals present in consumer products, registrants need information not only about the exposure and physicochemical properties of the chemical concerned, but also on the product's use patterns. The information on the safe use will be then documented, and communicated via the Chemical Safety Report (to the authorities) and the extended Safety Data Sheets (down the supply chain).

Consumer products exist in different forms and types, and have different uses (varying in the duration and frequency), and therefore also different associated Exposure Scenarios. In consequence, when identifying the use scenarios, it is important to consider these differences in the usage pattern and consumer behaviour to *realistically* characterise the consumers' exposures and risks.

Downstream Users (e.g. formulators) know how their products are commonly used by consumers. Since this information can contribute to the REACH exposure assessment and related communication, a joint-industry action was initiated within area 2 of the Chemical Safety Report/Exposure Scenario roadmap (hereinafter CSR/ES roadmap). FEICA – together with the Downstream Users of Chemicals Co-ordination group (DUCC) and CONCAWE (refining industry) – participated in the so-called "SCEDs project" to build the exposure inputs of common uses of adhesives and sealants products.

This document, prepared by the FEICA Exposure Scenario Task Force, provides the available FEICA's SCEDs in the harmonised template. Their values/determinants represent a consensus view of the adhesive and sealant industry on how the products they represent are used in Europe.

2. Meaning of the SCEDs

Sector-Specific Consumer Exposure Determinants (SCEDs) are sets of *realistic* exposure determinants that aim to facilitate the estimation of chemical exposure arising from the use of consumer products.

They were developed to provide "information input" into the registrant's consumer exposure assessment, by means of documenting the typical conditions of use for the substance incorporated into a specific consumer product. In this regard, the information they contain includes values on the product characteristics (e.g. concentration, physical form) and associated consumer habits and practices (e.g. amount used, frequency of use and place of use), all expressed in a form that can be directly fed into the commonly applied exposure assessment tools – e.g. CHESAR, TRA (V3.1).

All exposure determinants related to a given use are compiled together in the form of a **"SCED factsheet"**, which has a **standardised template** to facilitate the harmonisation and communication of safe use through the supply chain (see Annex I).

Information on the use of the SCEDs for consumer exposure assessments is available in the specific DUCC/Concawe guidance, published in 2014 within the framework of the "CSR/ES Roadmap".

3. Scope of the SCEDs

As indicated above, the SCEDs have been developed to transparently document the way the products, they cover are commonly used by consumers. Therefore, they **describe typical habits and practices of consumer products**, and are not substance-specific.

The SCEDs **cover direct uses** of consumer products or articles (but not secondary or accidental exposures). They address use conditions relevant for systemic repeated or continuous exposure (long-term DNEL).

The data source for the determinants provided within the SCEDs is mainly the well-known Tier II software tool ConsExpo 4.1. It contains defaults for models, as well as default parameter values compiled for a number of types of products - including adhesives and sealants. Exposure information is provided in so-called fact sheets (here: RIVM report 320104007 for do-it-yourself products). Whereas most values remained unchanged (e.g. frequency of use), some of the original RIVM values had to be proportionately adapted to the ECETOC TRA defaults (e.g. the default room volume of 10 m^3).

Each determinant within the SCED factsheet is further substantiated by suitable in-house information sources and they reflect the areas with the **highest uses/exposure conditions** in those cases where habits and practices vary across European countries.

The SCEDs were primarily designed to be used in CHESAR and ECETOC TRA v3.1, and thus are subject to this tools' underlying science, assumptions, and limitations. However, it is also possible to use the SCED information in other REACH consumer models.

It is important to note that whilst SCEDs are designed for **refinement of tier 1 REACH exposure** assessment (by providing information on the determinants used in an exposure assessment), they **do not affect the algorithm** inherent to the exposure model.

It is the responsibility of the **SCEDs users** to identify the appropriate product category.

4. FEICA SCEDs

The four FEICA SCEDs correspond to wider product sub-categories, and have the following characteristics:

- **FEICA PC1_1** (Universal glues) represents exposure situations that are characterised by low or medium amounts, small or moderate size surfaces, and a high frequency of use (examples: tube glue, universal hobby glue, wood glue, construction glue)

- **FEICA PC1_2** (Glues DIY-use) represents exposure situations that are characterised by high amounts, large surfaces, low frequency of use (examples: carpet glue, tile glue, wood parquet glue)

- **FEICA PC1_3** (Spray Glues) represents exposure situations where aerosols are formed that can be inhaled. An example would be the gluing of a poster to a wall or door.

- **FEICA PC1_4** (Joint sealants) represents exposure during sealing off long small gaps to obtain an air- and water-tight joint (examples: joint sealants delivered in cartridges)

It is to be noted that in the SCEDs, all determinants are predefined, with the exception of the concentration of the substance in the product, which has to be selected by the risk assessor.

The values of the determinants provided in the factsheet are to be used directly in the assessment tools (e.g. TRA V3.1, CHESAR). An explanatory note, with the rationale for the chosen values of each FEICA SCED, is provided in the FEICA supporting document.

5. Glossary

AC:	Article Category
CHESAR:	ECHA's Chemical Safety Assessment and Reporting tool
Concawe:	The oil companies' EU association for environment, health & safety in refining and distribution
CSA:	Chemical Safety Assessment
CSR:	Chemical Safety Report
DNEL:	Derived No Effect Level
DUCC:	Downstream Users of Chemicals Coordination Group
ECETOC:	European Centre for Ecotoxicology and Toxicology of Chemicals
ENES:	Exchange Network on Exposure Scenarios
ES:	Exposure Scenario
OC:	Operational Conditions
PC:	Product Category
RIVM:	Dutch National Institute for Public Health and the Environment
(ext-)SDS:	(extended) Safety Data Sheet
TRA:	Targeted Risk Assessment

6. References

FEICA survey – supporting paper: http://www.feica.eu/our-priorities/key-projects/reach.aspx

Revised SCEDs Template and guidance: http://www.ducc.eu/News.aspx#news5

How to use the SCEDs for chemical exposure assessment under REACH – Guidance for SCEDs users: http://www.ducc.eu/documents/20140424-Guidance%20documents%20on%20SCEDs-Final-V1.pdf

Exchange Network on Exposure Scenarios (ENES): http://echa.europa.eu/en/about-us/exchange-network-on-exposure-scenarios

Workshop on SCEDs - Summary report: http://echa.europa.eu/documents/10162/15669641/csr_es_roadmap_event_report_sced_en.pdf

Chemical Safety Report/Exposure Scenario roadmap: http://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap

CHEmical Safety Assessment and Reporting tool (CHESAR): https://chesar.echa.europa.eu/

ECETOC Targeted Risk Assessment (TRA): http://www.ecetoc.org/tra // **TRA - Technical Report 124**

ConsExpo Factsheets: http://www.rivm.nl/en/Topics/C/ConsExpo

ECHA Guidance on Information Requirements and Chemical Safety Assessment: http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Existing Default Values and Recommendations for Exposure Assessment: Norden Group

OECD Activities on Exposure Assessment: http://www.oecd.org/chemicalsafety/risk-assessment/oecdactivitiesonexposureassessment.htm

BfR Guidelines on Uncertainty Analysis in Exposure Assessments http://www.bfr.bund.de/cm/350/guidelines-on-uncertainty-analysis-in-exposure-assessments.pdf

US EPA Guidelines for Exposure Assessment: http://www.epa.gov/risk/guidelines-exposure-assessment

Eurostat: http://ec.europa.eu/eurostat/help/new-eurostat-website

7. Contact

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Publication reference: GUP-EX-H01-002

8. Annex I – FEICA's SCEDs

Specific Consumer Exposure Determinants ("SCEDS")

Products/activities covered by the SCED:

The SCED's data refers to regular glues or glues for hobby use, usually applied on *small surfaces*.

Applicability of the SCED (depending on substances properties):

The glues are used to perform small tasks, like gluing two small objects together. These glues are characterised by small amounts of product and frequent use.

Exposure Descriptor or Determinant	Value and [ESCOM phrase Code]
SCED characteristics	
Name of the SCEDs	**Universal Glues**
PC/AC descriptor	PC 1_01
SCED code	FEICA_SCED_1_01_a_v1
Code of other related SCED	n.a
Author	FEICA
Source of SCED	Website: http://www.feica.eu
Physical form of the product	Liquids
User characteristics	
Adult/child assumed	Product used by adult (defaults based upon adult exposure factors)
Common parameters	
Concentration of substance in mixture (g/g)	
Explanations	
Frequency of use over a day (event/day)	1
Rationale	Market surveillance data, survey on consumer habits & uses
Frequency of use over a year	Frequent (default)[1] 55
Rationale	RIVM report 320104007: 0,15 /day (Do-It-Yourself Products Fact Sheet p. 35 - 37; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses;
Dermal Specific Parameters	
Exposure via dermal route	Yes
Rationale	
Skin Contact Area	Two fingertips
Dermal transfer factor	0,1
Rationale	Substances included into or onto a hardened adhesive matrix cannot easily penetrate through the surface layer anymore to get in contact with the skin. Following the Stokes-Einstein equation, diffusion of molecules in liquids is controlled by temperature and viscosity. The latter is a function of the molecular weight of the matrix (ca. 10 000 g/mol in the beginning of the hardening process). During the curing process, that typically takes place within a few minutes, the mean free length of path for molecules decreases while the medium molecular weight of the matrix increases. A value of 10% is conservative and does not take into account the fact that only few chemicals have skin penetration rates > 5%.

[1] Event occurs at least weekly

Exposure Descriptor or Determinant	Value and [ESCOM phrase Code]
Inhalation Specific Parameters	
Exposure via inhalation route	Yes
Rationale	
Spray application?	No
Amount of Product used per application (g/event)	Covers use up to 9 g/event
Rationale	RIVM report 320104007 (Do-It-Yourself Products Fact Sheet p. 35 - 37; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses
Exposure Time per event (hr)	4
Rationale	RIVM report 320104007 (Do-It-Yourself Products Fact Sheet p. 35 - 37; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses
Inhalation transfer factor	1
Rationale	
Place of use	Indoor
Oral Specific Parameters	
Exposure via oral route	Oral exposure not foreseen
Rationale	Post-market surveillance;
Volume swallowed (cm3)	
Rationale	
Oral transfer Factor	
Rationale	

Specific Consumer Exposure Determinants ("SCEDs")

Products/activities covered by the SCED:
The SCED's data refers to DIY-Glues for *large surfaces*.

Applicability of the SCED (depending on substances properties):
The DIY-glues covered by this factsheet are used to perform large gluing tasks (e.g. carpet glue, tile glue, wood parquet glue). These glues are characterised by high amounts of product and low use frequencies.

Exposure Descriptor or Determinant	Value and [ESCOM phrase Code]
SCED characteristics	
Name of the SCEDs	**Glues DIY-use**
PC/AC descriptor	PC 1_02
SCED code	FEICA_SCED_1_02_a_v1
Code of other related SCED	n.a.
Author	FEICA
Source of SCED	Website: http://www.feica.eu
Physical form of the product	Liquids
User characteristics	
Adult/child assumed	Product used by adult (defaults based upon adult exposure factors)
Common parameters	
Concentration of substance in mixture (g/g)	
Explanations	
Frequency of use over a day (event/day)	1
Rationale	Market surveillance data, survey on consumer habits & uses
Frequency of use over a year	Very Infrequent[2] 0.5
Rationale	RIVM report 320104007: 1 / 2-8 year (Do-It-Yourself Products Fact Sheet p. 42 - 53; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses
Dermal Specific Parameters	
Exposure via dermal route	Yes
Rationale	
Skin Contact Area	Palm of hands
Dermal transfer factor	0.1
Rationale	Substances included into or onto a hardened adhesive matrix cannot easily penetrate through the surface layer anymore to get in contact with the skin. Following the Stokes-Einstein equation, diffusion of molecules in liquids is controlled by temperature and viscosity. The latter is a function of the molecular weight of the matrix (ca. 10 000 g/mol in the beginning of the hardening process). During the curing process, that typically takes place within a few minutes, the mean free length of path for molecules decreases while the medium molecular weight of the matrix increases. A value of 10% is conservative and does not take into account the fact that only few chemicals have skin penetration rates > 5%.

[2] Event occurs no more than every 6 months

Exposure Descriptor or Determinant	Value and [ESCOM phrase Code]
Inhalation Specific Parameters	
Exposure via inhalation route	Yes
Rationale	
Spray application?	No
Amount of Product used per application (g/event)	Covers use up to 7 600 g/event
Rationale	Rule of proportion for 22 000 gram parquet glue in 58 and 20 m^3, respectively. RIVM report 320104007 (Do-It-Yourself Products Fact Sheet p. 42 - 53; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses
Exposure Time per event (hr)	6
Rationale	RIVM report 320104007 (Do-It-Yourself Products Fact Sheet p. 42 - 53; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses
Inhalation transfer factor	1
Rationale	
Place of use	Indoor
Oral Specific Parameters	
Exposure via oral route	Oral exposure not foreseen
Rationale	Post-marketing surveillance experience;
Volume swallowed (cm3)	
Rationale	
Oral transfer Factor	
Rationale	

Specific Consumer Exposure Determinants ("SCEDs")

Products/activities covered by the SCED:
The SCED's data refers to glues available in the *form of a spray*, used to glue light objects to solid substrates (e.g. gluing a poster to a wall or door)

Applicability of the SCED (depending on substances properties):
The spray gluing tasks are not often performed

Exposure Descriptor or Determinant	Value and [ESCOM phrase Code]
SCED characteristics	
Name of the SCEDs	**Spray glues**
PC/AC descriptor	PC 1_03
SCED code	FEICA_SCED_1_03_a_v1
Code of other related SCED	n.a.
Author	FEICA
Source of SCED	Website: http://www.feica.eu
Physical form of the product	Liquids
User characteristics	
Adult/child assumed	Product used by adult (defaults based upon adult exposure factors)
Common parameters	
Concentration of substance in mixture (g/g)	
Explanations	
Frequency of use over a day (event/day)	1
Rationale	Market surveillance data; survey on consumer habits & uses
Frequency of use over a year	Occasional[3] 12
Rationale	RIVM report 320104007: 1 / month (Do-It-Yourself Products Fact Sheet p. 55 - 56; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses.
Dermal Specific Parameters	
Exposure via dermal route	Yes
Rationale	
Skin Contact Area	Fingertips
Dermal transfer factor	0.1
Rationale	Substances included into or onto a hardened adhesive matrix cannot easily penetrate through the surface layer anymore to get in contact with the skin. Following the Stokes-Einstein equation, diffusion of molecules in liquids is controlled by temperature and viscosity. The latter is a function of the molecular weight of the matrix (ca. 10 000 g/mol in the beginning of the hardening process). During the curing process, that typically takes place within a few minutes, the mean free length of path for molecules decreases while the medium molecular weight of the matrix increases. A value of 10% is conservative and does not take into account the fact that only few chemicals have skin penetration rates > 5%.

[3] Event occurs less than weekly but less than once a month

Exposure Descriptor or Determinant	Value and [ESCOM phrase Code]
Inhalation Specific Parameters	
Exposure via inhalation route	Yes
Rationale	
Spray application?	Yes
Amount of Product used per application (g/event)	Covers use up to 128 g/event
Rationale	Gluing a poster to a wall or door, or into a frame. The glue is applied on one surface. RIVM report 320104007 (Do-It-Yourself Products Fact Sheet p. 55 - 56; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses.
Exposure Time per event (hr)	4
Rationale	RIVM report 320104007 (Do-It-Yourself Products Fact Sheet p. 55 - 56; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses.
Inhalation transfer factor	1
Rationale	
Place of use	Indoor
Oral Specific Parameters	
Exposure via oral route	Oral exposure not foreseen
Rationale	Post-marketing surveillance experience;
Volume swallowed (cm3)	
Rationale	
Oral transfer Factor	
Rationale	

Specific Consumer Exposure Determinants ("SCEDs")

Products/activities covered by the SCED:
The SCED's data refers to 'joint sealants', used to fill and seal joints or openings between two or more substrates

Applicability of the SCED (depending on substances properties):
Joint sealants are usually not used for large surfaces, but for long joints with small diameters

Exposure Descriptor or Determinant	Value and [ESCOM phrase Code]
SCED characteristics	
Name of the SCEDs	**Joint sealants**
PC/AC descriptor	PC 1_04
SCED code	FEICA_SCED_1_04_a_v1
Code of other related SCED	n.a.
Author	FEICA
Source of SCED	Website: http://www.feica.eu
Physical form of the product	Liquids
User characteristics	
Adult/child assumed	Product used by adult (defaults based upon adult exposure factors)
Common parameters	
Concentration of substance in mixture (g/g)	
Explanations	
Frequency of use over a day (event/day)	1
Rationale	Market surveillance data; survey on consumer habits & uses
Frequency of use over a year	Very Infrequent[4] 3
Rationale	RIVM report 320104007: 3 /year (Do-It-Yourself Products Fact Sheet p. 57-61; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses.
Dermal Specific Parameters	
Exposure via dermal route	Yes
Rationale	
Skin Contact Area	Two fingertips
Dermal transfer factor	0.1
Rationale	Substances included into or onto a hardened sealant matrix cannot easily penetrate through the surface layer anymore to get in contact with the skin. Following the Stokes-Einstein equation, diffusion of molecules in liquids is controlled by temperature and viscosity. The latter is a function of the molecular weight of the matrix (ca. 10 000 g/mol in the beginning of the hardening process). During the curing process, that typically takes place within a few minutes, the mean free length of path for molecules decreases while the medium molecular weight of the matrix increases. A value of 10% is conservative and does not take into account the fact that only few chemicals have skin penetration rates > 5%.

[4] Event occurs no more than every 6 months

Exposure Descriptor or Determinant	Value and [ESCOM phrase Code]
Inhalation Specific Parameters	
Exposure via inhalation route	Yes
Rationale	
Spray application?	No
Amount of Product used per application (g/event)	Covers use up to 150 g/event
Rationale	Rule of proportion for 75 gram in 10 and 20 m3, respectively (RIVM report 320104007 - Do-It-Yourself Products Fact Sheet p. 57-61; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses.
Exposure Time per event (hr)	0,75
Rationale	RIVM report 320104007 (Do-It-Yourself Products Fact Sheet p. 57-61; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses.
Inhalation transfer factor	1
Rationale	Rule of proportion for 75 gram in 10 and 20 m3, respectively (RIVM report 320104007 - Do-It-Yourself Products Fact Sheet p. 57-61; W. ter Burg, H.J. Bremmer, J.G.M van Engelen); survey on consumer habits & uses.
Place of use	Indoor
Oral Specific Parameters	
Exposure via oral route	Oral exposure not foreseen
Rationale	Post-marketing surveillance experience;
Volume swallowed (cm3)	
Rationale	
Oral transfer Factor	
Rationale	