

SCED-based exposure scenarios for CSR and for extended safety data sheets

Introduction to an example generated by Chesar

1. The SCED factsheet template developed by industry

The factsheet in Annex 1 exemplifies how the SCED harmonised template can be used to compile a set of input information for the exposure assessment under REACH. The following types of information can be entered into the template:

Applicability of the SCED

- Products/activities covered by the SCED
- Applicability of the SCED (depending on substances properties)

SCED characteristics

- Name of the SCEDs
- PC/AC descriptor
- SCED code
- Code of other related SCED
- Author
- Source of SCED
- Physical form of the product

User characteristics

- Adult or child use covered

Common parameters

- Concentration of substance in mixture
- Frequency of use over a day
- Frequency of use over a year (for infrequent uses)

Dermal Specific Parameters

- Explanations if dermal exposure is not considered , because "No dermal contact is foreseen" or if "Dermal exposure assumed to be negligible"
- Body parts potentially exposed
- Dermal transfer factor, reflecting evidence of more limited transfer from product to skin surface than predicted by the model defaults

Inhalation Specific Parameters

- Explanations if inhalation exposure is not considered, because "inhalation exposure estimated to be negligible"
- Spray application (yes/no)
- Amount of Product used per application
- Exposure time resulting from application
- Inhalation transfer factor, reflecting limited availability of the used amount to cause exposure via inhalation
- Place of use (Indoor/Outdoor)

Specific Consumer Exposure Determinants (SCEDs)

Oral Specific Parameters

- Explanations if oral exposure is not considered, because "oral exposure not foreseen"
- Volume of product swallowed
- Oral transfer factor, reflecting evidence of more limited transfer from article surface to mouth than predicted by the model defaults

FEICA has worked out a set of information describing the conditions of use for substances contained in hobby glues (see Annex 1)

2. SCEDs in Chesar

Chesar version 2.3 will enable the use of SCEDs in the exposure assessment of consumer uses. The exposure estimates are generated by ECETOC TRA v3.1. embedded in Chesar.

When assessing a consumer contributing scenario in Chesar, an assessor will have the possibility to select ECETOC TRA v3.1 for the exposure assessment, and to select the relevant SCED if previously imported in its Chesar library¹. As a consequence:

- All the input parameters that are used by ECETOC TRA 3.1 are automatically fed in from the SCED to enable the calculation of exposure estimates for the 3 exposure routes. Only the concentration of the substance in the product can be modified by the assessor as this may vary for example depending on the the substance function in the product (e.g. additive compared to solvent). The substance properties relevant for the assessment are sourced from the IUCLID dataset and fed into the TRA via Chesar.
- The explanations (rational) related to the various parameters provided in the SCED are conveyed to the ES for the CSR to support the understanding by the readers of the CSR (e.g. ECHA or member state authorities)
- The relevant parameters are automatically conveyed to the ES for the SDS in the form of an ECom standard phrase².

3. Example of Exposure Scenarios for the CSR and for communication

The Exposure Scenarios for the CSR (Annex 2) and for the extended Safety Data Sheet (Annex 3) have been generated by running a consumer exposure assessment with ECETOC TRA v3.1 in Chesar, using the information contained in the SCED fact sheets provided by FEICA: "Universal Glues Hobby Use" (Annex 1).

It was assumed that the substance is an additive in glue with a concentration of 0.05 g/g and the following properties:

- Molecular weight: 300 g/mol
- Vapour pressure: 7.8 Pa at 20C

The following DNELs for General Population were used to derive a Risk Characterisation Ratio:

- Long term systemic for inhalation route: 6.08 mg/m³
- Long term systemic for dermal route: 3.5 mg/kg bw/day
- Long term systemic for oral route: 3.5 mg/kg bw/day

¹ It is expected that industry associations developing SCEDs will make their SCEDs also available in an IT format (XML) that can be imported into Chesar. Chesar supports the generation of the information in such a format. If a SCED factsheet is not available in such a format, it is always possible for any Chesar user to input all the information from the SCED factsheet directly in Chesar.

² ECom can be found on <http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/>

Specific Consumer Exposure Determinants (SCEDs)

Annex 2 is an extract from the full CSR generated by Chesar containing only section 9.1.2. *Consumer contributing scenario 1: Universal Glues Hobby Use (PC 1)*

The Exposure Scenarios for the CSR contains all the conditions of use (determinant for exposure) including the "rationale" reported in italic below the corresponding value of the condition of use.

The exposure estimates and RCR are only reported for those routes and type of effects for which a hazard has been identified (in this case only systemic long term effects). The TRA V.3.1 generates an exposure estimate for the single event. In the current example one event per day and a related exposure duration of 4h is assumed.

Please note

- The content of the examples are fully based on the information provided in the SCED factsheet
- There is possibly still a number of discussion points regarding the information in the fact sheet example, such as the need to be complete in referencing to the source of the information provided and the means to access this information (publication, website, ..).

Annex 3 is an extract from the full annex to the SDS generated by Chesar containing only one ES for the SDS³.

The ES for the extended Safety Data Sheets contains information for those determinants of exposure considered relevant to be communicated. The recipient of the communicated information is the formulator producing the consumer product (not the consumer). For him it is essential to check whether the conditions of use assumed by the registrant (product composition, dosing of product and the assumed habits/practices of consumers) match the characteristics of his product and foreseeable conditions under which it is used by the consumers.

³ For the ES for communication 2 versions have been generated: one with the ES subheadings (a) and one without (b). This is an option in Chesar.

Annex 1 – FEICA SCED Factsheet “Universal Glues Hobby Use” Specific Consumer Exposure Determinants (“SCEDS”)

Products/activities covered by the SCED:

The present SCED provides a set of determinants to assist in the exposure assessment of Universal Hobby Glues

Applicability of the SCED (depending on substances properties):

Two small objects are glued together with 9 g universal glue.

Exposure Descriptor or Determinant	Value
SCED characteristics	
Name of the SCEDs	Universal Glues Hobby Use
PC/AC descriptor	PC 1
SCED code	FEICA_SCED_1_1_a_v1
Code of other related SCED	n.a
Author	FEICA
Source of SCED	Website: http://www.feica.com/
Physical form of the product	Liquids
User characteristics	
Adult/child assumed	Covers adult use
Common parameters	
Concentration of substance in mixture (g/g)	
Explanations	
Frequency of use over a day (event/day)	1
Rationale	Market surveillance data
Frequency of use over a year	Frequent
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)
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. 10000 g/mol in the beginning of the hardening process). During the curing process, that typically takes

Specific Consumer Exposure Determinants (SCEDs)

Exposure Descriptor or Determinant	Value
	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 takes not into account that in addition only few chemicals have skin penetration rates > 5%.
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)
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)
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	

Annex 2 – Exposure scenario for the CSR

9.1.2. Consumer contributing scenario 1: Universal Glues Hobby Use (PC 1)

9.1.2.1. Conditions of use

ECETOC TRA Consumer V. 3.1:Sced used: FEICA_SCED_1_1_a_v1 Universal Glues Hobby Use

	Method
Product (article) characteristics	
• Concentration of substance in mixture: = 0.05 g/g <i>Additive in the glue [information added by the user, not extracted from the SCED]</i>	SCED based
• Exposure via Oral route: Oral exposure is considered to be not relevant <i>Post-market surveillance</i>	SCED based
• Spray: No	SCED based
Amount used, frequency and duration of use/exposure	
• Frequency of use over a year: Frequent <i>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)</i>	SCED based
• Frequency of use over a day: = 1 events/day <i>Market surveillance data</i>	SCED based
• Amount of product used per application: = 9 g/event <i>RIVM report 320104007 - Do-It-Yourself Products Fact Sheet p. 35 - 37; W. ter Burg, H.J. Bremmer, J.G.M van Engelen)</i>	SCED based
• Exposure time: = 4 hr <i>RIVM report 320104007 (Do-It-Yourself Products Fact Sheet p. 35 - 37; W. ter Burg, H.J. Bremmer, J.G.M van Engelen)</i>	SCED based
Measures related to information and behavioural advice to consumers including personal protection and hygiene	
• Adult/Child assumed: Adult	SCED based
• Place of use: Indoor	SCED based
Other conditions affecting consumers exposure	
• Inhalation factor: = 1	SCED based
• Body parts potentially exposed: Two fingertips	SCED based
• Dermal transfer factor: = 0.1 <i>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. 10000 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 takes not into account that in addition only few chemicals have skin penetration rates > 5%.</i>	SCED based

9.1.2.2. Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 1. Exposure concentrations and risks for consumers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
---------------------------------------	------------------------	-----------------------

Specific Consumer Exposure Determinants (SCEDs)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	0.662 mg/m³ (TRA Consumer v3.1)	RCR = 0.109
Dermal, systemic, long-term	0.012 mg/kg bw/day (TRA Consumer v3.1)	RCR < 0.01
Oral, systemic, long-term	0 mg/kg bw/day (TRA Consumer v3.1)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.112

Conclusion on risk characterisation

Annex 3a and b – Exposure scenario for the extended safety data sheet

Annex 3a : Exposure scenario for the extended safety data sheet

1. ES 1: Consumer use; Adhesives, sealants (PC 1)

1.1. Title section

Environment	
CS 1: (Contributing scenario name)	ERC 8c
Consumer	
CS 2: Universal Glues Hobby Use	PC 1

1.2. Conditions of use affecting exposure

1.2.1. Control of environmental exposure: (Contributing scenario name) (ERC 8c)

1.2.2. Control of consumer exposure: Universal Glues Hobby Use (PC 1)

Product (article) characteristics
Limit the substance content in the product to 0.05 g/g
Oral exposure is considered to be not relevant.
No spraying
Amount used, frequency and duration of use/exposure
Covers use up to 1.0 events/day
Covers use up to 9.0 g/event
Measures related to information and behavioural advice to consumers including personal protection and hygiene
Covers adult use
Other conditions affecting consumers exposure
Assumes that potential dermal contact is limited to two fingertips

1.3. Exposure estimation and reference to its source

1.3.1. Environmental release and exposure: Contributing scenario name

1.3.2. Consumer exposure: Universal Glues Hobby Use (PC 1)

SCED used: FEICA_SCED_1_1_a_v1; Universal Glues Hobby Use

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	0.662 mg/m ³ (SCED based)	0.109
Dermal, systemic, long-term	0.012 mg/kg bw/day (SCED based)	< 0.01
Oral, systemic, long-term	0 mg/kg bw/day (SCED based)	< 0.01
Combined routes, systemic, long-term		0.112

1.4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Annex 3b : Exposure scenario for the extended safety data sheet (no headline)

1. ES 1: Consumer use; Adhesives, sealants (PC 1)

1.1. Title section

Environment	
CS 1: (Contributing scenario name)	ERC 8c
Consumer	
CS 2: Universal Glues Hobby Use	PC 1

1.2. Conditions of use affecting exposure

1.2.1. Control of environmental exposure: (Contributing scenario name) (ERC 8c)

1.2.2. Control of consumer exposure: Universal Glues Hobby Use (PC 1)

Limit the substance content in the product to 0.05 g/g
Oral exposure is considered to be not relevant.
No spraying
Covers use up to 1.0 events/day
Covers use up to 9.0 g/event
Covers adult use
Assumes that potential dermal contact is limited to two fingertips

1.3. Exposure estimation and reference to its source

1.3.1. Environmental release and exposure: (Contributing scenario name) (ERC 8c)

1.3.2. Consumer exposure: Universal Glues Hobby Use (PC 1)

SCED used: FEICA_SCED_1_1_a_v1;Universal Glues Hobby Use

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	0.662 mg/m ³ (SCED based)	0.109
Dermal, systemic, long-term	0.012 mg/kg bw/day (SCED based)	< 0.01
Oral, systemic, long-term	0 mg/kg bw/day (SCED based)	< 0.01
Combined routes, systemic, long-term		0.112

1.4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES