Downstream Users of Chemicals Co-ordination group

concawe

SCEDs

Specific Consumer Exposure Determinants

How to use the SCEDs for chemical exposure assessment under REACH – Guidance for SCEDs user

April 2014
DUCC/CONCAWE

Version 1

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Foreword

This guidance is issued by the DUCC/CONCAWE SCEDs Task Force, which provided the project lead for the SCEDs-project.

The objective of the activity was to describe the principles and key considerations underpinning **SCEDs (Specific Consumer Exposure Determinants)** and to develop a library **of SCEDs** that reflect the principle situations of use for consumer chemical products formulated by the involved sectors. The SCEDs are intended to represent realistic assumptions for consumer exposure assessments.

This guidance was developed by **DUCC member associations** representing companies that use chemicals to formulate mixtures as finished products for end users, including consumers and professional users, and by **CONCAWE**, whose members sell formulated consumer products such as fuels and lubricants, as well as manufacture the petroleum substances used in such products. Participant DUCC members are A.I.S.E., CEPE, EFCC, FEA and FEICA. [1]

This document provides guidance **for the use of SCEDs** for consumer exposure assessment, be it by registrants in their chemical safety assessment (CSA) or by downstream users (in case they need to develop their own CSA) or for other REACH processes, as for example evaluation. The Guidance assumes that the user has some expertise in using the ECETOC TRA[2] tool as, at an initial stage, the SCEDs will need to be manually introduced into v3.1 of this tool. It is also planned that the SCEDs will be available for automatic application in Chesar[3] 2.3, the chemical safety assessment tool developed by ECHA. In this respect it needs to be noted that the use of SCEDs must be made according to general risk assessment process described in ECHA "Guidance on Information Requirements and Chemical Safety Assessment (IR/CSA) - Chapter R.15: Consumer Exposure Estimation"[4].

DISCLAIMER: This document has been prepared jointly by DUCC member associations and CONCAWE. It is made freely available to companies as guidance for the use of Specific Consumer Exposure Determinants in the framework of chemical safety assessment. The proposed SCEDS are meant to be applied as a full dataset and cannot cover any deviation. The proposed guidance is offered in utmost good faith and the information it contains is believed to be correct. Its authors do not assume any liability for any inaccuracy or incompleteness found in the content. Neither do they assume liability for any use made of the guidance content or for companies' assessments.

[1] A.I.S.E. : International Association for Soaps, Detergents and Maintenance Products, CEPE: European Council of the Paint, Printing Ink and Artists' Colours Industry, EFCC : The European Federation for Construction Chemicals, FEA: European Aerosol Federation, FEICA: Association of European Adhesive and Sealant Industry

[2] http://www.ecetoc.org/tra

[3] http://chesar.echa.europa.eu/

[4] http://echa.europa.eu/documents/10162/13632/information_requirements_r15_en.pdf

1. Introduction

1.1. Overview of an exposure assessment and risk characterisation

In order to perform a consumer exposure assessment/estimation under REACH, the assessor will need the following information:

- a minimum amount of information on the substance properties
- use(s) description in particular the Product Category (PC) by means of the use descriptor system[5],
- conditions of use: operational conditions and risk management measures (OC/RMM)

The **exposure estimation** is then undertaken using the above mentioned information as input parameters (determinants) in the exposure assessment tool.

The next step will be the **risk characterisation**, which consists of comparing the result of the quantitative exposure assessment with the applicable Derived No-Effect Level (DNEL). The assessor also needs to be in possession of the relevant DNELs – being up to him to define which values are appropriate, considering the relevant route and duration of exposure. When using an exposure assessment tool, the risk characterisation is done "automatically" and "simultaneously" with the exposure assessment. The result will be a given value, the risk characterisation ratio (RCR).

If the RCR is below 1, the assessment can stop as safe use is demonstrated. If the RCR is above 1, the exposure assessment needs to be further refined until the safe use (a RCR of <1) has been achieved.

The result of the exposure assessment demonstrating the safe use of a substance will be reflected in the substance Chemical Safety Report submitted by registrants and subsequently in the exposure scenarios to be annexed to a Safety Data Sheet. More information on Consumer Exposure Assessment can be found the ECHA "Guidance on IR/CSA - Chapter R.15: Consumer Exposure Estimation".

1.2. The SCEDs: what they are and how they relate to an exposure assessment

The **SCEDs (Specific Consumer Exposure Determinants)** are sets of more realistic exposure determinants to be used as "information input" in a consumer exposure assessment. Determinants of exposure are the main input parameters governing the release and exposure as defined in ECHA "Guidance on IR/CSA – Part D: Exposure Scenario Building"[6]. In the context of Chesar[7], a determinant is a condition or measure driving the exposure of a substance to man or environment (e.g. the amount of product used per day by consumer or the frequency of use of a product over the day). In ECETOC TRA v3.1, as in some other assessment tools, the determinants relevant for a particular assessment are pre-defined and built into the tool and thus the assessor only needs to provide appropriate limited number of input values for his case.

[5] http://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf
[6] http://echa.europa.eu/documents/10162/13632/information_requirements_part_d_en.pdf
[7] Chesar manual 6: https://chesar.echa.europa.eu/

The SCEDs document typical conditions of use of consumer products. The conditions of use are expressed in a form that can be fed into the commonly applied exposure assessment tools. This includes sets of determinants related to consumer habits and practises (e.g. quantity of product used, frequency of use, place of use…).

While the SCEDs are initially foreseen for use under ECETOC TRA and Chesar, it is also possible to use the SCED information in other REACH consumer models (such as CONSEXPO[8]).

The SCEDs provide information on the determinants that are used in an exposure assessment; they do not affect the algorithm inherent to the exposure model.

1.3. Scope of the SCEDs

The SCEDs have been developed by sector organisations to transparently document the way that their products are commonly used by consumers. In 2014, the first SCEDs will be made publicly available.

The SCEDs are primarily designed to be used in ECETOC v3.1 and will, for this reason, be subject to the tool's underlying science, assumptions, and limitations. For more information, please refer to the ECETOC Technical Reports No. 93, 107 and 114. The minimum content of the SCEDs addresses exposure determinants for the ECETOC TRAv3.1 consumer module although, as mentioned above, the SCEDs may contain additional information that can be used in other REACH consumer models.

Each determinant within the SCEDs has to be substantiated by reference to suitable information sources that, ideally, are open access and have been published and peer reviewed (the "rationale"). Preferably these determinants will refer to European data sources and/or be already utilised in regulatory processes (within the EU or beyond e.g. EPA, IPCS). The SCEDs are designed so that the resulting exposure scenario as a whole represents conservative conditions of exposure. Where habits and practices significantly vary across European countries/regions, then the SCEDs will reflect those areas with the highest uses/exposure conditions.

The SCEDs are associated with the following characteristics:

- they are designed for refinement of tier 1 REACH exposure assessment;
- they are meant to describe conservative, yet realistic exposure situations. Each individual determinant within a SCED is not necessarily a worst case value.
- they are consistent with the requirements of the ECHA "Guidance on IR/CSA - Chapter R.15: Consumer Exposure Estimation";
- they address use conditions relevant for systemic repeated long term exposure – i.e. they must be reviewed to confirm their relevance for local or acute end points (for example, frequency of use would not be an appropriate factor to modify for an acute assessment);
- they cover the direct uses of consumer products or articles. SCEDs specific to children will only be developed in cases where consumer products are actively marketed for use by children.

[8] http://www.rivm.nl/en/Topics/C/ConsExpo

- they do not cover indirect /secondary exposures or accidental exposures for child/adult (at this stage);
- they describe the use of a product. It is not substance specific; nevertheless, some limitations may apply depending on the substance properties (for example, handling/containment practices may vary depending upon volatility, such as the case for LPG vs. diesel fuels).
- They are, in practice mostly exemplified for formulations.

2. Description of the SCEDs

2.1. Information contained in a SCED factsheet

All exposure determinants related to a given use are compiled together in the form of a 'SCED factsheet'. Therefore, a given sector may develop one or more SCED factsheets.

SCEDs examples are provided in Annex 1. You can download here the empty SCEDs factsheet template: http://www.ducc.eu/Activities.aspx
Each SCED factsheet contains references and determinants as defined below. A short definition of each determinant is provided. More detailed documentation is also available in ECETOC Technical Reports No. 93, 107, 114.

In the SCEDs, all determinants are pre-defined / fixed, except for the concentration of the substance in the product which has to be selected by the assessor.
In the SCEDs, the value of the determinants to be used directly in ECETOC TRA v.3.1 / Chesar is given, the relevant rationale for the chosen value is then provided in the line below. This will include the reference to any data that support the choice of the value, e.g. sector industry data, scientific publication or report.

The SCEDs may contain additional information that can be used in other REACH consumer models; such kind of information is identified in blue text in the SCED factsheet.

The SCEDs will be aligned as far as possible with the ESCOM standard phrases catalogue in order to ease their communication along the supply chain. Relevant ESCOM phrases to be communicated are identified by the corresponding code for each applicable field of the factsheet. They are provided under bracket, an example is given for the standard phrase: "solids" - [11070000317].

The definition of the different SCEDs fields following the SCEDs factsheet structure is provided below.

The SCEDs factsheets start with the coverage and applicability of that particular SCED.

- **Products/activities covered by the SCED:**

Optional information provided to help the user to select the right SCED.

- **Applicability of the SCED (depending on substances properties):**

Optional information provided to help the user to select the right SCED. If the SCED is dependent on substance properties, the limitations will be described here.

Exposure Determinant or Descriptor	Value and [ESCOM phrase Code]
SCED characteristics	
Name of the SCED	The name of the SCED reflects products covered according to sector practices.
PC/AC descriptor	The product category (PC) describes in which types of chemical products (substances as such or in mixtures) the substance is finally contained when it is supplied, in this case to consumers. The article category (AC) describes the type of article into which the substance

Exposure Determinant or Descriptor	Value and [ESCOM phrase Code]
	has eventually been processed.
SCED code	<sector>SCED<PC/AC Code><number><letter><version> <Sector> The sector specifies the entity which is responsible for the content of the SCED. <SCED> To differentiate with other sector activities (SPERC etc…) <PC/AC Code> To assign to which product category it belongs <number> The first number specifies an index number given by the sector <letter> the letter is here to differentiate between the different set of default values that one SCED may contain. <version> version number in order to keep track of any update
Code of other related SCED	n.a. *or* <sector><SCED><PC/AC Code><number><letter><version>
Author	Sector Association name
Source of SCED	Sector Association website where the SCED can be found
Physical form of the product(s)	Assigned from the following possible options: • Solids; [11070000317] as ESCOM phrases example • Liquids; • Gas; • Solids & liquids • Solids & Gas • Liquids & Gas • Solids, Liquids & Gas
User characteristics	
Adult/child assumed	Assigned from the following possible options: • Product used by adult (defaults based upon adult exposure factors) • Product used by child (defaults based upon child exposure factors)
Common Determinants	
Concentration of substance in mixture (g/g)	Numerical (by default the maximum value is 1, corresponding to 100% concentration) Concentration of the substance in the product (mixture), based on product-specific information and or sector specific advice. This is the only parameter that should be selected by the assessor.
Explanations	Substance specific information Free text provided by sector (when available) giving advice on maximum concentration of a substance or family of substances being present in the product. If better/ more specific information is available to the assessor, it should be adapted.
Frequency of use over a day (event/day)	Numerical Number of times per day that a product is used, based on product-specific information.
Rationale	• If value remains unchanged from ECETOC TRA, the SCEDs state: "Unchanged from ECETOC TRA default value".

Exposure Determinant or Descriptor	Value and [ESCOM phrase Code]
	• If value is changed, a rationale must be provided.
Frequency of use over a year	Assigned from the following possible options: • Frequent (default) : event occurs at least once a week • Occasional; event occurs between once a week and once a month • Infrequent; event occurs between once a month and once every 6 months • Very infrequent. Event occurs no more than once in 6 months. Frequency band assigned depending on the number of times per year that the product is used.
Rationale	If different than default value "frequent", a rationale must be provided
Dermal Specific Determinants	
Exposure via dermal route	Assigned from the following possible options: • Yes (default); • Dermal exposure assumed to be negligible • No dermal contact foreseen;
Rationale	If answer different than yes, a rationale is provided
Skin Contact Area	Assigned from the following possible options: • 2 Fingertips • Finger tips (10) • Palm of one hand • Inside of 2 hands/Palm of 2 hands/one Hand • 2 Hands • Hands and forearms • Upper part of the body • Lower part of the body • Whole body except feet, hands and head • Whole body Based on the selected body part, the corresponding skin area (in cm^2) which is exposed to the product will be assigned automatically by ECETOC TRA.
Rationale	• If value remains unchanged from ECETOC TRA, the SCEDs state: "Unchanged from ECETOC TRA default value". • If value is changed, a rationale must be provided.
Dermal transfer factor[9]	Numerical – (by default the value is 1, corresponding to 100% available for exposure) This is the fraction (0 to 1) of the substance transferred from the product to the skin and represents a realistic worst case dose. This parameter is different from the skin absorption (in the SCEDs the skin absorption is always assumed to be 100 %).
Rationale	If different than 1, a rationale must be provided.

[9] For more details on transfer factor, please refer to annex 2

Exposure Determinant or Descriptor	Value and [ESCOM phrase Code]
Inhalation Specific Determinants	
Exposure via inhalation route	Assigned from the following possible options: • Yes (default) • Inhalation exposure assumed to be negligible
Rationale	If answer different than yes, a rationale is provided.
Spray application?	Assigned from the following possible options: • Yes • No
Amount of Product used per application (g/event)	Numerical Amount used, in g, based on product specific information.
Rationale	• If value remains unchanged from ECETOC TRA, the SCEDs state: "Unchanged from ECETOC TRA default value". • If value is changed, a rationale is provided.
Exposure Time per event (h)	Numerical Duration of the exposure, in hour, based on product-specific information and consumer habits.)
Rationale	If value remains unchanged from ECETOC TRA, the SCEDs state: "Unchanged from ECETOC TRA default value". If value is changed, a rationale is provided.
Inhalation transfer factor[10]	Numerical – (by default the value is 1, corresponding to 100% transfer) The inhalation transfer factor (0 to 1) represents the fraction of the substance or product that is released to air during a consumer use.
Rationale	If different than 1, a rationale is provided.
Place of use	Assigned from the following possible options: • Indoor • Outdoor Based on the place of use, the room volume and air change rate per hour are selected automatically according to ECETOC TRA.
Oral Specific Determinants	
Exposure via oral route	Assigned from the following possible options: • Yes (default) • Oral exposure assumed to be negligible
Rationale	If answer different than yes, a rationale must be provided
Volume swallowed (cm3)	Numerical Volume of product per event in contact with the mouth
Rationale	• If value remains unchanged from ECETOC TRA, the SCEDs state: "Unchanged from ECETOC TRA default value". • If value is changed, a rationale is provided.

Exposure Determinant or Descriptor	Value and [ESCOM phrase Code]
Oral transfer Factor[10]	Numerical – (by default the value is 1, corresponding to 100% transfer) Oral transfer factor (0 to 1) represents the fraction of the substance of interest that is likely to be ingested from a product or article during an exposure event.
Rationale	If different than 1, a rationale must be provided.

2.2. Application of the determinants

The application of the information (exposure determinants) within a SCED 'fact sheet' is consistent with the process described in the ECHA "Guidance on IR/CSA - Chapter R.15: Consumer Exposure Estimation" i.e. the information applicable to a tier 1 model (such as the ECETOC TRA) will first be applied to calculate the level of exposure. If risk is considered inappropriate (RCR>1), then the process can proceed by collecting new information to support performing a refined Tier 1 assessment or moving to Tier II or measured data. The SCEDs reflect the first option. SCEDs must cover all relevant routes of exposure for the use. Where a route of exposure is not considered relevant, then the SCED must include a clear (and ideally quantitative) rationale for this. In some cases, 'common sense' is applied (e.g. exposure by oral route in non-accidental circumstances may not be applicable to most product types).

2.3. Appropriate DNELs to be used with SCEDs

The exposure estimates derived from the use of SCEDs are relevant for long term systemic end-points; therefore, when estimating an RCR, the appropriate DNEL to be used is a chronic long term DNEL. While SCEDs may contain information useful for developing exposure estimates for other time periods as well, critical evaluation of the representativeness of the SCEDs elements and parameters would be needed before application to alternate time periods.

2.4. SCEDs developments and determinants representativeness

SCEDs can be developed for any situation where consumer exposures to chemicals are commonly encountered and risks need to be assessed. However, it is for each industry sector to decide whether to develop SCEDs for their sector.

SCEDs are developed by sector organisations. They represent a consensus view of that sector on how the products it represents are/should be used for the EU setting. After having developed the SCEDs, the sector organisation is expected to make it publicly available and to maintain it, enabling its content to be applied when developing consumer CSAs under REACH. DUCC and CONCAWE are willing to make the SCEDs available in a publicly accessible SCED library (See chapter 4.1)

2.5. Update of SCEDs determinants

A SCED should be reviewed on a regular basis and updated if and when appropriate new information is available. In cases where revisions occurred, version of SCEDs will be clearly identifiable by the last digit representing the version number.

3. Incentives and benefits of the SCEDs Project

3.1. ECETOC TRA update (consumer module) and the development of the SCEDs

It has been recognised that one of the potential areas for improvement of the ECETOC TRA v2 was the fact that consumer predictions were often too conservative to be routinely useful for many substance groups under REACH. The reason for this conservatism was twofold: the limited nature of the TRA's algorithms (that reflect those outlined in ECHA "Guidance IR/CSA - Chapter R.14: Occupational Exposure Estimation") and the fact that many of the default exposure determinants derive from worst case situations.

For this reason, the consumer module of ECETOC TRA v3.1 offers the possibility to develop more realistic exposure predictions through the "Add Subcategories" tab. This tab gives the user flexibility to estimate consumer exposure for a specific product(s) of their choice, beyond the current subcategories described in the TRA. This is done through the incorporation of more appropriate or 'specific' exposure determinants, like the SCEDs, where available and justifiable.

Following on from the development of the TRA v3, the discussions between industry and stakeholders on the development of SCEDs highlighted that the ECETOC TRA v3 still represents a conservative exposure representation of reality especially considering that it assumes that every consumer use and exposure takes place on a daily basis. ECETOC has therefore introduced v3.1 of the TRA that enables infrequent consumer uses to be addressed.

This updated version of the TRA has also been incorporated into Chesar v2.3.

The use of the SCEDs will not change the underlying algorithms in the TRA v3.1; the SCEDs simply serve to provide an additional set of refined determinants that can be used in the existing algorithms.

3.2. Expected benefits/improvements from using the SCEDs

The main benefits have been identified as being:

1) Improved tier 1 exposure estimation

   Use of the SCEDs improves the likelihood that the risk assessor will be able to demonstrate safe use, i.e. RCR<1, through a tier 1 assessment.

2) Transparent, freely accessible and well-documented dataset on consumer habits and practices

   The SCED, being available via participating sectors websites in a harmonised format, help transparent communication of consumer habits and practices dataset across supply chains.

   In addition, SCEDs may be useful for authorities that need to perform consumer risk assessment, for example in the course of Substance Evaluation under REACH or if needed for substance Authorisation or Restriction processes.

3) More realistic exposure scenarios for downstream users

The SCEDs will significantly improve the defaults used in the exposure algorithms, leading to more realistic predictions of consumer exposure, while still being conservative. This will benefit both registrants and downstream users (DU), who are more likely to receive an exposure scenario that covers their uses and does not contain impractical risk management measures (e.g. an unrealistic small amount of product for consumer use or too small percentage in the formulation or changes to packaging design). In general, it will avoid the need for unnecessary communication of risk management measures or operational conditions within affected supply chains.

4) Facilitation of Chemical Safety Assessment (CSA)

Particularly in the case of Small and Medium Enterprises (SMEs) with limited access to technical expertise on exposure modelling, more refined exposure estimates can be obtained without having to use more complex (higher tier) models.

5) Standardisation and harmonisation of communication in the supply chain

The SCEDs will also serve to standardise and harmonise the communication of information for the safe use in the supply chain, resulting in efficiency gains in supplier/DU dialogue. They are compatible with the ES format/layout recommended by ECHA.

4. Registrants/Downstream Users using SCEDs

4.1. Where to find the SCEDs

The relevant SCED are or will be available on the websites of the participating DUCC members (A.I.S.E., CEPE, EFCC, FEA and FEICA) and CONCAWE. A link to the SCEDs is also provided in DUCC website and reference is made on the Cefic Libraries.

4.2. Principles underpinning SCEDs

1. The application of the information (exposure determinants) within a SCED 'fact sheet' is consistent with the process described in the ECHA guidance on IR/CSA i.e. the information applicable to a Tier 1 model (such as the ECETOC TRA) will first be applied to calculate the level of exposure. If exposures/risks are considered inappropriate, the process will then proceed to collect additional exposure determinants and refine assessment until 'safe use' can be concluded.
2. SCEDs must cover all relevant routes of exposure for the use. Where a route of exposure is not considered relevant, then the SCED must include a clear (and ideally quantitative) rationale for this. In some cases, 'common sense' is applied (e.g. exposure by oral route in non-accidental circumstances is not applicable to most of product types).
3. SCEDs are developed by trade groups/associations. They represent a consensus view of that group on how the products that group represents are/should be used for the EU setting.
4. After having developed the SCED, the sector association is expected to make it publicly available, enabling its content to be applied when developing consumer CSAs under REACH. DUCC is willing to make the SCEDs available in a publicly accessible SCED library.
5. SCEDs can be developed for any situation where consumer exposures to chemicals are commonly encountered and need to be assessed. However, it is for each industry sector to decide to develop SCEDs for their sector.
6. The format and content of the SCED uses the template provided in Annex 1.
7. The minimum content of the SCED addresses exposure determinants for the ECETOC TRAv3.1 consumer module although the SCED may contain additional information.
8. Each data point within the SCED has to be substantiated by reference to suitable information sources that, ideally, are open access, have been published and peer reviewed. Preferably these will also refer to European data sources and/or be already utilised in regulatory processes (within the EU or beyond e.g. EPA, IPCS). SCEDs are designed so that the scenario as a whole represents a conservative representation of exposure. Each individual parameter of a SCED is not necessarily a worst case value. Rather, relationships between dependent factors (room size and use amount for a DIY product, for example) are considered so that the resulting scenario represents a conservative, yet realistic, exposure estimate when calculated with the ECETOC TRA v3.1 tool.

9. Where habits and practices significantly vary across European countries/regions, then the SCED will reflect those areas with the highest uses/exposure conditions.
10. A SCED should be reviewed and updated when appropriate and if new information is available.
11. In cases revisions occurred, version of SCEDs will be clearly identifiable.

4.3. Use of SCEDs in Chesar

Chesar 2.3 supports the use of SCEDs. The following functionalities have been implemented:

Functionalities meant for sector associations developing the SCEDs:

- Manual input of information from SCED factsheet into Chesar
- Generation of the SCED information in an XML format (Chesar file)
- Print of SCED factsheet from Chesar (based on the information input to Chesar)

Functionalities meant for users of SCEDs

- Import of SCED in Chesar format (XML)
- Exposure estimation using ECETOC TRA v3.1 using SCED as input
- Generation of ES in CSR on the basis of a TRA v3.1 assessment using a SCED
- Generation of ES for communication on the basis of a SCED

For more information on how to use the SCEDs in Chesar, please refer to the Chesar manuals available on https://chesar.echa.europa.eu/home .

Annex 1 – Example of SCED

CONCAWE_SCED_PC13_1_a_v1: Fuels, Liquid, Automotive Refuelling

Products/activities covered by the SCED:
Filling motor vehicle outdoors with a full tank of fuel every week
Applicability of the SCED (depending on substances properties):
Determinant values refer to gasoline as the fuel

Exposure Descriptor or Determinant	Value and [ESCOM phrase Code]
SCED characteristics	
Name of the SCEDs	Fuels, Liquid: Automotive Refuelling
PC/AC descriptor	PC13
SCED code	CONCAWE_SCED_PC13_1_a_v1
Code of other related SCED	CONCAWE_SCED_PC13_2_a_v1; CONCAWE_SCED_PC13_3_a_v1
Author	CONCAWE
Source of SCED	http://www.CONCAWE.be
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)	1
Explanations	>99% of formulated product is the substance
Frequency of use over a day (event/day)	1
Rationale	Unchanged from ECETOC TRA default value
Frequency of use over a year	Frequent
Rationale	Once/week; consistent with the 90th percentile of 5 times per month (0.17) and average of 3.1 times per month (0.1).
Dermal Specific Parameters	
Exposure via dermal route	Yes
Rationale	
Skin Contact Area	Palm of one hand
	Palm of one hand as only one hand holds the fuel nozzle. Based on a recent survey, 90% of respondents indicated that on no occasion or only sometimes did they have skin contact during refueling. These observations suggest a lower value than the TRA default of 857.5 cm^2. Consumer simulations (visualisation techniques) of the use suggest actual contact area likely to be less than 50 cm^2.
Dermal transfer factor	0.002
Rationale	Estimated conservative value for gasoline. This value is greater (more

Exposure Descriptor or Determinant	Value and [ESCOM phrase Code]
	conservative) than the 75th percentile of 0.00005 for hand contamination during pouring from a pesticide container
Inhalation Specific Parameters	
Exposure via inhalation route	Yes
Rationale	
Spray application?	No
Amount of Product used per application (g/event)	37500
Rationale	Based on 50 L fuel dispensed and density of 750 g/L. Value is consistent with reported refuelling amounts: 90th percentile of 53 L and average of 30 L
Exposure Time per event (hr)	0.05
Rationale	Consistent with reported refuelling time ranging from 0.3-3.5 mins, with an average of 1 min.
Inhalation transfer factor	0.002
Rationale	Measured evaporative losses of 4 – 10.4 g VOC emitted per gallon of gasoline during vehicle refuelling converts to an inhalation factor of 0.001 – 0.004 for automobiles without vapour capture systems. EU laws mandate vapour capture and applying the recovery system default value of 98% efficiency to this data gives an estimated emission of 0.0001-0.0003 weight fraction
Place of use	Outdoor
Oral Specific Parameters	
Exposure via oral route	Oral exposure assumed to be negligible
Rationale	Direct oral contact will only arise from intentional ingestion of the product. Significant indirect contact is unlikely due to volatility of substance.
Volume swallowed (cm3)	N/a
Rationale	
Oral transfer Factor	N/a
Rationale	

Annex 2 – Transfer factors

The transfer factor (TF) mentioned in Appendix F of TR107 for the ECETOC TRA consumer module refers to a coefficient used to describe the difference between the amount of the product/substance being handled (in the event) and the actual amount of material available for exposure during the event i.e. it describes the proportion of the material handled that is likely to be available for exposure (for either the dermal, inhalation and/or oral routes). The TF described by ECETOC must be distinguished from the transfer factor that is referred to in some other areas of risk assessment. For example the dermal TF has been (inappropriately) described (Kissel, 2011)[10] as referring to the amount of material that is absorbed through the skin and into the body. In this respect, the use of the TF by the TRA is a misnomer: in reality the TRA uses an 'exposure availability factor' i.e. one that distinguishes (within the context of the TRA algorithms) the difference between the amount of product used and the amount that is actually available as an exposure source (and which will also likely vary by exposure route). It is important to remember that the TRA always assumes 100% skin absorption of substances under consideration.

The factor will also vary with the type of use and product characteristics. For example, the factor could change across different scenarios e.g. fuelling a car with a gas or liquid is likely to have different exposure consequences for the inhalation, dermal and oral routes. Within the TRA, the factor is generally assumed to be '1' (100% release) unless otherwise stated (for example, within the SCED, where a supporting rationale would also need to be provided.

The following specific comments apply to the transfer factors for the inhalation, dermal and oral routes:

Inhalation transfer factor

The inhalation transfer factor (ITF, >0 to 1) represents the fraction of the substance or product that is released to air during a consumer use. For example, a factor of 0.05 would be applied in a case where 5% of a substance/product is released to air. i.e. the ITF generally applies to scenarios where all of the product being handled is not released to into the air during the use event, such as is the case for the solid components of paints or when a car is being filled with fuel. In the absence of data to the contrary, a conservative default of 100% is assumed.

Dermal transfer factor

For dermal exposures, the ECETOC TRA applies an algorithm that uses skin surface area; product concentration and the thickness of the product layer to calculate dermal loading. Consistent with Prud'homme et al (2006)[11], the layer thickness is set at 0.1 mm (0.01 cm), based on data that relate to direct handling of liquid products. However, for many uses, dermal exposures which cover the whole area of skin to a uniform (and conservative) thickness are unlikely, for example where exposure is indirect. The DTF is therefore applied to adjust the loading to a level that is more representative of that experienced in the actual scenario (which is a function of the actual exposed skin area and likely product thickness).

[10] Kissel, J C. (2011) "The mismeasure of dermal absorption". Journal of Exposure Science and Environmental Epidemiology 21, 302-309

[11] L.C.H. Prud'homme de Lodder, H.J. Bremmer, J.G.M. van Engelen. RIVM reprt 320104003/2006. Cleaning products fact sheet. To assess the risks for the consumer.

Within the context of the TRA, the dermal transfer factor (DTF, >0 to 1) therefore represents the fraction of the theoretical worst case dose that is most appropriate for that scenario. For example, a DTF of 0.05 would reflect the circumstances of the scenario determined that only 5% of the theoretical worst case was available for exposure. For example, dermal exposure when fuelling a car results from a consumer holding the handle of the fuel pump filling nozzle. But resulting dermal exposure does not occur via contact with a single uniform layer of fuel. Rather, because the exposure event is one where the contact is indirect, then the affected skin area is not uniform. Clearly, justification of this parameter can be difficult. But simulation experiments (both quantitative and qualitative) enable it to be described.

In this sense the DTF may not be the most accurate description; rather, the fraction represents a form of dermal exposure availability factor. It should also be emphasized that the DTF does not refer to or account for the amount of material that might then be subsequently absorbed through the skin and into the body (and which the TRA conservatively assumes to be 100%).

Oral transfer factor

Oral transfer factor (OTF, >0 to 1) represents the fraction of the substance of interest that is likely to be ingested from a product or article during an exposure invent. (ECETOC Technical Reports 107 and 114). This would be the case, for example, if a child was to suck clothing and an assessment was being made of the exposure to cleaning product residues some, but not all, the residue could be expected to be released. For example, if only 5% of the product is transferred and available for ingestion, the OTF is 0.05. As a conservative estimate, 100% is assumed as a default for those scenarios where ingestion is considered a likely exposure route.

Annex 3 – How to use the SCEDs in ECETOC TRA v3.1

The determinants provided within a SCED can be used directly in the "Add Subcategories" tab of the ECETOC TRA v3.1 Consumer module to refine exposure assessment (instead of the current defaults).

- After filling the "User input" sheet adequately, go to the "Add Subcategories" sheet to add a new product subcategory;
- As with the parameters in the "User Input" sheet, parameter values for yellow cells are required before the tool will calculate exposure estimates and RCRs. Blue cells contain pre-populated default values which will be used unless specific values are entered by the user;
- Select a product from a dropdown list of PCs and ACs in Column B. This list contains both PCs and ACs already calculated with default input parameters;
- In Column D, enter the product subcategory name;
- Select the relevant exposure routes for the new subcategory in columns H, J, and K. At the same time, select adult or child exposure for the selected routes;
- Fill in the different columns with the information provided in the SCEDs;
- Go to the "Results by Prod Subcat" to view the results for the new subcategories, created in column D of the "Add subcategories" sheet. Only pathway-specific exposure estimates and RCRs are displayed in this sheet.

  Obs: The total exposure will exclude inhalation exposure estimates unless they are calculated in units of mg/kg/day. To ensure inhalation exposure estimates are included in the total exposure estimate, enter an inhalation reference value in units of mg/kg/day (cell B10 in "User Input" sheet). If an inhalation reference value in mg/m3 has already been entered, this will have to be deleted first before an inhalation reference value in units of mg/kg/day can be entered.
- To view the algorithms and parameters used to calculate route-specific exposure estimates, select either the "Dermal (Prod Subcat), Oral (Prod Subcat), or Inhalation (Prod Subcat) tab.

Annex 4 – Acronyms

AC	Article Category
A.I.S.E.	International Association for Soaps, Detergents and Maintenance
CEPE	European Council of the Paint, Printing Ink and Artists' Colors Industry
Chesar	Chemical Safety Assessment and Reporting tool
CONCAWE	The oil companies' European association for environment, health and safety in refining and distribution
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 TRA	European Center for Ecotoxicology and Toxicology of Chemicals Targeted Risk Assessment
ECHA	European Chemicals Agency
EFCC	European Federation for Construction Chemicals
EPA	U.S. Environmental Protection Agency
ERC	Environmental Release Category
ES	Exposure Scenario
EU	European Union
EUSES	European Union System for the Evaluation of Substances
ext-SDS	Extended Safety Data Sheet
FEA	European Aerosol Federation
FEICA	European Association Adhesives and Sealants
IPCS	International Programme on Chemical Safety
IR/CSA	Information requirements and Chemical Safety Assessment
IUCLID	International Uniform Chemical Information Database
LEV	Local Exhaust Ventilation
OC	Operational Conditions
PC	(Chemical) Product Category
RCR	Risk Characterisation Ratio
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
SME	Small and Medium Entreprise
spERCs	Specific Environmental Release Categories