

# **User Manual for Consumer GES/CSA Tool, EGRET**

## **Version 2.1 – February 2023**

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# User Manual for Consumer GES/CSA Tool, EGRET

## Disclaimer

*The European Solvents Industry Group (ESIG) and its user's trade associations grouped in ESVOC have published the European Solvents Industry Group Generic exposure scenario Risk and Exposure Tool (EGRET).*

*This information contained within the tool is to the best of the ESIG/ESVOC's knowledge and belief accurate and reliable as at the date indicated. However, no representation, warranty or guarantee is made as to its accuracy, reliability or completeness. It is the users' responsibility to satisfy themselves as to the suitability and completeness of such information for their own particular use(s). This is intended to be a screening tool and is not a substitute for and should not be relied upon in place of appropriate technical advice, more refined knowledge of consumer exposure information, or common sense.*

*Chemical companies are individually responsible for their respective REACH registrations.*

## Notice

- Please make sure to use Excel with the Windows format settings as a dot (not a comma) as the decimal separator.
- To change the regional settings, go to the "Settings" app and then navigate to Time & Language > Language and Region > Administrative language settings, then go to the first tab called "Formats" and select an English format in the first box and press OK.
- EGRET can only be used to assess exposure and risk quantitatively with relevant DNELs available, not qualitative risk.
- DNELs for inhalation should be entered only as ng/m<sup>3</sup>, µg/m<sup>3</sup> or mg/m<sup>3</sup>.

## Version history

- November 2015 – V2 published – fully revised and extended User Manual for EGRET V2
- November 2017 – V2.1 Inclusion of Domain of Application, no other changes. Refer also to the 'EGRET CSA Block Tool'. This Microsoft Excel spreadsheet tool can be used to generate CSA Block Files for importing exposure assessments conducted using EGRET v2 into CHESAR 3.2.

- November 2022 – Correction of a bug causing issues for the communication between the EGRET file and the CSA block. The conversion of the relative density and vapour pressure was not correctly done, causing format errors in the data extracted from the CSA Block Tool and leading to the CSA Block Tool failing to generate .chr files.
- February 2023 – ‘EGRET CSA Block Tool’ is now able to convert DNELs from mg to µg/ng.

The name of the CSA Block tool can now be changed, yet if the XLS template/spreadsheet is renamed, the user will be prompted that the file is not found.



## Introduction

The European Solvents Industry Group (ESIG) Generic Exposure Scenario (GES) Risk and Exposure Tool (referred to as EGRET) has been developed to evaluate the potential risk to consumers who use products that contain solvents under REACH (Ref. 1). The tool generates:

- a. Estimates of consumer exposure to solvents through the dermal, oral, and inhalation routes of exposure
- b. Risk Characterization Ratios (RCRs) for each identified exposure route
- c. Exposure Scenario narratives that describe the Operational Conditions and Risk Management Measures necessary to achieve an RCR less than the target RCR using the EuPhrac standard phrases library.

The tool is based on the European Center for Ecotoxicology and Toxicology of Chemicals (ECETOC) Targeted Risk Assessment (TRA) ver2 consumer module (Ref. 2). EGRET includes additional refinements in the default estimates of exposure included in the TRA (sometimes termed Tier 1.5 in REACH). These refinements are included in the CSA tool in a section titled “TRA Tier 1+” and are based upon the guidance in Appendix F of the ECETOC Technical Report No. 107 (Ref. 3) and Technical Report No. 124 (Ref. 4).

Each line within the tool represents an exposure assessment for a specific Product Category (PC) (Ref. 5) identified as relevant to consumer handling of solvents. These individual assessments are consolidated under an ESIG Generic Exposure Scenario (GES) Title (see Part 1, Table 2). For each GES title, the CSA for each PC compares the Derived No Effect Level (DNEL) for the substance to a systemic RCR and introduces Risk Management Measures (RMMs) based on a “control banding” approach<sup>1</sup> to achieve a systemic RCR that is less than a target RCR.

The DNEL values are analogous to No Observed Adverse Effect Levels (NOAELs). The tool automatically populates RMMs only when the systemic RCR is greater than the target RCR selected by the user. If the RCR for the local effect is greater than the target RCR, the user must manually alter values in the Operational Conditions (OCs).

EGRET is intended for screening level evaluations. If the exposure estimates obtained with this tool are high, then it may be appropriate to perform higher tier analyses.

At present EGRET can only be used to evaluate consumer exposure from using a chemical product, not exposure from using an article.

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<sup>1</sup> This feature was not implemented in the fuels GES, as it was not considered appropriate to reduce the concentration or refine other defaults. For the fuels GES, examples of higher tier analysis have been included in appendix B.

This User Manual supports Version 2 of the EGRET tool. Refer to the Tool's worksheet titled "Updates" for the adjustments against Version 1. The new features in Version 2 include:

- Enhanced control banding with automated selection of Risk Management (RMMs) to provide an extra margin of safety
- ECETOC-TRA use frequency bands to assess risks for infrequent exposure
- Instruction on how to use with Specific Consumer Exposure Determinants (SCEDs)
- Two additional parameters for scaling (Skin Contact Area and Amount Swallowed)
- Assessment of additional types of risk (other than long-term systemic)
- Updated air exchange rate for outdoor scenarios to match ECETOC-TRA ver3.1
- Simplified user interface for output in a Chemical Safety Assessment (CSA) format

## Domain of Application

EGRET has been developed based on the ECETOC TRA for use in estimating consumer exposures to hydrocarbon solvents. However, it is also capable of being applied to other substances that have similar physicochemical properties and use scenarios. For such substances, users will need to determine if the substance falls within the applicability domain of EGRET as follows:

1. review the relevant EGRET GES and associated default values to determine if they are applicable
2. determine the level of persistence of the substance, as EGRET does not include kinetic capabilities that would enable toxicologically similar substances with long biological half-lives to be effectively assessed
3. take account of additional restrictions associated with infrequent exposure for substances.

EGRET develops exposure and risk estimates using the following hierarchy:

1. Event exposure is compared to the acute DNEL when available. If the acute target Risk Characterisation Ratio (RCR) is exceeded, manual adjustment of exposure parameters is required and documented as a Risk Management Measure (RMM)
2. Daily exposure is compared to the chronic DNEL when available. Units are as follows and consistent with the DNEL units and basis:
  - a. Oral/dermal: mg/kg/day
  - b. Inhalation: 24-hour TWA in mg/m<sup>3</sup>
3. Infrequent exposure:
  - a. Daily exposure is compared to the chronic DNEL. If the RCR exceeds the selected target RCR level, frequency of exposure is factored in based upon the ECETOC TRA frequency banding approach.
  - b. If this RCR still exceeds the target level, RMMs are automatically applied.

### Infrequent Exposure – additional restrictions

The ECETOC TRA frequency banding approach is valid for substance endpoints where the effect is related to the cumulative dose. In determining whether the approach is valid for a particular substance, the following should be taken into account. ***It is advised to seek input from a toxicologist experienced with the substance(s) in question.***

1. Exclusion of substances whose dose rates are an influential factor in their toxicity
2. Further substance evaluation to determine the suitability of infrequent exposure adjustment where the following conditions exist:
  - Genotoxicants
  - Substances that promote an immune reaction, or induce auto-immunity in individuals
  - Substances with non-steady state or known potential for non-linear kinetics
  - Substances with long half-life of elimination (weeks to years)
  - Substances for which a toxic metabolite is produced only under conditions of high exposure



- Corrosive or irritating substances (degree of irritation may be important), or physical hazards (flammability)
- Substances with portal of entry effect and chronic DNEL based upon an alternate exposure route (but should have an acute DNEL)
- Developmental hazard potential identified or expected
- Non-genotoxic carcinogenic hazard identified.

### **Applicability of Haber's Rule to ESIG Solvents**

Haber's Rule is applicable to HC solvents with carbon number  $\leq 9$  or considered to be volatile.

For those HC solvents that are classified for local effects such as irritancy, aspiration hazard, appropriate controls are determined following a qualitative assessment, which is beyond the scope of EGRET.

For a list of Registered Hydrocarbon and Oxygenated solvents, please click on the following links:

- For OSPA substances: [https://www.esig.org/wp-content/uploads/2023/04/OSPA\\_REACH\\_keydata\\_202304.pdf](https://www.esig.org/wp-content/uploads/2023/04/OSPA_REACH_keydata_202304.pdf)
- For HSPA substances: [https://www.esig.org/wp-content/uploads/2022/04/Attachment-3-HSPA-Naming-Convention\\_April2022.pdf](https://www.esig.org/wp-content/uploads/2022/04/Attachment-3-HSPA-Naming-Convention_April2022.pdf)

## Part I: Using the Tool

### 1) Getting Started

- The tool contains 9 worksheets. Table 1 briefly describes each worksheet.

Table 1: Worksheets in the EGRET

| Worksheet Name          | Description  |
|-------------------------|--|
| <b>Updates</b>          | Log of tool updates  |
| <b>User Guidance</b>    | Instructions on how to use the tool  |
| <b>Picklist</b>         | Description of the drop-down picklists used in the tool  |
| <b>Standard Phrases</b> | Standard phrases for Operational Conditions and Risk Management Measures   |
| <b>CSA</b>              | Chemical safety assessment   |
| <b>Narrative</b>        | Narrative  |
| <b>References</b>       | Reference citations for parameter values used in table 2b (TRA Tier1+)   |
| <b>OCpopulating</b>     | Flow chart of Operational Condition (OC) function algorithm. This worksheet is for informational purposes only.    |
| <b>RMMpopulating</b>    | Flow chart of Risk Management Measure (RMM) function algorithm. This worksheet is for informational purposes only. |

- In the CSA worksheet, each row represents a unique product subcategory that has been pre-populated with exposure determinant values that taken together represent a conservative exposure for that use. Product Categories (PCs) that were not in the original ECETOC TRA tool are denoted by blue text.

#### GES-specific workbooks

- The “master” version of the tool downloaded from the ESIG website contains all PCs that are included in the ESIG/ESVOC GES list, as well as PC subcategories contained within the ECETOC TRA tool.
- The simplest way to use EGRET for consumer exposure assessments is to identify whether any relevant consumer uses have already been described using Generic Exposure Scenarios (GES). Using GESs simplifies the process of constructing the Chemical Safety Assessment (CSA) and its subsequent communication (for example, as part of the Annex to the extended safety data sheet). The ESIG/ESVOC Use Maps identify the relevant PCs for consumer use of solvents; details can be found on the ESIG REACH website.
- GES-specific workbooks (Table 2) can be created from EGRET’s master template by hiding those rows with PCs that are not relevant for the use, adding the GES use title in cell B13, its description in cell B14, and its PCs in cell B15 in the CSA workbook; and hiding the irrelevant rows in the Narrative worksheet.

Table 2: Eight workbooks for the identified Solvents GES Use Titles and associated Product Categories codes\*

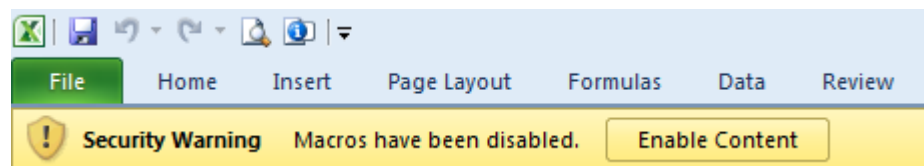
| CSA workbooks        | GES Use Titles                       | Product Categories Codes  |
|----------------------|--------------------------------------|---|
| 1 Coating.xls        | Use in coatings                      | PC1, PC4, PC8 (excipient only), PC9, PC15, PC18, PC23, PC24, PC31, PC34 |
| 2 Cleaning.xls       | Use in cleaning agents               | PC3, PC4, PC8 (excipient only), PC9, PC24, PC35, PC38                   |
| 3 Lubricants.xls     | Lubricants                           | PC1, PC24, PC31   |
| 4 Agrochemical.xls   | Use in agrochemicals                 | PC12, PC27  |
| 5 Fuels.xls          | Use as a fuel                        | PC13  |
| 6 FunctionFluid.xls  | Functional fluids                    | PC16, PC17  |
| 7 Deicing.xls        | De-icing and anti-icing applications | PC4   |
| 8 WaterTreatChem.xls | Water treatment chemicals            | PC36, PC37  |

\* Note: Earlier use maps contained PC codes that are no longer part of the current use descriptor system (Ref. 5.). The affected PCs have been reassigned by ECHA to other PC codes as follows:

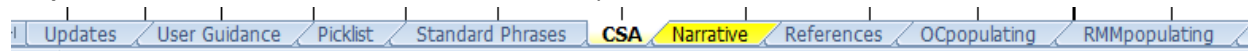
- PC5 reassigned to PC1 (adhesives), PC9b (fillers, putties, modelling clay), PC9c (finger paints) and PC10 reassigned to PC9a (coatings and paints, thinners, paint removers) both relevant to GES Use in Coatings;
- PC6 reassigned to PC31 (Polishes and wax blends) relevant for the Lubricants GES;
- PC22 reassigned to PC27 relevant for the Agrochemical GES.

## 2) Using the Tool

**Step 1:** When opening the tool for the first time, enable the macros to ensure the tool functions properly.



**Step 2:** Select the CSA worksheet to enter user inputs.



**Step 3:** Input variables: Enter physical/chemical properties of the substance in the user input table. The user can enter a substance name (cell S3), change default values for the molecular weight (g/mole) (cell U3) and vapor pressure (Pa) (cell Y3). When the user enters the molecular weight (MW) and vapor pressure (VP), a saturated vapor concentration (cell AC3) for the substance is automatically calculated and applied within the tool as an upper bound for all inhalation exposure estimates. A fraction released to air (cell AA4) associated with the VP entered will also be calculated automatically, to be consistent with the VP bands in the TRA consumer tool (Table 3). Note: The preset values for MW and VP in the user input table generate a saturated vapor concentration that exceeds inhalation exposure predictions for all built-in scenarios. SVC will only be invoked as an upper bound if the user enters a MW.

|   | Q                          | R                                     | S    | T                                  | U    | V                                   | W      | X                                     | Y      | Z  | AA    | AB  | AC              |
|---|----------------------------|---------------------------------------|------|------------------------------------|------|-------------------------------------|--------|---------------------------------------|--------|--|-------|---|-----------------|
| 1 |                            |                                       |      |                                    |      |                                     |        |                                       |        |  |       |   |                 |
| 2 | <b>User Input Table</b>    |                                       |      |                                    |      |                                     |        |                                       |        |  |       |   |                 |
| 3 | Substance Properties:      | Substance Name                        |      | Molecular Weight (g/mole)          | 5000 | Physical property                   | liquid | Substance volatility (Pa):            | 300000 | TRA volatility range   | high  | Saturated Vapour Concentration (mg/m <sup>3</sup> ) | 605474396.8     |
| 4 | Common Parameter Defaults: | Thickness Layer (cm)                  | 0.01 | Density (g/cm <sup>3</sup> )       | 1.0  | Body Weight (kg)                    | 60.0   | Inhalation Rate (m <sup>3</sup> /hr)  | 1.4    | fraction released to air   | 1     | Life Cycle Stage / Sector of Use                    | Consumer (SU21) |
| 5 | References Values (DNELs): | dermal long-term systemic (mg/kg/day) | 20.0 | dermal local (mg/cm <sup>2</sup> ) |      | oral long-term systemic (mg/kg/day) | 20.0   | inhalation systemic (mg/kg/24 hr day) |        | inhalation long-term systemic (mg/m <sup>3</sup> ) for 24 hr day | 100.0 | inhalation local (mg/m <sup>3</sup> )               |                 |

Table 3: Vapor pressure bands in ECETOC TRA consumer

| Default Vapor Pressure Band (non-spray)                    | Default fraction released to air |
|--|----------------------------------|
| <b>A: Vapor pressure <math>\geq</math> 10 Pa</b>           | 1                                |
| <b>B: Vapor pressure between 1 and 10 Pa</b>               | 0.1                              |
| <b>C: Vapor pressure between 0.1 and 1 Pa</b>              | 0.01                             |
| <b>D: Vapor pressure between <math>&lt;</math> 0.01 Pa</b> | 0.001                            |

**Step 4:** Input variables: Enter reference value(s) (DNEL) in the user input table. Use the “Delete” key to clear out unnecessary DNELs (WARNING: do not use the SPACE key) – for example, if there is no dermal long-term systemic DNEL for a substance, delete the value from cell S5. Note: The user can enter only one inhalation long term systemic DNEL value either in mg/m<sup>3</sup> (cell AA5) or in mg/kg/day (cell Y5).

**Step 5:** (OPTIONAL) Select one of the three target RCRs (0.9, 0.5, and 0.2) in cell BZ4 to establish the threshold for the automatic control banding option. The tool’s default setting is a target RCR of 0.9. Other target RCRs (i.e., 0.5 and 0.2) offer an even higher degree of safety for the consumers.

|   | BX | BY         | BZ                               |
|---|----|------------|----------------------------------|
| 3 |    |            |                                  |
| 4 |    | Target RCR | 0.9                              |
| 5 |    |            | <div> 0.9<br/>0.5<br/>0.2 </div> |

EGRET is based upon the ECETOC TRA v2 consumer module and designed mainly to assess long term systemic exposure for dermal, oral and inhalation exposure routes when relevant. However, EGRET expands the capability of the TRA consumer module to assess other risk effects. Table 4 summarizes how EGRET can be used for various types of exposure assessment and RCR calculations.

Note: In the RCR calculation, inhalation systemic DNELs are compared to exposures averaged over a 24-hour day. In accordance with the REACH Technical Guidance, users should align the inhalation time-weighted averaging period to the nature of the DNEL endpoint.

Table 4. EGRET for various types of risk assessment

| Exposure Routes           | DNELs available in CSR       | DNELs entry field   | Exposure estimation   | RCR  | Notes                        |
|---------------------------|------------------------------|---|---|--|------------------------------|
| <b>Inhalation</b>         | Systemic effects - long-term | cell AA5<br>(inhalation long-term systemic (mg/m <sup>3</sup> ) for 24hr day) | column BI<br>(Mean inhalation concentration (24hr TWA) on day of exposure (mg/m <sup>3</sup> )) | column BP<br>(RCR systemic (24hr TWA inhalation mg/m <sup>3</sup> ))           | frequent use (≥1/week)       |
|                           |                              |   | column BJ<br>(Mean inhalation concentration yearly (mg/m <sup>3</sup> ))                        | column BT<br>(RCR systemic (inhalation yearly, based on mg/m <sup>3</sup> ))   | use frequency <1/week        |
|                           | Systemic effects - acute     | cell AA5<br>(inhalation long-term systemic (mg/m <sup>3</sup> ) for 24hr day) | column BI<br>(Mean inhalation concentration (24hr TWA) on day of exposure (mg/m <sup>3</sup> )) | column BP<br>(RCR systemic (24hr TWA inhalation mg/m <sup>3</sup> ))           | frequent use (≥1/week)       |
|                           | Local effects - long-term    | —   | —   | —  | not covered                  |
|                           | Local effects - acute        | cell AC5<br>(inhalation local (mg/m <sup>3</sup> ))                           | column BG<br>(Mean Inhalation Event Concentration (mg/m <sup>3</sup> ))                         | column BM<br>(RCR inhalation local (based on Activity TWA mg/m <sup>3</sup> )) | based on event concentration |
| <b>Dermal<sup>1</sup></b> | Systemic effects - long-term | cell S5<br>(dermal long-term systemic (mg/kg/day))                            | column BA<br>(Predicted Dermal Exposure, Daily (mg/kg/d))                                       | column BN<br>(RCR systemic (dermal, daily, based on mg/kg/d))                  | frequent use (≥1/week)       |
|                           |                              |   | column BB<br>(Predicted Dermal Exposure, Chronic (mg/kg/d))                                     | column BR<br>(RCR systemic (dermal, chronic, based on mg/kg/d))                | use frequency (<1/week)      |
|                           | Systemic effects - acute     | cell S5<br>(dermal long-term systemic (mg/kg/day))                            | column BA<br>(Predicted Dermal Exposure, Daily (mg/kg/d))                                       | column BN<br>(RCR systemic (dermal, daily, based on mg/kg/d))                  | frequent use (≥1/week)       |
|                           | Local effects - long-term    | —   | —   | —  | not covered                  |
|                           | Local effects - acute        | cell U5<br>(dermal local (mg/cm <sup>2</sup> ))                               | column BC<br>(Predicted Dermal Exposure, Local (mg/cm <sup>2</sup> ))                           | column BL<br>(RCR dermal local (based on mg/cm <sup>2</sup> ))                 | based on dermal loading      |
| <b>Oral</b>               | Systemic effects - long-term | cell W5<br>(oral long-term systemic (mg/kg/day))                              | column BD<br>(Predicted Oral Exposure, daily (mg/kg/d))   | column BO<br>(RCR systemic (oral, daily, based on mg/kg/d))                    | frequent use (≥1/week)       |
|                           |                              |   | column BE<br>(Predicted Oral Exposure, Chronic (mg/kg/d))                                       | column BS<br>(RCR systemic (oral, chronic, based on mg/kg/d))                  | use frequency <1/week        |
|                           | Systemic effects - acute     | cell W5<br>(oral long-term systemic (mg/kg/day))                              | column BD<br>(Predicted Oral Exposure, daily (mg/kg/d))   | column BO<br>(RCR systemic (oral, daily, based on mg/kg/d))                    | frequent use (≥1/week)       |

1. For dermal exposure estimation, the daily and local values are all the acute values since time is not a factor in the calculation. The dermal exposure is estimated based on the same algorithm used in the TRA i.e. (=product ingredient X skin contact area X Thickness of layer X use frequency X density X 1000 / body weight) without accounting for exposure duration.

Table 5. Organization of CSA worksheet

| Column(s)                       | Descriptions   |
|---------------------------------|--|
| <b>B- E</b>                     | Descriptions of Generic Exposure Scenarios, PCs and subcategories  |
| <b>F- AA</b>                    | ECETOC TRA ver2 Operating Conditions, PECs (Predicted Exposure Concentrations) and RCRs; Operating Conditions (columns F through P) can be hidden by clicking on "-" above column Q. Predicted inhalation exposure in mg/m3 upper bounded with saturated vapor concentration (SVC) has also been included (column U).  |
| <b>AB - AZ</b>                  | TRA+ (or EGRET) Operating Conditions and basis   |
| <b>BA-BK (except column BH)</b> | PECs based upon TRA+. Exposures are given as day of use and chronic (i.e., considers how many days a year the use occurs) for dermal and oral. For dermal, local exposures are also calculated. For inhalation, exposures are calculated as the concentration during the exposure event, the concentration averaged for the day of exposure (to be consistent with systemic DNEL basis) and also the chronic concentration averaged considering how many days a year the use occurs. (Based upon p. 7 of October 2012 version 2.1 of Chapter R-15: Consumer Exposure Estimation)   |
| <b>BH</b>                       | Indicator for basis of inhalation event concentration (i.e., SVC if saturated vapor concentration is used, or else blank if predicted inhalation exposure is used)   |
| <b>BL - BU</b>                  | Substance-specific RCRs calculated for TRA+ conditions (i.e., when no RMMs are used)   |
| <b>BV</b>                       | Summary of Operating Conditions (these are based on the standard phrases found in the worksheet with the same name)  |
| <b>BW</b>                       | Summary of RMMs when needed (these are based on the standard phrases found in the worksheet with the same name)  |
| <b>BX</b>                       | Indicator for the exposure estimates used as the basis for final substance-specific RCRs. It includes one of 4 phrases: Based upon daily use; Based upon infrequent use (<365 days/year); Based upon daily use + RMM; Based upon infrequent use + RMM. The column automatically populates and carries over the associated RCRs in the following order: <ol style="list-style-type: none"> <li>1. If the TRA+ day of use values result in RCRs &lt; the target RCR without RMMs, these values are used unchanged.</li> <li>2. If RCRs were &gt; the target RCR and products are used daily, then the daily use + RMM auto-populate.</li> <li>3. If products are not used daily, then the infrequent use values are used if they have RCR &lt; the target RCR, otherwise.</li> <li>4. If products are not used daily and RCR was &gt; the target RCR, infrequent use + RMMs are used.</li> </ol> |
| <b>BY-CB</b>                    | Final substance-specific RCRs including RMMs when needed.  |
| <b>CC-CE</b>                    | Final substance-specific PECs including RMMs when needed.  |
| <b>CG-GS</b>                    | Control bands. Used in development of the needed RMM set for each of the 4 Control bands (i.e., very low, low, medium, and high); can be viewed by clicking on the "+" sign at the top of columns DM, EO, FQ or GS.  |

### 3) Viewing Results

The tool automatically calculates RCRs for the TRA and TRA+ conditions. Where TRA+ conditions result in an RCR greater than the target RCR, the sheet automatically defines RMMs needed to meet an RCR less than the target RCR with the exception of the fuel scenarios. The substance-specific Predicted Exposure Concentrations and RCRs are based on Operational Conditions (OCs) of the TRA+ and additional RMMs if needed. Information on OCs and RMMs, if needed, is automatically populated into the narrative.

- Predicted Exposure Concentration estimates and substance-specific RCRs based on ECETOC TRA ver2 tool (Column Q to AA).

|    | D                             | E   | Q   | R                                 | S                                       | T                                     | U   | V                                  | W                                       | X          | Y                          | Z  | AA                |
|----|-------------------------------|---|---|-----------------------------------|---|---------------------------------------|---|------------------------------------|---|------------|----------------------------|--|-------------------|
| 10 | Relevant Use Sentinel Product | Product sub Category Sentinels                            | TIER1 Predicted Exposure - ECETOC TRA based on defaults |                                   |   |                                       |   |                                    | Risk Characterization based on defaults |            |                            |  |                   |
|    |                               |   | Predicted Dermal Exposure (mg/kg/d)                     | Predicted Oral Exposure (mg/kg/d) | Predicted Inhalation Exposure (mg/kg/d) | Predicted Inhalation Exposure (mg/m³) | Predicted Inhalation Exposure - upper bounded with SVC when available (mg/m³) | Total Predicted Exposure (mg/kg/d) | RCR (dermal)                            | RCR (oral) | RCR (inhalation mg/kg/day) | RCR (inhalation upper bounded with SVC when available mg/m3) | RCR (all routes ) |
| 11 |                               |   |   |                                   |   |                                       |   |                                    |   |            |                            |  |                   |
| 12 |                               |   |   |                                   |   |                                       |   |                                    |   |            |                            |  |                   |
|    | PCT:Adhesives, sealants       | Glues, hobby use  | 1.8   | n/a                               | 12.3                                    | 135.0                                 | 135.0   | 14                                 | 0.09                                    | n/a        | n/a                        | 1.93   | 2.02              |
| 13 |                               |   |   |                                   |   |                                       |   |                                    |   |            |                            |  |                   |
|    | PCT:Adhesives, sealants       | Glues DIY-use (carpet glue, tile glue, wood parquet glue) | 214   | n/a                               | 30825.0                                 | 225000.0                              | 225000.0  | 30846                              | 1.07                                    | n/a        | n/a                        | 3214.29  | 3215.36           |
| 14 |                               |   |   |                                   |   |                                       |   |                                    |   |            |                            |  |                   |

- Predicted Exposure Concentration estimates and substance-specific RCRs based on TRA+ tool (Column BA to BU)

|    | D                             | E   | BA  | BB   | BC  | BD                                       | BE   | BF   | BG  | BH   | BI   | BJ  | BK   | BL   | BM  | BN   | BO   | BP  | BQ                               | BR   | BS   | BT   | BU                                 |
|----|-------------------------------|---|---|--|---|--|--|--|---|--|--|---|--|--|---|--|--|---|----------------------------------|--|--|--|------------------------------------|
|    | Relevant Use Sentinel Product | Product sub Category Sentinels                            | TRA Tier 1- Predicted Exposure - ECETOC TRA - refined estimates |  |   |  |  |  |   |  |  |   |  | TRA Tier1- Risk Characterization - refined estimates |   |  |  |   |                                  |  |  |  |                                    |
|    |                               |   | Predicted Dermal Exposure, Daily (mg/kg/d)                      | Predicted Dermal Exposure, Chronic (mg/kg/d) | Predicted Dermal Exposure, Local (mg/m <sup>3</sup> ) | Predicted Oral Exposure, daily (mg/kg/d) | Predicted Oral Exposure, Chronic (mg/kg/d) | Predicted Inhalation Exposure, daily (mg/kg/d) | Mean Inhalation Exposure Concentration (mg/m <sup>3</sup> ) | Indicator for Basis of the Inhalation Exposure Concentration (SVC 1: Standard Vapor Concentration is used) | Mean Inhalation Concentration (24hr TWA) on Day of Exposure (mg/m <sup>3</sup> ) | Mean Inhalation Concentration Yearly (mg/m <sup>3</sup> ) | Total Predicted Exposure (mg/kg/d)- day of use for TRA comparison only | RCR dermal local (based on mg/m <sup>3</sup> )       | RCR inhalation local (based on Activity TWA mg/m <sup>3</sup> ) | RCR systemic (dermal, daily, based on mg/kg/d) | RCR systemic (oral, daily, based on mg/kg/d) | RCR systemic (24hr TWA inhalation mg/m <sup>3</sup> ) | RCR systemic (all routes, daily) | RCR systemic (dermal, chronic, based on mg/kg/d) | RCR systemic (oral, chronic, based on mg/kg/d) | RCR systemic (inhalation, yearly, based on mg/m <sup>3</sup> ) | RCR systemic (all routes, chronic) |
| 10 |                               |   |   |  |   |  |  |  |   |  |  |   |  |  |   |  |  |   |                                  |  |  |  |                                    |
| 11 |                               |   | day of use  | chronic                                      | event   | day of use                               | chronic                                    | event  |   |  | day of use   | chronic   |  |  |   | 20   | 20   | 70  |                                  | 20.0   | 20.0   | 70.0   |                                    |
| 12 | PCt:Adhesives, sealants       | Glues, hobby use  | 1.79  | 1.79   | 3.00  | n/a                                      | n/a  | 4.67   | 51.5  |  | 0.52   | 0.525   | 5.46   | n/a  | n/a   | 0.09   | n/a  | 0.12  | 0.21                             | 0.09   | n/a  | 0.12   | 0.21                               |
| 13 | PCt:Adhesives, sealants       | Glues DIY-use (carpet glue, tile glue, wood parquet glue) | 5.50  | 0.06   | 3.00  | n/a                                      | n/a  | 3547.96  | 26997.51  |  | 6474.30  | 64.744  | 3553.46  | n/a  | n/a   | 0.26   | n/a  | 92.49   | 92.77                            | 0.00   | n/a  | 6.92   | 6.93                               |
| 14 |                               |   |   |  |   |  |  |  |   |  |  |   |  |  |   |  |  |   |                                  |  |  |  |                                    |

- Operational conditions for TRA+ exposure assessment are automatically populated in column BV.

|    |                               |   |  |
|----|-------------------------------|---|--|
| 1  |                               |   |  |
| 2  |                               |   |  |
|    | D                             | E   | BV   |
|    | Relevant Use Sentinel Product | Product sub Category Sentinels                            | Operation Conditions (OCs)   |
| 10 |                               |   |  |
| 11 |                               |   |  |
| 12 |                               |   |  |
| 13 | PC1:Adhesives, sealants       | Glues, hobby use  | Unless otherwise stated, covers concentrations up to 30% [ConsOC1]; covers use up to 364 days/year[ConsOC3]; covers use up to 1 time/on day of use[ConsOC4]; covers skin contact area up to 35.73 cm <sup>2</sup> [ConsOC5]; for each use event, covers use amounts up to 9g [ConsOC2]; covers use under typical household ventilation [ConsOC8]; covers use in room size of 20m <sup>3</sup> [ConsOC11]; for each use event, covers exposure up to 4.00hr/event[ConsOC14];  |
| 14 | PC1:Adhesives, sealants       | Glues DIY-use (carpet glue, tile glue, wood parquet glue) | Unless otherwise stated, covers concentrations up to 30% [ConsOC1]; covers use up to 1 day/year[ConsOC3]; covers use up to 1 time/on day of use[ConsOC4]; covers skin contact area up to 110.00 cm <sup>2</sup> [ConsOC5]; for each use event, covers use amounts up to 6390g [ConsOC2]; covers use under typical household ventilation [ConsOC8]; covers use in room size of 20m <sup>3</sup> [ConsOC11]; for each use event, covers exposure up to 6.00hr/event[ConsOC14]; |

- The overall Operational Conditions for all the product subcategories are populated in the Narrative worksheet (section 2.1)

|    |   |  |
|----|---|--|
| 10 | Section 2.1                                     | Control of consumer exposure   |
| 11 | Product characteristics                         |  |
| 12 | Physical form of product                        | liquid   |
| 13 | Vapour pressure (Pa)                            | 300000   |
| 14 | Concentration of substance in product           | Unless otherwise stated, cover concentrations up to 100% [ConsOC1]   |
| 15 | Amounts used                                    | Unless otherwise stated, covers use amounts up to 13800g [ConsOC2]; covers skin contact area up to 857.5cm <sup>2</sup> [ConsOC5]  |
| 16 | Frequency and duration of use/exposure          | Unless otherwise stated, covers use frequency up to 365 days per year [ConsOC3]; Unless otherwise stated, covers use frequency up to 4 times per day [ConsOC4]; covers exposure up to 8 hours per event [ConsOC14] |
| 17 | Other Operational Conditions affecting exposure | Unless otherwise stated assumes use at ambient temperatures [ConsOC15]; assumes use in a 20 m <sup>3</sup> room [ConsOC11]; assumes use with typical ventilation [ConsOC8].  |

- For a product subcategory whose RCRs are above 1, the cells will be highlighted in pink. If its RCRs are greater than the target RCR selected by the user (cell BZ4) but less than 1, the cell will be highlighted in yellow. For a scenario with an RCR greater than the target RCR, RMMs will automatically be populated in column BW based on the control banding approach (except for the fuel scenarios).



[illegible]

#### 4) Viewing Defaults

The default parameters (Operational Conditions) used in ECETOC TRAv2 exposure calculations are listed in columns F to P. The user can unhide the columns by clicking the “plus” sign above column Q to see all the TRA defaults. For PCs or product subcategories without defaults in the ECETOC TRA tool, the parameter values here are the same as their TRA+ defaults (because the worksheet setup requires TRA conditions to be filled in). These cases are denoted in blue text in the tool.

|   |   |                                |   |               |   |                       |                            |                                 |                      |                           |                  |                    |                                   |   |
|---|---|--------------------------------|---|---------------|---|-----------------------|----------------------------|---------------------------------|----------------------|---------------------------|------------------|--------------------|-----------------------------------|---|
| 1 |   |                                |   |               |   |                       |                            |                                 |                      |                           |                  |                    |                                   |   |
| 2 |   |                                |   |               |   |                       |                            |                                 |                      |                           |                  |                    |                                   |   |
|   | D                                       | E                              | F   | G             | H | I                     | J                          | K                               | L                    | M                         | N                | O                  | P                                 | Q |
|   | in the Supply Chain                     |                                | Table 2a: Characterising the Risk - based on defaults (ECETOC TRA ver2 Consumers) |               |   |                       |                            |                                 |                      |                           |                  |                    |                                   |   |
|   |   |                                | all all all d o i i i   |               |   |                       |                            |                                 |                      |                           |                  |                    |                                   |   |
|   | Relevant Use Sentinel Product           | Product sub Category Sentinels | Product ingredient (g/g)  | adult / child |   | Product is spray? (S) | frequency (events per day) | Skin surface contact area (cm²) | Amount Swallowed (g) | Amount Used per event (g) | room volume (m³) | exposure time (hr) | Predicted Dermal Exposure (mg/kg) |   |
|   |   |                                |   | d             | o | i                     |                            |                                 |                      |                           |                  |                    |                                   |   |
|   | PC1:Adhesives, sealants                 | Glues, hobby use               | 0.3   |               |   |                       |                            |                                 |                      |                           |                  |                    | 18                                |   |
|   |   |                                |   | A             |   | A                     | 1                          | 35.73                           |                      | 9                         | 20               | 4                  |                                   |   |
|   | PC4_n:Anti-freeze and de-icing products | Washing car window             | 0.01  |               |   | A                     | 1                          |                                 |                      | 0.5                       | 34               | 0.01666667         | n/a                               |   |
|   |   |                                |   |               |   | A                     |                            |                                 |                      |                           |                  |                    |                                   |   |

The parameters used in the TRA+ exposure calculation are listed in Table 2b (from column AB to AZ) in EGRET. Each parameter value has a comment column next to it to provide the basis for the value.

|     | D                             | E   | AB  | AC   | AD                             | AE  | AF            | AG  | AH                   | AI                        | AJ   | AK   | AL                       | AM   | AN                    | AO                    | AP          | AQ          | AR          | AS | AT | AU | AV | AW | AX | AY | AZ |  |
|-----|-------------------------------|---|---|--|--------------------------------|---|---------------|---|----------------------|---------------------------|--|--|--------------------------|--|-----------------------|-----------------------|-------------|-------------|-------------|----|----|----|----|----|----|----|----|--|
| 9   | In the Supply Chain           |   | Table 2b: Characterising the Risk - after refinement of exposure estimate |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 10  |                               | all   | all   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 11  | Relevant Use Scenario Product | Product sub Category Scenario                             | TERO- ECETOC TRA - exposure modifiers                                     |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 12  |                               |   | Product frequency (per day) (g/day)                                       | Frequency (events per day) (g/day) (1 only used for chronic assessment - updated - consistent with TRA frequency band) | Skin surface contact area (m²) | Use Dilution Factor   | Dermal Factor | Glove efficiency  | Amount Swallowed (g) | Amount used per event (g) | Inhalation Factor (fraction of total use substance inhaled, in, amount used) | Location (industrial, residential, garage) | Air Exchange Rate (1/hr) | Dilution Factor (incorporating Air Exchange Rate applied to TRA for rough inhalation calc) | Room Volume (m³)      | Exposure time (hours) |             |             |             |    |    |    |    |    |    |    |    |  |
| 13  | Value                         | Comments  | Value   | Comments   | Value                          | Comments  | Value         | Comments  | Value                | Comments                  | Value  | Comments                                   | Value                    | Comments   | Value                 | Comments              |             |             |             |    |    |    |    |    |    |    |    |  |
| 14  | PCU Adhesives, reseller       | Gloves, hobby use   | TRA default   | 1  | TRA default, daily             | TRA default   |               |   |                      |                           | TRA default  |  | indoor, typical          | 0.50   | PCU general fast flow | 0.30                  | 20.00       | TRA default | TRA default |    |    |    |    |    |    |    |    |  |
| 15  | PCU Adhesives, reseller       | Gloves DIF use (reseller glove, like glove, used per day) | 0.3   | TRA default  | 0.01                           | PCU Adhesives (reseller use, gloves and floor glue all in 1 hr, here used 1 hr) | 0.01          | PCU Adhesives (reseller use, gloves and floor glue all in 1 hr, here used 1 hr) |                      | 0.01                      | indoor, typical  | 0.50                                       | PCU general fast flow    | 0.30   | 20.00                 | TRA default           | TRA default |             |             |    |    |    |    |    |    |    |    |  |
| 16  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 17  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 18  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 19  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 20  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 21  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 22  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 23  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 24  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 25  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 26  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 27  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 28  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 29  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 30  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 31  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 32  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 33  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 34  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 35  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 36  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 37  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 38  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 39  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 40  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 41  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 42  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 43  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 44  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 45  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 46  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 47  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 48  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 49  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 50  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 51  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 52  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 53  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 54  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 55  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 56  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 57  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 58  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 59  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 60  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 61  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 62  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 63  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 64  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 65  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 66  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 67  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 68  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 69  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 70  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 71  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 72  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 73  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 74  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 75  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 76  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 77  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 78  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 79  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 80  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 81  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 82  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 83  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 84  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 85  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 86  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 87  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 88  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 89  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 90  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 91  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 92  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 93  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 94  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 95  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 96  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 97  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 98  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 99  |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |
| 100 |                               |   |   |  |                                |   |               |   |                      |                           |  |  |                          |  |                       |                       |             |             |             |    |    |    |    |    |    |    |    |  |

The use Inhalation Factor, Dilution Factor, and Dermal Factor parameters (highlighted yellow in the tool) provide the ability to include a modifying factor for the exposure estimate when justified by supporting information.

- Inhalation Factor = the fraction of the total amount handled that is lost to air.
- Dilution Factor = the ratio of the original volume to the final volume prior to or during use.
- Dermal Factor = the % of the total amount handled that is transferred to the skin.

For example, there may be the case where a skin absorption rate is available for a substance. In this case, the dermal factor in column AJ can be calculated external to the CSA worksheet (see Appendix C for an example). These values can then be entered in column AJ in the CSA tool to further refine the predicted dermal exposure estimates. The predicted dermal exposure value is multiplied by the Dermal Factor resulting in an estimate of absorbed dose.

Please note the internal DNEL should be used if the Dermal Factor derived from the absorption rate has been applied in the risk assessment.

The default within the tool is that the Dilution Factor, Dermal Factor, and Inhalation Factor are all 1 (i.e., there was no modification to the exposure estimate). Only in cases where they differ from 1, do comments need to be included as to their basis.

The use frequency values have been updated in EGRET to be consistent with the use frequency band in TRAv3.1 (Table 6).

Table 6. Use frequency band in TRAv3.1

| Frequency of Exposure | Multiplier | Description           |
|-----------------------|------------|-----------------------|
| Frequent              | 1          | ≥ 1/week              |
| Occasional            | 0.2        | 1/month ~ 1/week      |
| Infrequent            | 0.04       | 1/ 6 months ~ 1/month |
| Very infrequent       | 0.01       | <1/6 months           |

## 5) Narrative Generation

The tool automatically populates the Exposure Scenario (ES) narrative in the “Narrative” worksheet.

|    | A  | B   | C   |
|----|--|-----|---|
| 1  | Section 1  |     | Exposure Scenario Title   |
| 2  | Title  |     | GES USES  |
| 3  | Sector of Use (SU code)  |     | 21  |
| 4  | Use Descriptor (PC codes)  |     | PC LISTS  |
| 5  | Processes, tasks, activities covered   |     | DESCRIPTIONS  |
| 6  | Environmental Release Category   |     | 0   |
| 7  | Specific Environmental Release Category  |     | 0   |
| 8  | Section 2  |     | Operational conditions and risk management measures   |
| 9  | Field for additional statements to explain scenario if required - pending better understanding from ECHA |     |   |
| 10 | Section 2.1  |     | Control of consumer exposure  |
| 11 | Product characteristics  |     |   |
| 12 | Physical form of product   |     | liquid  |
| 13 | Vapour pressure (Pa)   |     | 300000  |
| 14 | Concentration of substance in product  |     | Unless otherwise stated, cover concentrations up to 100% [ConsOC1]  |
| 15 | Amounts used   |     | Unless otherwise stated, covers use amounts up to 37500g [ConsOC2]; covers skin contact area up to 6600cm2 [ConsOC5]  |
| 16 | Frequency and duration of use/exposure   |     | Unless otherwise stated, covers use frequency up to 365 days per year [ConsOC3]; Unless otherwise stated, covers use frequency up to 4 times per day [ConsOC4]; covers exposure up to 8 hours per event [ConsOC14]  |
| 17 | Other Operational Conditions affecting exposure  |     | Unless otherwise stated assumes use at ambient temperatures [ConsOC15]; assumes use in a 20 m³ room [ConsOC11]; assumes use with typical ventilation [ConsOC8].   |
| 18 | Section 2.1.1  |     | Product categories  |
| 19 | PC1:Adhesives, sealants—Glues, hobby use   | OC  | Unless otherwise stated, covers concentrations up to 30% [ConsOC1]; covers use up to 364 days/year[ConsOC3]; covers use up to 1 time/on day of use[ConsOC4]; covers skin contact area up to 35.73 cm2 [ConsOC5]; for each use event, covers use amounts up to 9g [ConsOC2]; covers use under typical household ventilation [ConsOC8]; covers use in room size of 20m3[ConsOC11]; for each use event, covers exposure up to 4.00hr/event[ConsOC14];  |
| 20 |  | RMM | No specific RMMs identified beyond those OCs stated   |
| 21 | PC1:Adhesives, sealants—Glues DIY-use (carpet glue, tile glue, wood parquet glue)                        | OC  | Unless otherwise stated, covers concentrations up to 30% [ConsOC1]; covers use up to 1 day/year[ConsOC3]; covers use up to 1 time/on day of use[ConsOC4]; covers skin contact area up to 110.00 cm2 [ConsOC5]; for each use event, covers use amounts up to 6390g [ConsOC2]; covers use under typical household ventilation [ConsOC8]; covers use in room size of 20m3[ConsOC11]; for each use event, covers exposure up to 6.00hr/event[ConsOC14]; |
| 22 |  | RMM | Avoid using at a product concentration greater than 10% [ConsRMM1];   |
|    | PC1:Adhesives, sealants—Glue from spray  | OC  | Unless otherwise stated, covers concentrations up to 30% [ConsOC1]; covers use up to 11 days/year[ConsOC3]; covers use  |

## 6) Scaling

The Operational Conditions experienced by a Downstream User can differ from the default values specified in the tool. If necessary, the user can modify the default value of one parameter and compensate for this variation by changing the value of another parameter to ensure the safe use of the product. This is referred to as scaling (ref. 6).

Seven parameters in Table 2b in the CSA worksheet (TRA Tier1+) are unlocked to enable modification when needed:

- Product ingredient
- Skin surface contact area
- Use dilution factor
- Dermal factor
- Amount swallowed
- Amount used per event
- Inhalation factor

If the user modifies any of these parameters, the tool prompts the user to enter justification for the change in the column labelled 'Comments'. It is important for the user to always do a “reality check” during scaling on the scenario as a whole. For example, if a product use amount is known to be lower than the default in the tool, the concentration in the product could be increased proportionally and still result in the same RCR.

## **7) Specific Consumer Exposure Determinants (SCEDs)**

The SCEDs are sets of refined exposure determinants which can be used as inputs in exposure tools to obtain more realistic exposure estimates. Various industry sectors (such as A.I.S.E., CONCAWE, FEICA, etc.) have developed or are developing SCEDs for the consumer uses that are associated with the activities of these sectors. Information on how to use and develop SCEDs is available via the Downstream Users of Chemicals Coordination group (DUCC) and Conservation of Clean Air and Water in Europe (CONCAWE) (Ref. 7). The SCEDs template (Ref. 8) supports their use in ECHA's Chesar (Chemical Safety Assessment and Reporting tool).

Not all exposure parameters available in the SCEDs template can be used to modify the inputs to the EGRET tool (Table 2b). The exposure parameters that can be modified in EGRET are: product concentration, skin contact area, dermal transfer factor, amount swallowed through volume swallowed, amount used per event, and inhalation transfer factor. The exposure parameters that cannot be modified in EGRET are frequency, exposure duration, place of use, and oral transfer factor. If the information on these parameters provided in a SCED differs from the EGRET defaults, then some manual intervention (through linear scaling) is needed.

## Part II: Basis of the Tool

### 1) Four Control Bandings

This is an automated part of the tool. EGRET is set up so that if a systemic RCR is greater than the target RCR, the tool automatically populates a set of RMMs that result in a systemic RCR that is less than the specified target RCR (cell BZ4).

The approach taken was to first develop a set of 4 different DNEL ranges, each referred to as a control band (cell CH2 – cell CL7). The control bands were estimated to cover the range of general population DNELs likely to be encountered. Then, for each control band, a set of RMMs was developed that would result in an RCR less than the target RCR for the lowest DNEL value of the band, that is, the lowest DNEL value in the range. This approach ensures that, for **any** DNEL value within the band, the tool would calculate an RCR less than the target RCR. More details can be found in the Zaleski publication (Ref. 9).

Each control band is unhidden by clicking on the “+” at the top of column DM, EO, FQ or GS.

View when the control bands are collapsed:

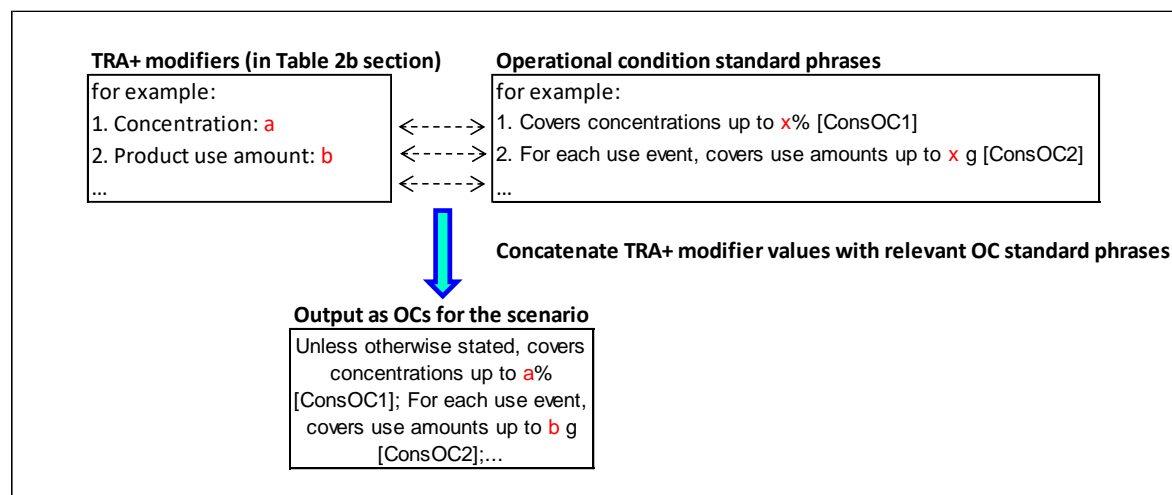
|    |   |                                       |  |                           |  |  |  |  |   |              |            |                  |               |           |               |           |               |           |               |           |    |  |  |  |
|----|---|---------------------------------------|--|---------------------------|--|--|--|--|---|--------------|------------|------------------|---------------|-----------|---------------|-----------|---------------|-----------|---------------|-----------|----|--|--|--|
| 1  | BY  | BZ                                    | CA                                       | CB                        | CC   | CD   | CE   | CF   | CG  | CH           | CI         | CJ               | CK            | CL        | DM            | DN        | EO            | EP        | FQ            | FR        | GS |  |  |  |
| 2  |   |                                       |  |                           |  |  |  |  |   |              |            |                  |               |           |               |           |               |           |               |           |    |  |  |  |
| 3  |   |                                       |  |                           |  |  |  |  |   |              |            |                  |               |           |               |           |               |           |               |           |    |  |  |  |
| 4  | Target RCR  | 0.3                                   |  |                           |  |  |  |  |   |              |            |                  |               |           |               |           |               |           |               |           |    |  |  |  |
| 5  |   |                                       |  |                           |  |  |  |  |   |              |            |                  |               |           |               |           |               |           |               |           |    |  |  |  |
| 6  |   |                                       |  |                           |  |  |  |  |   |              |            |                  |               |           |               |           |               |           |               |           |    |  |  |  |
| 7  |   |                                       |  |                           |  |  |  |  |   |              |            |                  |               |           |               |           |               |           |               |           |    |  |  |  |
| 8  |   |                                       |  |                           |  |  |  |  |   |              |            |                  |               |           |               |           |               |           |               |           |    |  |  |  |
| 9  |   |                                       |  |                           |  |  |  |  |   |              |            |                  |               |           |               |           |               |           |               |           |    |  |  |  |
| 10 | Risk Characterization - including RMMs when needed (substance Specific) |                                       |  |                           |  |  |  | TRA- Predicted Exposure - including RMM when needed (substance specific) |   |              | Chronic    |                  |               |           |               |           |               |           |               |           |    |  |  |  |
|    | RCR systemic (dermal, based on mg/kg/d)                                 | RCR systemic (oral, based on mg/kg/d) | RCR systemic (inhalation based on mg/m3) | RCR systemic (all routes) | Predicted Systemic Dermal Exposure (mg/kg/d) | Predicted Systemic Oral Exposure (mg/kg/d) | Predicted Systemic Inhalation Exposure (mg/m3) | PCS  | Subcategories   | PEC (dermal) | PEC (oral) | PEC (inhalation) | Control BAND1 | Total RCR | Control BAND2 | Total RCR | Control BAND3 | Total RCR | Control BAND4 | Total RCR |    |  |  |  |
| 11 | d   | o                                     | i  | t                         | d  | o  | i  |  |   | c            | c          | c                |               |           |               |           |               |           |               |           |    |  |  |  |
| 12 | 0.09  | n/a                                   | 0.12                                     | 0.21                      | 1.79   | n/a  | 8.52   | PC1Adhesives, sealants   | Glues, hobby use  | 1.79         | n/a        | 8.52             |               | 0.90      |               | 0.90      |               | 0.70      |               | 0.17      |    |  |  |  |
| 13 | 0.00  | n/a                                   | 0.32                                     | 0.32                      | 0.02   | n/a  | 22.40  | PC1Adhesives, sealants   | Glues DIY-use (carpet glue, tile glue, wood parquet glue) | 0.06         | n/a        | 64.74            |               | 0.55      |               | 0.90      |               | 0.90      |               | 0.65      |    |  |  |  |



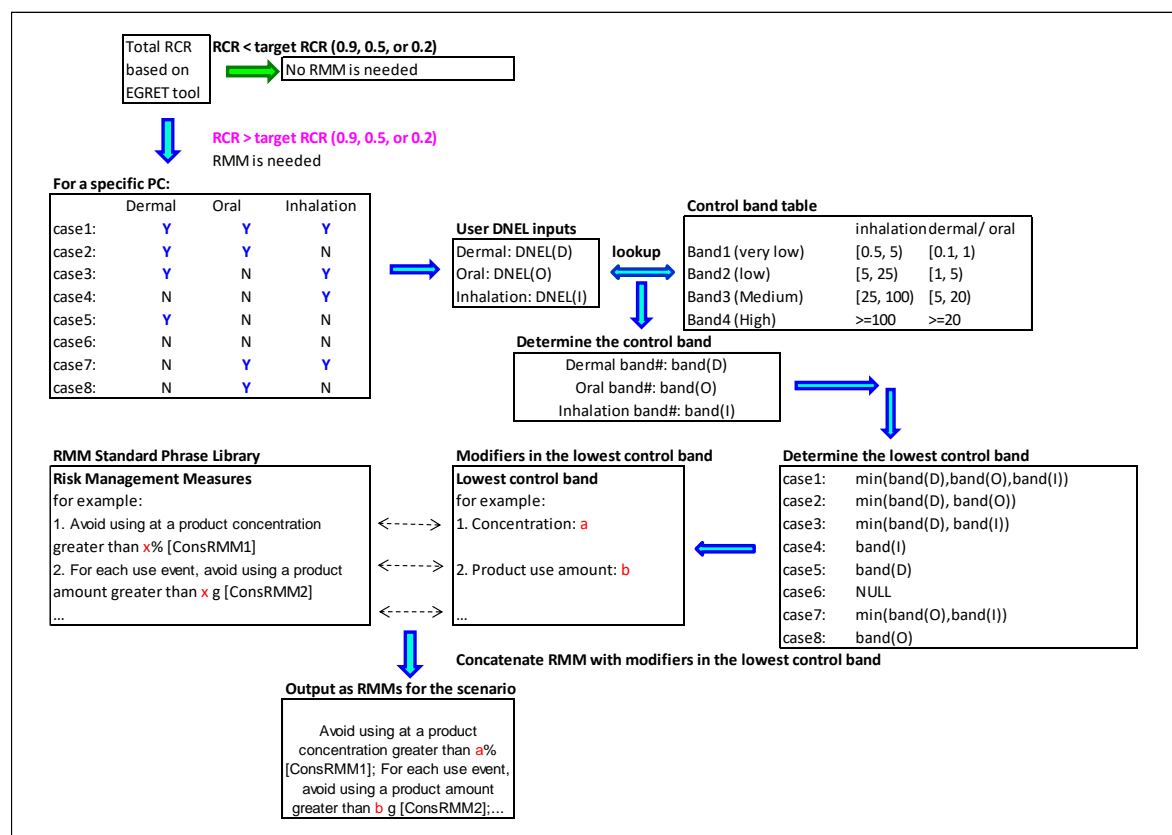
## 2) Mechanics of the Workbook

There are two auto-populating functions for OCs and RMMs.

OC populating function:



RMM populating function:



### 3) Comparison of the Features in TRAv3.1 vs EGRET 2

| Features                            | TRA v3.1                                 | EGRET v2  |
|-------------------------------------|--|---|
| PCs/Articles                        | Both (10 PCs and 6 ACs)                  | PCs only (22 PCs)                                     |
| Sentinel category                   | yes                                      | no  |
| Type of risk                        | systemic only                            | systemic and local effects                            |
| Exposure estimations                | daily/chronic <sup>1</sup> concentration | event/daily/chronic concentration                     |
| Air exchange rate                   | yes (0.6 for indoor, 2.5 for outdoor)    | yes (0.6 for indoor, 1.5 for garage, 2.5 for outdoor) |
| Locations                           | indoor/ outdoor                          | indoor/outdoor/garage                                 |
| Parameter defaults                  | conservative values                      | refined values  |
| Transfer factors                    | oral, dermal, inhalation                 | see next line   |
| Route specific factors <sup>2</sup> | transfer factors as above                | inhalation, dermal, use dilution                      |
| Use of glove                        | no                                       | yes (placeholder)                                     |
| Populate OCs and RMMs               | no                                       | yes   |
| Standard phrases                    | no                                       | yes   |
| Narrative generation                | no                                       | yes   |
| Control bandings                    | no                                       | yes   |
| Vapor pressure bands                | yes                                      | yes   |
| Frequency bands                     | yes                                      | yes   |
| Saturated vapor concentration       | yes                                      | yes   |
| Add new subcategories               | yes                                      | yes   |

1. Chronic represents a yearly average exposure to be consistent with the long term DNEL.
2. Route specific factors can be used as transfer factors in TRA, but could be used as other factors as well (e.g., dilution factor). Here they simply represent the linear modifications to the tool exposure estimates based on more detailed information available that will result in exposure reduction in the scenario.

### 4) Tool Limitations

This tool does not automatically generate Risk Management Measures for local effect exposure assessments. If there is a local effect for a specific substance/product, then the user must manually generate RMMs. For dermal local exposure, this is accomplished by iterating the process of changing the product ingredient, use dilution factor, dermal factor and glove use. For inhalation local exposure, this is accomplished by iterating the process of changing the product ingredient, amount used per event and inhalation factor in Table 2b in the tool.

This tool does not specifically address aerosol exposures. Spray scenarios assume 100% of the amount used is released to air, regardless of substance vapor pressure, with the caveat that saturated vapor concentrations are used as an upper bound for all inhalation scenarios, including sprays.



Note: This tool is a screening level tool that does not consider higher tier analysis aspects such as persistence (P) or bioaccumulation (B). The applicability of the approach provided in the tool must be evaluated for substances that meet the criteria for classification as CMRs. Also, certain aspects such as frequency banding would not be appropriate for substances that are classified as P or B. This tool also should not be used for any endpoint (e.g., respiratory sensitization) for which a qualitative assessment is more appropriate.

## 5) References

1. ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R15 Consumer Exposure Estimation, V2.1 Oct 2012
2. ECETOC (European Center for Ecotoxicology and Toxicology of Chemicals) TRA consumer tool user guidance.
3. ECETOC (European Center for Ecotoxicology and Toxicology of Chemicals) Targeted Risk Assessment, Technical Report No. 107. European Centre for the Ecotoxicology and Toxicology of Chemicals, Brussels. 2009.
4. ECETOC (European Center for Ecotoxicology and Toxicology of Chemicals) Targeted Risk Assessment, Technical Report No. 124. European Centre for the Ecotoxicology and Toxicology of Chemicals, Brussels. 2014.
5. ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R12, Use Descriptor System V2. March 2010
6. ECHA Guidance for downstream users. Version 2.1. 2014.
7. DUCC/CONCAWE. How to use the SCEDs for chemical exposure assessment under REACH – Guidance for SCEDs user. April 2014. <http://www.ducc.eu/documents/20140424-Guidance%20documents%20on%20SCEDs-Final-V1.pdf>
8. DUCC. SCEDs template, April 2014. [http://www.ducc.eu/documents/20140423\\_SCEDs\\_Template\\_Final.pdf](http://www.ducc.eu/documents/20140423_SCEDs_Template_Final.pdf)
9. Zaleski RT, Qian H, Zelenka MP, George-Ares A, Money C. European solvent industry group generic exposure scenario risk and exposure tool. *Journal of Exposure Science and Environmental Epidemiology*. 2014. 24:27-35.

## 6) Glossary

| Terms        | Explanations  |
|--------------|---|
| <b>CSA</b>   | Chemical Safety Assessment: determines whether risks (to man and/or the environment) are considered to exist arising from the use of the substance.   |
| <b>CSR</b>   | Chemical Safety Report: documents the chemical safety assessment (CSA) for a substance on its own, in a preparation or in an article or a group of substances.  |
| <b>DNEL</b>  | Derived No Effect Level: defined as the level of exposure to the substance below which no adverse effects are expected to occur under REACH. The DNEL is generally expressed as external values, but can be expressed as internal biomarker value (i.e., the internal DNEL referred in this manual) in some cases (ECHA chapter R8). For example, DNEL long-systemic refers to a DNEL derived for systemic effects from long term exposure. |
| <b>EA</b>    | Exposure Assessment: includes i) exposure scenario building and ii) exposure estimation.  |
| <b>ES</b>    | Exposure Scenario: addresses the set of conditions, including Operational Conditions and Risk Management Measures, covering the substance life-cycle, which describe how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.   |
| <b>GES</b>   | Generic Exposure Scenario: describes the OC/RMMs needed to manage risks arising from the typical conditions of use(s) of a certain type of substance (e.g., solvents, pigments, resins, detergents) within a certain sector industry (area of use). GESs are usually available to cover the whole life cycle of the type of substance.  |
| <b>OCs</b>   | Operational Conditions: are the basic boundary conditions that describe the potential for exposure in any situation   |
| <b>RMMs</b>  | Risk Management Measures: describe the type of technical controls necessary to manage exposures to acceptable levels  |
| <b>SCEDs</b> | Specific Consumer Exposure Determinants: are sets of refined exposure determinants to obtain a more realistic exposure estimates.   |

## Appendix A: List of Equations in EGRET

### Abbreviations:

| Variable abbreviation | Descriptions   |
|-----------------------|--|
| ACH                   | Air Exchange Rate  |
| A <sub>use</sub>      | Amount of product used   |
| A <sub>swallow</sub>  | Amount of product swallowed  |
| BW                    | Body Weight  |
| CA                    | Contact Area   |
| D                     | Density  |
| DFA                   | Dilution Factor due to Air Exchange Rate                                       |
| DF                    | Dermal Factor (fraction that is transferred from product to skin)              |
| EFC                   | Efficiency   |
| ET                    | Exposure Time  |
| F <sub>e</sub>        | Fraction of Emission   |
| FQ                    | Frequency multiplier   |
| GE                    | Glove Efficiency   |
| MW                    | Molecular Weight   |
| PEC                   | Predicted Exposure Concentration   |
| IEF                   | Inhalation Exposure Factor (fraction of total use spilled/evaporated)          |
| IR                    | Inhalation Rate  |
| PI                    | Product Ingredient (weight fraction)   |
| RV                    | Room Volume  |
| SVC                   | Saturated Vapor Concentrations   |
| TL                    | Thickness of Layer   |
| TPE                   | Total Predicted Exposure   |
| UDF                   | Use Dilution Factor (ex. if 100-fold dilution, dilution factor = 1/100 = 0.01) |
| VP                    | Vapor Pressure   |
| V <sub>swallow</sub>  | Product volume swallowed   |

Note, the variable abbreviations with prime below (e.g., FQ') are the variables used in TRA+ (or EGRET).

### Equations in Table 2a:

#### Column Q (Predicted Dermal Exposure in mg/kg/day)

$$PEC_d = \frac{PI * CA * FQ * TL * D * 1000}{BW}$$

TL = 0.001cm for PC3 - Air care, continuous action (solid and liquid). Basis: ECETOC TRA

TL = 0.1cm for PC36 - Water softeners and PC37 - Water treatment chemicals. Basis: Increased above ECETOC TRA due to potential for greater water contact.

TL = 0.01cm for all other PCs. Basis: ECETOC TRA

BW = 10kg for Children, 60kg for Adult. Basis: ECETOC TRA

FQ>=1 by ECETOC TRA defaults

#### Column R (Predicted Oral Exposure in mg/kg/day)

$$PEC_o = \frac{PI * A_{swallow} * FQ * 1000}{BW}$$

BW=10kg (only for Children)

FQ>=1 by defaults

#### Column S (Predicted Inhalation Exposure in mg/kg/day)

$$PEC_i = \frac{PI * A_{use} * FQ * F_e * ET * IR * 1000}{RV * BW}$$

For spray products,  $F_e = 1$  always. Basis: ECETOC TRA

For non-spray products,  $F_e = 1$  for high vapor pressure (>10Pa), 0.1 for medium vapor pressure (1-10Pa), 0.01 for medium low vapor pressure (0.1-1Pa) and 0.001 for low vapor pressure (<=0.1Pa). Basis: ECETOC TRA

FQ>=1 by defaults

#### Column T (Predicted Inhalation Exposure in mg/m<sup>3</sup>)

$$PEC_i = \frac{PI * A_{use} * FQ * F_e * 1000}{RV}$$

FQ>=1 by defaults

### Column U (Upper-bounded predicted Inhalation Exposure in mg/m<sup>3</sup>)

Saturated Vapor Concentration at standard temperature and pressure:

$$SVC(mg / m^3) = \frac{VP * 10^6}{101.325 * 10^3} * \frac{MW}{24.45} \quad \text{Basis: ECETOC TRA TR93, appendix F}$$

$$PEC_{i(UB)} = \min(PEC_i, SVC)$$

### Column V (total predicted exposure in mg/kg/day)

Summation of the predicted exposure from all pathways (column Q, R and S):

$$TPEC(mg / kg / day) = PEC_d(mg / kg / day) + PEC_o(mg / kg / day) + PEC_i(mg / kg / day)$$

### Column AA (total RCRs)

Summation of the RCRs from all pathways (column W, X and Y) - only using the exposure estimates in mg/kg/day

### Equations in Table 2b:

#### Column BA (Predicted dermal exposure, daily in mg/kg/day)

$$PEC_{d-daily}' = PEC_d * GE * \frac{PI'}{PI} * \frac{CA'}{CA} * \frac{FQ'(\geq 1)}{FQ} * UDF * DF$$

DF, please refer to a separate workbook (dermalfactor.xls) for its calculation.

FQ' < 1/day, FQ' = FQ

TL = 0.001cm for PC3 - Air care, continuous action (solid and liquid)

TL = 0.1cm for PC36 - Water softeners and PC37 - Water treatment chemicals

TL = 0.01cm for all other PCs

#### Column BB (Predicted dermal exposure, chronic in mg/kg/day)

$$PEC_{d-chronic}' = PEC_d * GE * \frac{PI'}{PI} * \frac{CA'}{CA} * \frac{FQ'}{FQ} * UDF * DF$$

#### Column BC (Predicted dermal exposure, local in mg/cm<sup>2</sup>)

$$PEC_{d-local}' = PI * TL * D * 1000 * GE * UDF * DF$$

**Column BD (Predicted oral exposure, daily in mg/kg/day)**

$$PEC_{o-daily}' = PEC_o * \frac{PI'}{PI} * \frac{A'_{swallow}}{A_{swallow}} * \frac{FQ'(\geq 1)}{FQ}$$

FQ' < 1/day, FQ' = FQ

**Column BE (Predicted oral exposure, chronic in mg/kg/day)**

$$PEC_{o-chronic}' = PEC_o * \frac{PI'}{PI} * \frac{A'_{swallow}}{A_{swallow}} * \frac{FQ'}{FQ}$$

**Column BF (Predicted inhalation exposure, daily in mg/kg/day)**

$$PEC_{i-daily}' = PEC_i * \frac{PI'}{PI} * \frac{A'_{use}}{A_{use}} * \frac{FQ'(\geq 1)}{FQ} * \frac{ET'}{ET} * \frac{RV}{RV'} * DFA$$

$$DFA = \frac{\int_0^{ET'} e^{-ACH * t} dt}{ET'} \quad \text{Basis: RIVM ConsExpo}$$

FQ' < 1/day, FQ' = FQ

**Column BG (Mean event concentration in mg/m<sup>3</sup>, bounded with the SVC)**

$$PEC_{TWA} = \min\left(\frac{\frac{PI' * A'_{use} * F_e * 1000 * IEF}{RV'} \int_0^{ET'} e^{-ACH * t} dt}{ET'}, SVC\right)$$

$$\int_0^{ET'} e^{-ACH * t} dt = \frac{1 - e^{-ACH * ET'}}{ACH} \quad \text{Basis: RIVM ConsExpo}$$

For spray products,  $F_e = 1$  always.

For non-spray products,  $F_e = 1$  for high vapor pressure (>10Pa), 0.1 for medium vapor pressure (1-10Pa), 0.01 for medium low vapor pressure (0.1-1Pa) and 0.001 for low vapor pressure (<=0.1Pa).

**Column BH (Indicator for basis of inhalation event concentration (SVC if Saturated Vapor Concentration is used))**

Indicates if the inhalation mean event concentration is based on saturated vapor concentration.

#### Column BI (Mean inhalation concentration (24hr TWA) on day of exposure in mg/m<sup>3</sup>)

$$PEC_{TWA-daily} = \frac{PEC_{TWA} * ET' * FQ'(\geq 1)}{24}$$

FQ' < 1/day, FQ' = FQ

#### Column BJ (Mean inhalation concentration, yearly in mg/m<sup>3</sup>)

$$PEC_{TWA-yearly} = \frac{PEC_{TWA} * ET' * FQ'}{24}$$

#### Column BK (Total prediction exposure in mg/kg/day – day of use for TRA comparison only)

Summation of the predicted exposure from all pathways (column BA, BD and BF):

$$TPEC'(mg / kg / day) = PEC'_{d-daily}(mg / kg / day) + PEC'_{o-daily}(mg / kg / day) + PEC'_{i-daily}(mg / kg / day)$$

#### Column BV (Operation Condition populating)

Concatenate the OC standard phrases with the parameters in the table 2b with the OC standard phrase code at the end.

OCpopulating (the first parameter in the table 2b (e.g., AB13): the last parameter in the table 2b (e.g., AY13))

#### Column BW (Risk Management Measure populating)

Concatenate the RMM standard phrases with the parameters in the Control band tables with the RMM standard phrase code at the end.

RMMpopulating (range of exposure pathway, dermal DNEL input, oral DNEL input, inhalation DNEL input, range of RCRs based on TRA+, range of Control band1, range of Control band2, range of Control band3, range of Control band4, target RCR)

#### Column BY – CB (Final substance specific RCRs, including RMMs when needed)

RCRpopulating (dermal DNEL input, oral DNEL input, inhalation DNEL input, range of RCRs based on TRA+, indication of exposure pathway, range of Control band1, range of Control band2, range of Control band3, range of Control band4, target RCR)

#### Column CC – CE (Predicted exposure estimates including RMMs when needed)

PECpopulating (dermal DNEL input, oral DNEL input, inhalation DNEL input, range of RCRs based on TRA+, indication of exposure pathway, range of Control band1, range of Control band2, range of Control band3, range of Control band4, target RCR)

### **Equations in control banding**

Equations below are used in control band 1, but are the same for those in other three control bands.

#### **Column CP-DB (efficiencies)**

RMM effectiveness (or efficiency) is defined as the percentage reduction in exposure concentration or emission (release) produced by application of the RMMs based on ECHA chapter R.13

Concentration (column CQ):

$$EFC_1 = \frac{PI_{TRA+} - PI_{dnel-band}}{PI_{TRA+}}$$

Amount of use (column CS):

$$EFC_2 = \frac{A_{TRA+} - A_{dnel-band}}{A_{TRA+}}$$

Glove factor (column CU):

$$EFC_3 = \frac{Glove_{TRA+} - Glove_{dnel-band}}{Glove_{TRA+}}$$

Amount swallowed (column CW):

$$EFC_4 = \frac{A_{swallow(TRA+)} - A_{swallow(dnel-band)}}{A_{swallow(TRA+)}}$$

Air exchange rate: (column CZ):

$$EFC_5 = \frac{\int_0^{ET'_{TRA+}} e^{-ACH_{TRA+} * t} dt - \int_0^{ET'_{TRA+}} e^{-ACH_{dnel-band} * t} dt}{\int_0^{ET'_{TRA+}} e^{-ACH_{TRA+} * t} dt}$$

Room volume (column DB):



$$EFC_6 = \frac{\frac{1}{RV_{TRA+}} - \frac{1}{RV_{dnel-band}}}{\frac{1}{RV_{TRA+}}} = \frac{RV_{dnel-band} - RV_{TRA+}}{RV_{dnel-band}}$$

### Column DC-DE (PECs)

PEC based on RMM, dermal (mg/kg/day) (column DC):

$$PEC_{dermal-dnel} = PEC_{d-chronic} \times \frac{PI_{dnel-band}}{PI_{TRA+}} \times GE_{dnel-band}$$

PEC based on RMM, oral (mg/kg/day) (column DD):

$$PEC_{oral-dnel} = PEC_{o-chronic} \times \frac{PI_{dnel-band}}{PI_{TRA+}} \times \frac{A_{swallow(dnel-band)}}{A_{swallow(TRA+)}}$$

PEC based on RMM, inhalation (mg/m<sup>3</sup>) (column DE):

$$PEC_{inhalation-dnel} = PEC_{I-chronic} \times \frac{PI_{dnel-band}}{PI_{TRA+}} \times \frac{A_{dnel-band}}{A_{TRA+}} \times \frac{\int_0^{ET'} e^{-ACH_{dnel-band} \times t} dt}{\int_0^{ET'} e^{-ACH_{TRA+} \times t} dt}$$

### Column DF-DI (substance specific RCRs)

Column DF:  $RCR_{dermal-dnel} = \frac{PEC_{dermal-dnel}}{DNEl_{dermal}}$

Column DG:  $RCR_{oral-dnel} = \frac{PEC_{oral-dnel}}{DNEl_{oral}}$

Column DH:  $RCR_{inhalation-dnel} = \frac{PEC_{inhalation-dnel}}{DNEl_{inhalation}}$

Column DI:  $RCR_{total-dnel} = RCR_{dermal-dnel} + RCR_{oral-dnel} + RCR_{inhalation-dnel}$

### Column DJ-DM (control banding RCRs)

Column DJ:  $RCR_{dermal-dnel-banding} = \frac{PEC_{dermal-dnel}}{DNEl_{lowest-dermal-dnel-in-the-band}}$

Column DK:  $RCR_{oral-dnel-banding} = \frac{PEC_{oral-dnel}}{DNEL_{lowest-dermal-dnel-in-the-band}}$

Column DL:  $RCR_{inhalation-dnel-banding} = \frac{PEC_{inhalation-dnel}}{DNEL_{lowest-dermal-dnel-in-the-band}}$

Column DM:  $RCR_{total-dnel-banding} = RCR_{dermal-dnel-banding} + RCR_{oral-dnel-banding} + RCR_{inhalation-dnel-banding}$

## Appendix B: Examples of Tier 2 Scenarios

The tool can be modified to incorporate higher Tier estimates, including higher Tier exposure tools and also monitoring data. Examples of possible modifications are described below.

Example PC13 Fuels, subcategory automotive refuelling – Incorporation of monitoring data, skin permeability, and higher Tier dermal model (SkinPerm) results:

### 1) Changes in TRA+ input parameters:

| Relevant Use Sentinel Product | Product sub Category Sentinels                      | TIER1+ ECETOC TRA - exposure modifiers             |          |  |                      |          |                           |  |  |  |                                      |                          |                                     |   |                  |  |                       |  |
|-------------------------------|---|--|----------|--|----------------------|----------|---------------------------|--|--|--|--------------------------------------|--------------------------|-------------------------------------|---|------------------|--|-----------------------|--|
|                               |   | Dermal Factor                                      |          | Glove efficiency   | Amount Swallowed (g) |          | Amount Used per event (g) |  | Inhalation Factor (fraction of total use spilled/evaporated, i.e., amount lost)      |  | Location (indoors, outdoors, garage) | Air Exchange Rate (1/hr) |                                     | Dilution Factor incorporating Air Exchange Rate applied to TRA for mg/kg inhalation calc. | Room Volume (m3) |  | Exposure time (hours) |  |
|                               |   | Value  | Comments |  | Value                | Comments | Value                     | Comments   | Value  | Comments   |                                      | Value                    | Comments                            |   | Value            | Comments                                 | Value                 | Comments                                       |
| PC13:Fuels                    | Liquid - subcategories added: Automotive Refuelling |  |          |  |                      |          | 37500                     | est. fuel tank size 50 L converted using gasoline density of 750 kg/m3 | 0.0020   | expect low % loss during refueling due to evaporation /spill | outdoor                              | 0.60                     | est. conservative value for outdoor | 0.99  | 100              | Stoffrem anager volume used for outdoors | 0.050                 | 3mins, 97th percentile- Vainiotalo et al. 1999 |
|                               |   | Tier 2: inhalation measured data and Tier 2 dermal |          | SkinPerm modeling utilized dermal uptake flux of 0.0023 mg/cm2-hr based upon bulk gasoline and hydrocarbon |                      |          |                           |  | Measured air concentration = max. gasoline vapor conc. from Hakola and Saarinen 2000 |  |                                      |                          |                                     |   |                  |  |                       | 0.05   |

### 2) Exposure estimates:

| Relevant Use Sentinel Product | Product sub Category Sentinels                      | TRA Tier 1+ Predicted Exposure - ECETOC TRA - refined estimates |  |   |  |  |  |   |   |  |   |
|-------------------------------|---|---|--|---|--|--|--|---|---|--|---|
|                               |   | Predicted Dermal Exposure, Daily (mg/kg/d)                      | Predicted Dermal Exposure, Chronic (mg/kg/d) | Predicted Dermal Exposure, Local (mg/cm2) | Predicted Oral Exposure, daily (mg/kg/d) | Predicted Oral Exposure, Chronic (mg/kg/d) | Predicted Inhalation Exposure, daily (mg/kg/d) | Mean Inhalation Event Concentration (mg/m³) | Mean Inhalation Concentration (24hr TWA) on Day of Exposure (mg/m3) | Mean Inhalation Concentration Yearly (mg/m3) | Total Predicted Exposure (mg/kg/d) - day of use for TRA comparison only |
|                               |   | day of use  | chronic                                      | event                                     | day of use                               | chronic                                    | day of use                                     | event                                       | day of use  | chronic                                      |   |
| PC13:Fuels                    | Liquid - subcategories added: Automotive Refuelling | 35.00   | 5.01   | 10.00                                     | 0.00                                     | 0.00                                       | 0.84   | 738.86                                      | 1.54  | 0.220  | 35.84   |
|                               | Tier 2: inhalation measured data and Tier 2 dermal  | 0.0004  |  | 0.00010                                   |  |  | 0.62   | 531.00                                      | 1.11  | 0.158  | 0.62  |

Example PC13 Fuels, subcategory scooter refuelling– Incorporation of monitoring data, skin permeability, and higher Tier dermal model (SkinPerm) results:

### 1) Changes in TRA+ input parameters:

| Relevant Use Sentinel Product | Product sub Category Sentinels   | TIER1• ECETOC TRA - exposure modifiers |  |                  |                      |          |                           |  |   |   |                                      |                          |                                     |   |       |  |       |                                     |       |          |
|-------------------------------|--|--|--|------------------|----------------------|----------|---------------------------|--|---|---|--------------------------------------|--------------------------|-------------------------------------|---|-------|--|-------|-------------------------------------|-------|----------|
|                               |  | Dermal Factor                          |  | Glove efficiency | Amount Swallowed (g) |          | Amount Used per event (g) |  | Inhalation Factor (fraction of total use spilled/evaporated, i.e., amount lost) |   | Location (indoors, outdoors, garage) | Air Exchange Rate (1/hr) |                                     | Dilution Factor incorporating Air Exchange Rate applied to TRA for mg/kg inhalation calc. |       | Room Volume (m3)                         |       | Exposure time (hours)               |       |          |
|                               |  |  |  |                  |                      |          |                           |  |   |   |                                      |                          |                                     |   |       |  |       |                                     |       |          |
|                               |  | Value                                  | Comments   |                  | Value                | Comments | Value                     | Comments   | Value   | Comments  |                                      | Value                    | Comments                            |   | Value | Comments                                 | Value | Comments                            | Value | Comments |
| PC13:Fuels                    |  |  |  |                  |                      |          | 3750                      | est. fuel tank size 5 L converted using gasoline density of 750 kg/m3                | 0.0200  | expect low % loss during refueling but more than for automotive | outdoor                              | 0.60                     | est. conservative value for outdoor | 0.99  | 100   | Stoffen manager volume used for outdoors | 0.03  | 2mins. Est. as shorter than vehicle |       |          |
|                               | Liquid - subcategories added: Scooter Refuelling                                   |  |  |                  |                      |          |                           |  |   |   |                                      |                          |                                     |   |       |  |       |                                     |       |          |
|                               | Tier 2: inhalation measured data and Tier 2 dermal: used same as vehicle refueling |  | SkinPerm modeling utilized dermal uptake flux of 0.0023 mg/cm2-hr based upon bulk gasoline and hydrocarbon |                  |                      |          |                           | Measured air concentration = max. gasoline vapor conc. from Hakola and Saarinen 2000 |   |   |                                      |                          |                                     |   |       |  | 0.03  | 2mins. Est. as shorter than vehicle |       |          |

### 2) Exposure estimates:

| Relevant Use Sentinel Product | Product sub Category Sentinels<br><br>+  | TRA Tier 1- Predicted Exposure - ECETOC TRA - refined estimates |  |  |  |  |  |   |   |  |   |
|-------------------------------|--|---|--|--|--|--|--|---|---|--|---|
|                               |  | Predicted Dermal Exposure, Daily (mg/kg/d)                      | Predicted Dermal Exposure, Chronic (mg/kg/d) | Predicted Dermal Exposure, Local (mg/cm2 ) | Predicted Oral Exposure, daily (mg/kg/d) | Predicted Oral Exposure, Chronic (mg/kg/d) | Predicted Inhalation Exposure, daily (mg/kg/d) | Mean Inhalation Event Concentration (mg/m³) | Mean Inhalation Concentration (24hr TWA) on Day of Exposure (mg/m3) | Mean Inhalation Concentration Yearly (mg/m3) | Total Predicted Exposure (mg/kg/d) - day of use for TRA comparison only |
|                               |  | day of use  | chronic                                      | event                                      | day of                                   | chronic                                    | day of use                                     | event                                       | day of use  | chronic                                      |   |
| PC13:Fuels                    | Liquid - subcategories added: Scooter Refuelling                                   | 35.00   | 5.01   | 10.00                                      | 0.00                                     | 0.00                                       | 0.56   | 742.62                                      | 1.02  | 0.146  | 35.56   |
|                               | Tier 2: inhalation measured data and Tier 2 dermal: used same as vehicle refueling | 0.00024   |  | 0.00007                                    |  |  | 0.37   | 531.00                                      | 0.73  | 0.104  | 0.37  |

Examples of incorporating CONSEXPO modelled results utilizing TRA+ operating conditions for two PC9 subcategories:

| Relevant Use Sentinel Product                       | Product sub Category Sentinels              | TRA Tier 1- Predicted Exposure - ECETOC TRA - refined estimates |  |   |  |  |  |  |  |
|---|---|---|--|---|--|--|--|--|--|
|   |   | Predicted Dermal Exposure, Daily (mg/kg/d)                      | Predicted Dermal Exposure, Chronic (mg/kg/d) | Predicted Dermal Exposure, Local (mg/cm2) | Predicted Oral Exposure, daily (mg/kg/d) | Predicted Oral Exposure, Chronic (mg/kg/d) | Predicted Inhalation Exposure, daily (mg/kg/d) | Mean Inhalation Event Concentration (mg/m <sup>3</sup> ) | Mean Inhalation Concentration (24hr TWA) on Day of Exposure (mg/m <sup>3</sup> ) |
|   |   | day of use  | chronic                                      | event                                     | day of use                               | chronic                                    | day of use                                     | event  | day of use   |
| PC9a:Coatings and paints, fillers putties, thinners | Solvent rich, high solid, water borne paint | 19.65   | 0.31   | 2.75                                      | 0.00                                     | 0.00                                       | 285.31   | 5679.70  | 520.64   |
|   | Tier 2: ConsExpo estimates                  | 0.26  |  |   |  |  |  |  | 343.00   |
| PC9a:Coatings and paints, fillers putties, thinners | Aerosol <b>spray</b> can                    | 0.00  | 0.00   |   | 0.00                                     | 0.00                                       | 18.79  | 2493.83  | 34.29  |
|   | Tier 2: ConsExpo estimates                  |   |  |   |  |  |  |  | 2.92   |

## Appendix C: Example of Dermal Factor Calculation if a Dermal Absorption Rate is Available

A "Dermal Factor", i.e., a modifier for the dermal exposure estimate, may be based upon a variety of data. One type of data is a Dermal Absorption Rate. If a Dermal Absorption Rate is available in mg/cm<sup>2</sup>/hr, and the dermal DNEL value is based upon internal dose (rather than external contact), the approach described below could be used to estimate values that may be included as Dermal Factors in the spreadsheet. To further refine the dermal exposure, the user may apply a Dermal Factor using the skin contact time instead of the scenario's total exposure time.

$$\text{DermalFactor} = \frac{\text{DermalExposureEstimate(withDermalAbsorptionRate)}}{\text{DermalExposureEstimate}}$$

$$\text{DermalExposureEstimate} = \frac{\text{ProductIngredient(g/g)} * \text{ThicknessLayer(cm)} * \text{Density(g/cm}^3\text{)} * \text{ContactArea(cm}^2\text{)} * 1000}{\text{BodyWeight(kg)}}$$

$$\text{DermalExposureEstimate(DermalAbsorptionRate)} = \frac{\text{DermalAbsorptionRate(mg/cm}^2\text{/hr)} * \text{ContactArea(cm}^2\text{)} * \text{ExposureTime(hr)}}{\text{BodyWeight(kg)}}$$



$$\text{DermalFactor} = \frac{\text{DermalAbsorptionRate(mg/cm}^2\text{/hr)} * \text{ExposureTime(hr)}}{\text{ProductIngredient(g/g)} * \text{ThicknessLayer(cm)} * \text{Density(g/cm}^3\text{)} * 1000(\text{mg/g})}$$

|   |       |
|---|-------|
| Dermal Absorption Rate (mg/cm <sup>2</sup> /hr) | 0.002 |
| Thickness Layer (cm)                            | 0.01  |
| Density (g/cm <sup>3</sup> )                    | 1.0   |

| Relevant Use Sentinel Product | Product sub Category Sentinels                            | adult / child |      |            | Product ingredient (weight fraction) (g/g) |             | Exposure time (hours) |             | Dermal Factor |
|-------------------------------|---|---------------|------|------------|--|-------------|-----------------------|-------------|---------------|
|                               |   | dermal        | oral | inhalation | Value                                      | Comments    | Value                 | Comments    |               |
| PC1:Adhesives, sealants       | Glues, hobby use  | A             |      | A          | 0.3  | TRA default | 4                     | TRA default | 0.00267       |
| PC1:Adhesives, sealants       | Glues DIY-use (carpet glue, tile glue, wood parquet glue) | A             |      | A          | 0.3  | TRA default | 6                     | TRA default | 0.00400       |