# Exposure Scenario for Chemical Safety Report and Communication Example:

## Consumer use of a substance in cleaning products

**EXPOSURE SCENARIO FOR CHEMICAL SAFETY REPORT AND COMMUNICATION**
**EXAMPLE: CONSUMER USE OF A SUBSTANCE IN CLEANING PRODUCTS**

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## Overview

REACH is based on the principle that industry should manufacture, import or use substances or place them on the market in a way that human health and the environment are not adversely affected. For substances manufactured or imported in quantities at or above 10 tonnes per year and that are classified as dangerous or considered as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), the chemical safety assessment (CSA) is the instrument to:

- Assess the intrinsic hazards of substances;
- Assess the exposure of man and the emission to the environment that result from manufacture and uses throughout the life cycle of the substances.
- Characterise the risks identified following the assessment of exposure/emission; and
- Identify and document the conditions of manufacture and use which are needed for controlling the risks to human health and the environment. This includes the operational conditions (OC) and risk management measures (RMM). In REACH this set of information is called the **exposure scenario** (ES)

The outcome of the CSA, including relevant data, justifications and judgements has to be documented in a chemical safety report (CSR)[1].

When an ES is developed, the company carrying out the assessment shall inform its direct customers and the actors further down the supply on the conditions of use (i.e. the operational conditions and risk management measures) to ensure control of risk. For this purpose the relevant information from the CSR is compiled into one or more exposure scenarios (ES) to be annexed to the safety data sheet (SDS).

The exposure scenario in the contexts of the CSR and the safety data sheet have different purposes, and thus their content may differ. For example, the exposure scenario in the CSR will contain justifications and comments, the exposure scenario annexed to the safety data sheet will not. However, the operational conditions and risk management measures relevant for each task must be consistent.

The aim of this document is to describe, by means of an example[2], an iterative procedure for the assessment of consumer and environmental exposure to a substance which is commonly used in consumer products and how to build an exposure scenario for both the CSR and communication once the exposure assessment and risk characterisation have been completed.

Exposure can be considered as a single event, as a series of repeated events or as continuous exposure. In the exposure assessment the levels of exposure need to be considered, as well as other parameters such as the duration and frequency. Exposure assessments should take account of acute and chronic effects and whether they are local or systemic.

Consumer exposure can be estimated in a tiered manner. The process starts with a screening estimation (Tier 1) designed to be conservative. If the result of the screening is that exposure is below the thresholds established from toxicological studies (for instance the appropriate DNEL= derived no effect level), then it can be concluded that there is “no concern”, and the risks from using the product are deemed to be controlled. If the Tier 1

[1]Annex 1 of REACH provides the requirements for the CSA and format for the CSR
[2]Built on the basis of ECHA Guidance on Information Requirements and Chemical Safety Assessment (IR/CSA)

assessment does not generate an acceptable level of risk, the estimate has to be refined, by iteration until the risk characterisation shows that risks identified are adequately controlled. The Tier 1 estimate can be refined through using real data or alternatively a higher Tier model can be applied that takes account of other factors that influence the exposure result.

This example shows how the application of the ECETOC TRA Consumer tool (Tier 1) and then ConsExpo (version 4.1, a Tier 2 tool) generate different exposure results. The ConsExpo computer tool does require some prior knowledge and expertise to ensure it is used correctly.

More detail on the estimation tools used in this project, and exposure estimation generally, can be found in ECHA Guidance on information requirements and chemical safety assessment R.15. - Consumer exposure estimation (v.2, 2010). Guidance R.15 explains the core concepts, input parameters, strengths and limitations of the different tools. An important aspect of this example is a practical demonstration of how the limitations within the models can be addressed and reflected in exposure scenarios for the chemical safety report (CSR) and for communication.

This example is therefore intended to support production of good quality exposure scenarios in the chemical safety report and subsequently, in simplified form to provide good quality, tailored, information down the supply chain.

The example concentrates on risks arising from (eco)toxicological properties of a substance in consumer use. Physical health hazards are not considered in this example.

It must be emphasised that this example is focused on one particular substance used in a well defined type of cleaning products. Thus the example is not necessarily representative for substances with other properties or for other uses.

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# 1. INTRODUCTION

## 1.1 Background

The exposure scenario[3] is one of the main innovations of the REACH Regulation. The exposure scenario aims to document how to safely use chemicals. ECHA recognises publication of examples is a good way to illustrate how an exposure scenario can look like in practice. Examples will help to establish between industry and authorities a common understanding of the information that an exposure scenario should contain. These examples have been developed in cooperation with industry.

The aim of this project was to develop an example of an exposure scenario for a Chemical Safety Report (CSR). Further it is intended to show how the results of the process are communicated via an annex of the safety data sheet for one substance used by consumers, and then to demonstrate control of risk based on the release and exposure estimations leading to characterisation of risk for human health and the environment.

The consumer cleaning product sector was identified as a possible partner for this project. A substance used in cleaning and washing products (Product Category – PC - 35) has been selected as an example.

The objectives of the project are summarized below:

- To develop a reference example of an exposure scenario for the CSR and subsequent communication, specific to 'consumer use' of substances. This is intended as a guide for industry.
- To test the formats, guidance[4] and tools for industry, including Chesar, in order to provide feedback to the development teams within ECHA.

## 1.2 Project outcome

The outputs of the project are:

- A summary document which:
    - describes the project and the results obtained;
    - presents the criteria adopted for the selection of substances and uses;
    - describes the methodology used for the assessment;
    - details the major issues, constraints and lessons learned (**Chapter 2**, *in particular* ***paragraph 2.1*** *deals with substance selection and properties,* ***paragraph 2.2*** *with generating the 'exposure scenarios for CSR' including exposure assessment and risk characterisation and* ***paragraph 2.3*** *with generating the exposure scenario for communication from the information contained in the CSR.)*
- The exposure scenarios for the Chemical Safety Report (Sections 9 and 10 of the CSR, **Appendix 1**), which includes[5]:

[3]REACH, Annex I, Section 0.7: "An exposure scenario is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These sets of conditions contain a description of both the risk management measures and operational conditions which the manufacturer or importer has implemented or recommends to be implemented by downstream users"

[4]ECHA Guidance on information requirements and chemical safety assessment: Part D: Exposure Scenario Building (Version 1.1, May 2008 and version 2, May 2010)

- Description of use conditions and risk management measures
- Exposure estimation for both environment and human health[6]
- The risk estimation and risk characterisation ratio for both the environment and human health[7]

- The exposure scenario for onward communication (**Appendix 2**) based on those developed for the CSR and taking into consideration current ECHA guidance and comments provided by downstream users' associations. The exposure scenario is intended for communication between the registrant and industrial customers *(who produce mixtures (cleaning products) for consumer end-use).*

Sections 9 and 10 of the CSR (**Appendix 1**) and ES for communication (**Appendix 2**) have been generated with ECHA's Chemical Assessment and Reporting Tool, Chesar[8] (version 1.2).

The examples also help to identify possible answers to the following questions:

- Exposure scenario for CSR
  - How to report operational conditions and model assumption(s) in the CSR to ensure transparency and reproducibility of the exposure estimates?
  - What level of detail is the registrant expected to assess for the different types of consumer product in which the substance may be included?
  - Is there a need for a REACH-orientated consumer-related exposure estimation tool which includes some of the elements found in more advanced tools (Tier 2 tool) such as ConsExpo?
- Exposure scenario for communication
  - How to address the role that different actors in the supply chain are required to play in exposure scenarios, in order to ensure that the conditions of safe use as described in the ES are really implemented?
  - Apart from risk management measures (RMMs) related to product design and behavioural advice to the consumer, what other types of information could be provided, as a minimum?
  - To what extent should the assumptions on consumer habits and practices and the standard operational conditions for the different product types be:
    - made explicit in the exposure scenario for communication or
    - referenced to an external source of documentation?
  - How should information be communicated to the formulator of the consumer product on exposure estimates and the resulting risk characterisation?
  - How best to communicate on the concept of scaling to the formulator related to consumer products?

[5]In the current example, the ES for both CSR and communication represent only part of the life-cycle of the substance. The REACH Regulation requires that the assessment covers all stages of a life-cycle.
[6]REACH Annex I, Section 5
[7]REACH Annex I, Section 6
[8] http://chesar.echa.europa.eu/

## 1.3 Main findings

- The example is about a substance of low hazard for both human health and environment which can be released to air and waste water during its use in cleaning products. Consequently, the use of a Tier 1 exposure assessment tool should cover most of the uses, and the need for differentiation into product subcategories should be relatively low. In practice however it turned out that the currently available consumer exposure estimation tools (ECETOC TRA consumer and ConsExpo) do not sufficiently support such logic, and thus further development of the tools would be desirable**.**
- The example is also representative for the exceptional case that a DNEL for (a mild) local effect is available. This triggered the need to apply a Tier 2 exposure estimation model for event exposure for certain sub product groups.
- The example demonstrates how the available Tier 1 tool for consumer exposure assessment (ECETOC TRA consumer) can be used to demonstrate safe use for some product subcategories within the category of *washing and cleaning products* (Product Category 35) but not others. For some product subcategories the TRA is too conservative to demonstrate safe use and a higher Tier tool (ConsExpo) was needed.
- The ECETOC TRA was applied in a slightly modified way to assess long term (repeated) inhalation exposure against the chronic DNEL. The event concentration for inhalation predicted by the tool was averaged out over the day before being compared with the chronic DNEL. This was based on documentation available that such products are normally used only once a day.
- For the presentation of the assessment in the CSR an approach has been chosen that aims to provide for a high level of transparency. This will facilitate the work of persons expected to read and eventually update the CSR at a later stage or authorities evaluating the CSR.
- For the exposure scenario for communication two options have been worked out:
    1. Long (full) version: Detailed information on assumptions about generic conditions of use has been reported.
    2. Short (reduced) version: The information is limited to those conditions of use which are directly related to the product design and basic use characteristic determined by the individual manufacturer of the consumer product. In this option, a link to an external source of documentation has been included.

  Both approaches are acceptable provided that references to external documentation are well reported and readily accessible; the short version may be easier to use in some circumstances, particularly by small and medium-sized enterprises (SMEs).
- The example for the exposure scenario for communication is still work in progress and ECHA is interested to receive comments on the way the ES for communication should be structured. Please note: The ES for communication is as yet not expressed in standard phrases; the phrases used in this document have been generated in Chesar for the specific examples. Once a complete phrase catalogue will be made available by industry, the use of standard phrases would be highly recommended to facilitate communication amongst actors in the supply chain.

# 2. BUILDING A CONSUMER EXPOSURE SCENARIO FOR CSR AND FOR COMMUNICATION

## 2.1 Substance selection and properties

An alcohol widely used as a liquid component in several cleaning products (PC35) has been selected as an example reference substance.

The substance is potentially used in a wide range of cleaning products, such as[9]:

- Laundry and dishwashing products:
    - Detergent liquids – laundry products
    - Hand dishwashing liquids
    - Machine dishwashing products - rinse aids
- Liquid surface cleaners:
    - All-purpose cleaners (including sprays)
    - Abrasive liquids
    - Sanitary cleaners like bathroom cleaners (including sprays)
    - Floor cleaners
    - Carpet cleaners
    - Glass cleaners (including sprays)

From market data provided by the industry and taking into account data contained in RIVM fact sheet to be used with ConsExpo (see footnote 7), the concentration of the substance in washing and cleaning products is typically < 5% but the maximum level of use, 15%, was used for a conservative exposure assessment, with 2 exceptions:

- Abrasive liquid: only up to 5%
- Carpet cleaners: up to 30%

The substance is volatile, readily biodegradable, water soluble and has a low octanol-water partition coefficient. It is classified as highly flammable (harmonised classification) and, if concentrations are above 50%, as an eye irritant (self-classification).

[9]Reference: RIVM report 320104003/2006 - Cleaning products Fact Sheet

**Table 1: Physicochemical properties and Classification and Labelling**

| SUBSTANCE INFORMATION | | |
|---|---|---|
| **General properties** | | |
| 1 | Physical state at 20 ºC and 101,3 kPa | Liquid |
| 2 | Vapour pressure (kPa) at 20 ºC | 5.726 |
| 3 | Water solubility | 790 g/L at 20 ºC |
| 4 | Octanol-Water partitioning coefficient (log Kow) | - 0.35 |
| 5 | Biodegradation screening test | Readily biodegradable |
| **Classification and labelling** | | |
| 6 | Substance classified as CMR PBT/vPvB | No |
| 7 | Substance classification (R/H phrases) | Directive 67/548/EEC: R11 Highly flammable<br>Regulation (EC) No 1272/2008: H225: Highly flammable liquid and vapour.<br>H319: Causes serious eye irritation (>50%) |

The manufacturer of the substance has provided DNELs for the general population covering the following routes of exposure and type of effects:

- Long term systemic effects - dermal
- Long term systemic effects – inhalation
- Long term systemic effects – oral
- Acute local inhalation for respiratory sensory irritation.

The substance is classified as an eye irritant at concentrations above 50% via splashes but no DNEL is available for this route / scope of effect.

All PNECs have been provided by the manufacturer, except for secondary poisoning, since the substance is not bioaccumulative as indicated by a low octanol-water partition coefficient.

All relevant DNELs and PNECs are summarized in Table 2.

**Table 2: (Eco)toxicological information**

| SUBSTANCE INFORMATION | | |
|---|---|---|
| **Toxicological information (general population)** | | |
| 1 | DNEL long term systemic – Inhalation | 114 mg/m$^3$ |
| 2 | DNEL long term systemic – Dermal | 206 mg/kg/d |
| 3 | DNEL long term systemic – Oral | 87 mg/kg/d |
| 4 | DNEL local acute – Dermal[10] | Not available |
| 5 | DNEL local acute – Inhalation | 950 mg/m$^3$ |
| **Ecotoxicological information** | | |
| 6 | PNEC freshwater | 0.96 mg/L |
| 7 | PNEC freshwater sediment | 3.6 mg/kg dry weight |
| 8 | PNEC marine water | 0.79 mg/L |
| 9 | PNEC marine water sediments | 2.96 mg/kg dry weight |
| 10 | PNEC agricultural soil | 0.63 mg/kg dry weight |
| 11 | PNEC STP | 580 mg/L |

[10]Eye irritancy is currently covered by acute local effects via dermal exposure in IUCLID 5

The toxicological and ecotoxicological information provided by the manufacturer of the substance trigger the following consequences:

- A quantitative risk assessment is needed in order to cover the long term systemic effect for both consumers and humans via the environment exposed to the substance via dermal, oral and inhalation routes.
- In this specific case, a quantitative risk assessment is also needed to cover the acute local effects for consumers exposed to the substance via the inhalation route.
- A qualitative assessment has been added in relation to eye irritation in order to cover the acute local effects via dermal exposure (eye irritancy endpoint).

These effects have been considered when building the exposure scenarios and when calculating exposure estimation and the risk characterisation ratio(s) for consumers.

## 2.2 Exposure Assessment and Exposure Scenarios for CSR

A CSR has been generated using ECHA's Chemical Safety Assessment and Reporting Tool,Chesar. Relevant information arising from hazard assessment and relevant for ES generation has been briefly summarized in the previous section.

When using Chesar for exposure assessment and generation of exposure scenarios the following terms are key:

- use
- stage
- contributing scenario.

In Chesar[11]:

- The **uses** of a substance are described in a life-cycle tree structure. This structure includes 8 different "**stages**": manufacturing stage, formulation stage (for production of mixtures), end-use stage of the substance as such or in a mixture (3 main user groups exist: industrial worker, professional worker and consumer) and article service life if relevant (again three main user groups). For each of these 8 stages, one or more exposure scenarios can be built.
- The number of exposure scenarios per **stage** depends on how the substance is used. For consumer **uses**, the product categories as defined in ECHAs Guidance R.12 are used to describe the scope of a single exposure scenario. As a generic example, washing and cleaning products (PC35) are usually meant to be released to air or to waste water, while pigments in paints (PC9) are meant to stay on the painted object. Thus the characteristic of the use from the environmental perspective is very different. As a consequence two different exposure scenarios would be built for PC35 and PC9.
- At each **stage**, a worker or a consumer can carry out different activities (= **uses**) characterised by the corresponding operational conditions and risk management measures. The consumer activities with a substance can be briefly described via the product (sub)category they are using, since the nature of the product predetermines the foreseeable use. The set of operational conditions and risk management measures related to a "use" is called the "**contributing scenario**". One or more of these contributing scenarios form an exposure scenario.

The following principles and assumptions have been applied for generating the exposure scenarios and exposure estimations:

[11]Chesar user manual – Part 2 – Reporting uses(as updated 5 August 2011)
Link: http://chesar.echa.europa.eu/download/documents/Chesar_user_manual_2_use_reporting1_2.pdf

- All the input parameters that enable the calculations of exposure levels to which consumers, humans via environment and environment are exposed have been reported in the CSR. This ensures transparency of the assessment and reproducibility of the estimations. The determinants that reflect the conditions of use and the risk management measures are reported in the exposure scenario (and corresponding contributing scenarios). Other parameters which are important for the calculation but address more the assumptions in the model(s), rather than describing the condition of use, are reported in the exposure tables included in the CSR.
- Product categories and product subcategories are key input parameters for consumer exposure estimation. One contributing scenario has been associated with each product subcategory relevant for the assessment. The aggregation of different product subcategories was made under the following conditions:
    - Different product subcategories could be characterised by a largely common feature (e.g. use of surface cleaner diluted before application).
    - It was possible to identify one subcategory representing the worst case in terms of exposure for all relevant routes and type of effect.
    - The condition of use related to the subcategory with the highest exposure covered other product subcategories (i.e. higher amount used, larger surface of area of application, etc.).
    - Aggregation of contributing scenarios is done on a case-by-case basis.
- In the first instance the ECETOC TRA for consumers[12] (Tier I model) has been used for the exposure assessment. ConsExpo[13]has been used in situations where the ECETOC TRA could not determine the safe use within a product subcategory.
- For the environment, the assessment is based on environmental release categories (ERC) with the assumption that any emission to water may pass through a sewage treatment plant (STP) before release to surface water takes place. The EUSES fate and transport model as implemented in Chesar has been used to calculate the exposure levels for both the environment and human via the environment. Even if the contributing scenario for the environment and the related exposure estimation has been included in CSR, the focus reported in this project has been directed to consumer exposure only.

The output of the ECETOC TRA exposure assessment for the relevant product category (PC35) and the related product subcategory identified in ECETOC TRA for consumers is summarized in Table 3; the output of the assessment is expressed in terms of risk characterisation ratio (RCR), which represents the ratio between the exposure level and the relevant DNEL.

[12] http://www.ecetoc.org
[13] http://www.rivm.nl/en/healthanddisease/productsafety/Main.jsp

**Table 3: Product subcategory, input parameters and risk characterisation ratio (RCR) using ECETOC TRA for consumers**

| Product subcategory (ECETOC TRA) | Product design and amounts per event | Condition of use | RCR [a,b,c] |
|---|---|---|---|
| 1. Laundry and dish washing products | Concentration of substance = 15%<br>Product amount = 50 g | Frequency = daily<br>Duration of exposure = 60 min<br>Exposed body part = two hands<br>Room volume = 20 $m^3$ | Inh. ST = 0.39<br>Inh. LT = 0.14<br>Der. LT = 0.1 |
| 2. Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners ) | Concentration of substance = 30%[14]<br>Product amount = 250 g | Frequency = daily<br>Duration of exposure = 20 min<br>Exposed body part = two hands<br>Room volume = 20 $m^3$ | **Inh. ST = 3.9**<br>Inh. LT = 0.41<br>Der. LT = 0.2 |
| 3. Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners) | Concentration of substance = 15%<br>Product amount = 35 g | Frequency = daily<br>Duration of exposure = 4 hours<br>Exposed body part = two hands<br>Room volume = 20 $m^3$ | Inh. ST = 0.28<br>Inh. LT = 0.38<br>Der. LT = 0.1 |

Note:

(a) Air concentrations for the substance (event concentrations) from ECETOC TRA for consumers have been compared to the DNEL for acute local inhalation;

(b) The air concentration (event) averaged over the day[15] has been compared to the DNEL for long term systemic inhalation.

(c) Inh ST: Inhalation short term exposure; Inh LT: Inhalation long term exposure; Der LT: Dermal long term exposure

### *2.2.1 Application of ConsExpo methodology*

Due to the RCR for inhalation short term exposure above 1 (RCR = 3,9, see Table 3), a Tier 2 exposure assessment via ConsExpo 4.1 has been performed in order to further address the use of surface cleaning products (subcategory 2 for PC 35 in ECETOC TRA – see Table 3) and obtain a more precise exposure estimation.. The relevant sub-product categories as set out in the RIVM Fact Sheet have been used as a reference for the purposes of this assessment. For the conditions of use, the default assumptions as documented in the ConsExpo RIVM Fact Sheets (see footnotes 17, 18, 19) have been adopted and included as the conditions of use in the exposure scenario for the CSR. Looking at the different surface cleaner (not spray application) sub-products described in the RIVM Fact Sheet[16] and potentially containing the selected substance, the following sub-products have been selected for the purposes of this assessment:

- The use of a diluted cleaning product in a surface cleaning application has been modelled using the most exposure-relevant subproduct represented by a floor cleaning product[17].
- The use of an undiluted surface cleaning product is modelled by an abrasive product[18], which includes toilet cleaners. Since ConsExpo makes a different assumption on the use of an undiluted product compared to that describing a product diluted before use, it was not possible to merge this use with the previous one.

[14] Carpet cleaners
[15] Assuming the product is used not more then once per day, as described in RIVM fact sheet (maximum frequency is related to dishwashing product and all purpose or glass spray cleaners and is about once per day)
[16] Reference: RIVM report 320104003/2006 - Cleaning products fact sheet
[17] RIVM report 320104003/2006 - Cleaning products fact sheet: paragraph 8.1.1 (Floor cleaning product)
[18] RIVM report 320104003/2006 - Cleaning products fact sheet: paragraph 6.1 (Abrasive liquid)

- The use of a carpet cleaner[19] has been evaluated separately since it covers a special use with a different set of conditions of use, such as high volume / quantity used in a cleaning operation.

Five contributing scenarios were then identified to cover the consumer use of the selected substance in a washing and cleaning product:

- Contributing Scenario 1: laundry and dishwashing products (ECETOC TRA for consumers exposure assessment)
- Contributing Scenario 2: spray cleaner (ECETOC TRA assessment)
- Contributing Scenario 3: surface cleaning product diluted before use (floor cleaner assessed with ConsExpo 4.1)
- Contributing Scenario 4: abrasive liquid cleaner (ConsExpo 4.1 assessment)
- Contributing Scenario 5: carpet cleaner (ConsExpo 4.1 assessment)

Different tasks within the same product subcategory have been merged for the purposes of the exposure assessment in order to reduce the granularity of the relevant contributing scenario.(For instance ConsExpo differentiates, when “diluting the substance in water”, between mixing and loading and the final application phase.)

Exposure estimation for air inhalation via ConsExpo 4.1 has used the evaporation model (as recommended in the RIVM Fact Sheet, see footnotes 17, 18, 19), where the air concentration is calculated according to a mass transfer equation[20]. Other approaches included in ConsExpo (such as the instantaneous release model and the constant rate model) were not able to demonstrate the safe use of the substance. The air concentration during the use phase has been used to assess short term effects on consumers, while the event concentration averaged over the day has been used to assess against chronic endpoints.

For dermal exposure, the ConsExpo instant application model, in which all the substance is supposed to be applied directly onto the skin, has been used; in this situation, the dose absorbed during the day of exposure has been used to assess chronic effects.

Exposure via the oral route was not a relevant factor for a product containing the example reference substance and therefore not considered further in the assessment.

A qualitative assessment has been performed in relation to eye irritation. In this case, the concentration of the substance in the product is the key determinant in order to control acute local dermal effects; the substance is classified as an eye irritant at concentrations above 50%.

[19] RIVM report 320104003/2006 - Cleaning products fact sheet: paragraph 8.2.1 (Carpet cleaning liquid)

[20] The more suitable Thibaudaux mass transfer equation, describing a release of compound from a water solution, has been used for the exposure estimation, instead of the Languimir equation suggested in the above mentioned RIVM Fact Sheet which was considered as too conservative in this case.

In the following boxes, some of the main issues and lessons learned from these examples are summarized.

**Issue 1: Tier I models for exposure estimation for consumers**

The available Tier I model (ECETOC TRA for consumers) is a straightforward and REACH-oriented tool. Exposure estimation is directly related to PC/AC category and few product sub-categories; it depends on a small number of determinants. Unfortunately, the degree of conservativeness in the model, for both model assumptions and default values (which are often not variable) limits the usability. According to the industry and based on current experience, around 70-80% of hazardous substances cannot pass the first screening using this Tier I model.

**Lesson Learned**

Regarding ECETOC TRA for consumers (Tier I model), there is a need to improve the usability of the tool to overcome some of the conservatism whilst keeping the same product-category approach and the Tier 1 model (instantaneous release) to maintain some degree of conservatism. Based on the experience with the current example, the following improvements would be useful:

1. Enable averaging of event exposure over the day if sufficient evidence is available on how often the product is normally used in a day (the current default assumption is once per day)
2. Allow for a standard ventilation rate;
3. Enable the modification or setting of product-related defaults based on transparent documentation provided by sector groups.

**Issue 2: Granularity of the assessment and condition of use**

The use of a highly conservative Tier 1 tool triggers the need for Tier II tools for consumer exposure assessment, in particular ConsExpo 4.1. ConsExpo 4.1 is not REACH oriented as the number of input parameters, the complexity of the model assumptions and the high degree of product differentiation make it difficult to use the tool for efficient and routine building of exposure scenarios under REACH.

**Lesson Learned**

1. The example illustrates the complexity within the choices a registrant can make in his assessment using ConsExpo. Each assumption would need to be documented in the CSR. The scientific documentation of the model does not provide for easy justification within the CSR of the decisions taken to achieve an output. (For example, the mass transfer equation and why the equation can be used for a product subcategory and the conditions of use related to it.)

2. Merging of contributing scenarios can reduce the number of assessments. This can lead to acceptable outcomes but there are no set rules within ConsExpo to ensure consistency within product types and between substances. If such merging is not possible, exposure assessment is more complex and exposure scenarios for communication become longer.

## 2.3 Exposure Scenario for Communication

The exposure scenario for communication is meant to relay relevant information from the registrant's chemical safety assessment to the downstream users of the substance so they can make judgements about necessary risk management measures.

For substances in mixtures intended for consumer use, the formulators, and potentially the companies producing the final product for consumers, are the target for the exposure scenario.

The exposure scenario for communication has four sections:

- Section 1: The Title section
  - Indicates the types of consumer products specifically addressed in the exposure scenario (ES).The example addresses the uses of a substance in washing and cleaning products. From the title section a downstream user should be able to identify whether the ES is relevant to him.
- Section 2: Operational Conditions and Risk Management Measures
  - Ensures safe use of the substance from environmental (section 2.1) and human health perspective (section 2.2 to 2.6 for different product subcategories). To ensure that the information is presented to the downstream user in a structured way, it is sorted under a number of headings consistent with the structure of the exposure scenario in the CSR. Based on the information in this section a company producing consumer products should be able to establish whether
    - The design and use characteristics of its products (concentration of substance, viscosity, dustiness of product, particular form of application - spray application, dilution before use) or recommended amount per use event are in line with assumptions of the registrant in his assessment
    - The generic assumptions on consumer habits and practices in relation to a particular type of product (e.g. frequency of use by a "normal consumer") are valid for its product
    - Whether the registrant made assumptions in his assessment that would impact on the technical instruction or behavioural advice given to consumers

    Details on generic conditions under which a product type is used (e.g. application surface, room volumes, ventilation rates) and model assumptions behind the assessment are not specified in the exposure scenario. It is assumed that such conditions of use are an inherent (and well documented) part of the definition of a product (sub)category and the corresponding assessment method, and that modifications at the level of the single registrant or downstream user are not required.
- Section 3: Summarises registrant's exposure estimation and risk characterisation
  - This is potentially relevant to the downstream user and in this section the registrant communicates key values from the exposure estimates and risk characterisation. The registrant also states which methods have been used to generate these values.

- Section 4: Need for recalculation
    - An opportunity to provide information so that the downstream user can recalculate exposures to take account of specific conditions of use and scaling[21]. Such "scaling advice" has not been provided within this example.[22]

All the information in the ES for communication should be expressed in standard phrases from a harmonised phrase catalogue as soon as a complete phrase catalogue will be made available. The current example does not contain standard phrases as these are being developed by industry. The phrases reported in the example have been generated within Chesar.

The example of the "exposure scenario for communication" has been produced in two versions:

1. Long (full) version: Detailed information on assumptions about generic conditions of use have been reported.
2. Short (reduced) version: The information is limited to those conditions of use which are directly related to the product design and basic use characteristic determined by the individual manufacturer of the consumer product.

**Note**: The worked example refers to a substance of relatively low hazard. Consequently the extent of the information in the exposure scenario and the level of detail presented here may not be fully representative for other cases where more hazardous substances are used in a cleaning product.

In the following boxes, some of the main issues and lessons learned from these examples are summarized.

**Issue 3: Minimum information to be reported in the exposure scenario (ES) for communication**
The content of Section 2 may be limited to those conditions of use which are directly related to the product design and the basic use characteristic determined by the individual manufacturer of the consumer product.

**Lesson Learned**
- The extent and level of detail for a consumer exposure assessment depends on the assessment method applied. Many product-related default assumptions are documented in the exposure estimation tool itself. In practice, only a very limited part of the conditions that impact on the consumer exposure estimate can be checked or modified at the level of an individual company. All the other information should be well documented and accessible but not necessarily be included into the exposure scenario for communication.
- The type of conditions and the level of detail to be communicated depend on the hazard profile of the substance. The current example is not representative for more hazardous substances.

[21]The aim of scaling is to allow flexibility in checking if your own or your customers' uses are covered by an exposure scenario. In principle you should comply with the conditions of use indicated in your supplier's exposure scenario. However, if you have another combination of operational conditions and risk management measures which allow you to achieve the same level of safety, you can use scaling to demonstrate that you are in compliance

[22]Section 4 of the current example has been left empty (see Appendix 2) since "scaling advice" for consumers is still work in progress

**Issue 4: ES for communication: Sections 3 and 4 and options for scaling**
The usefulness of the information in the Sections on exposure estimation and risk characterisation to be communicated.

**Lessons Learned**

- The reference to the exposure assessment method used by the registrant is essential for the formulators to be able to understand and process the conditions and measures communicated in Section 2. Assessment of the same product with different tools or defaults leads to different risk characterisation ratios.
- If the risk characterisation ratios, which should be reported in Section 3, are significantly lower than 1 (e.g. 0.2) a formulator of the consumer product may conclude that the concentration and amount communicated in Section 2 of the ES for communication do not represent the limits of safe use, and hence adequate control of risk may still be ensured if the substance is used in higher concentrations, amounts or frequency. In such a case, a downstream user (DU)might consider that his use is covered by the supplier's ES even if the concentration, amount or frequency is slightly higher than what is stated in the ES. However, taking account of the large variability in consumer behaviour and recognition of possible multiple exposures to the same substances from different products in the consumer setting, the "filling up" of the risk characterisation at downstream user level to an RCR closer to 1 without carrying out a downstream user CSA is not recommended. In any case, the prerequisite for interpreting an ES in the way described is to fully understand how the registrant had built the ES (methodology and tools used). Guidance and examples will help the downstream user to implement, and work within the boundaries set by, the ES communicated by the registrant without compromising the safe use of a substance.
- There are only two variable parameters per product category that are suitable for scaling based on the available Tier 1 models. Concentration of the substance in the product and the product amount per event are both contributing to the amount of substance released to air and therefore are interchangeable. All other quantitative determinants are linked to the generic conditions of use associated with a product category, and they should therefore not be subject to scaling by individual companies.

# 3. REFERENCES


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# Appendix 1 – ES for CSR

Exposure scenarios describing the conditions of use, exposure estimation and risk characterisation related to the example are reported in sections 9 and 10 of the CSR.

The main parts of the CSR, as generated by Chesar 1.2[23], are briefly discussed below in order to facilitate the reading of the Appendix; the focus has been placed on the human health part of the exposure scenario (i.e. the contributing exposure scenarios and exposure assessment covering consumer uses).

- Section 9.0.1: General tables showing uses and exposure scenarios covered in the CSR are reported. In this example, the tables are very simple since the CSR is covering one exposure scenario only.
- Section 9.0.2: Reports the scope and type of exposure assessment. Essentially this means what route of exposure and type of effect (directed by hazard data) should be assessed and whether assessment should be qualitative or quantitative[24].
- Section 9.1.1.x: Presents the contributing scenarios. (In the Appendix, the first one relates to the environment, then follow the contributing scenarios covering exposure to consumers.) In particular there is:
    - Supporting information to add detail to described uses and tasks covered by the contributing scenario for consumers
    - The structure of the contributing scenarios for human health follow the Chesar logic; in particular each determinant (reflecting a condition of use or risk management measure) is linked to the route of exposure (Inhalation, Dermal, Oral) and the type of effect (Local, Systemic and Acute or Long term) for which the determinant has been used for exposure estimation.
- Section 9.1.2.x: Provides the exposure estimation for each contributing scenario (9.1.2.1 for the environment and from 9.1.2.2 for consumer exposure); with respect to consumer exposure the following information is reported:
    - Exposure estimation in the appropriate unit for each relevant route and type of effect.
    - Exposure assessment tools (ECETOC TRA, ConsExpo) or method used for the exposure assessment
    - Other remarks including:
        - model assumptions (needed for calculation but not reflecting the condition of use and hence not reported in the exposure scenario); and
        - more detailed information on the source of the exposure concentration or dose.
- Section 10.1.1: The risk characterisation for human health is reported for each contributing scenario. In the tables the following information is reported:

[23]Chesar version 1.2 August 2011

[24]The exposure assessment follows the provisions of the ECHA Guidance B.8 on the scope of the exposure assessment available at the time of publication. A revised version of this guidance is currently under consultation and an updated publication is expected in the autumn 2011. For the state of play of the consultation procedure please go to the Consultation Procedure page on the ECHA web site

- Risk characterisation ratio for each relevant route and type of effect.
- Justifications for qualitative risk assessment
- Combined risk to take into account exposure via different routes (i.e. dermal + inhalation) and the man via environment contribution.

# CHEMICAL SAFETY REPORT

**Substance Name:** Alcohol

**EC Number:**

**Registrant's Identity:**

# 9. EXPOSURE ASSESSMENT

## 9.0. General information

### 9.0.1. Overview of exposure scenarios and uses

**Table 1. Overview of exposure scenarios (ES) described in sections 9.1ff.**

| ES number | Exposure scenario name | Manufacture / Use / Subsequent service life | Stage No.*) |
|---|---|---|---|
| 1 | Consumer use of alcohol in washing and cleaning product | Consumer use of alcohol in washing and cleaning product<br>- Consumer use of laundry and dishwashing product<br>- Consumer use of trigger spray cleaner products<br>- Consumer use of liquid cleaning product for manual surface application<br>- Consumer use of abrasive product for manual surface application<br>- Consumer use of liquid cleaner for cleaning carpet | C-1 |
| *) A stage number consists of an abbreviation of the main life cycle stage followed by a consecutive number.<br><br>Manufacture: M-#, Formulation: F-#, Industrial end use: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial settings): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#. | | | |

**Table 2. Overview of uses broken down by life cycle stages and the exposure scenarios (ES) described in sections 9.1ff.**

| Main life cycle stage | Stage No. *) | Manufacture / Use / Subsequent service life | Related subsequent service life | Market sector | Tonnage (tonnes per year) | ES No. |
|---|---|---|---|---|---|---|
| | | Manufacture/Import<br>- 40000.0 tonnes/year | | | 40000.0 | |
| Consumer end use | C-1 (IUC-1) | Consumer use of alcohol in washing and cleaning product (ERC 8a)<br>- Consumer use of laundry and dishwashing product (PC 35)<br>- Consumer use of trigger spray cleaner products (PC 35)<br>- Consumer use of liquid cleaning product for manual surface application (PC 35)<br>- Consumer use of abrasive product for manual surface application (PC 35)<br>- Consumer use of liquid cleaner for cleaning carpet (PC 35) | | | 40000.0 | 1 |
| *) A stage number consists of an abbreviation of the main life cycle stage followed by a consecutive number.<br><br>Manufacture: M-#, Formulation: F-#, Industrial end use: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial settings): SL-IW- | | | | | | |

| Main life cycle stage | Stage No. *) | Manufacture / Use / Subsequent service life | Related subsequent service life | Market sector | Tonnage (tonnes per year) | ES No. |
|---|---|---|---|---|---|---|
| #, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.<br><br>In IUCLID section 3.5, the identified uses are denoted with integer or whole numbers and no acronyms can be added for the stage types. As Formulation uses and Industrial end uses are included in the same IUCLID table when imported from Chesar, different numbers are used for better distinction, i.e. numbers starting at 1001 for Formulation and starting at 2001 for Industrial end uses. In the CSR both numbering systems are reported. | | | | | | |

## 9.0.2. Scope and type of exposure assessment

### 9.0.2.1. Environment

**Table 3. Scope and type of exposure assessment based on hazard assessment**

| Protection target | Type of assessment | Explanation / Justification |
|---|---|---|
| **Water:** Fresh Water (Pelagic) | **Quantitative** | Quantitative exposure assessment (EUSES 2.1) and risk characterisation |
| **Water:** Fresh Water (Sediment) | **Quantitative** | Quantitative exposure assessment (EUSES 2.1) and risk characterisation |
| **Water:** Marine Water (Pelagic) | **Quantitative** | Quantitative exposure assessment (EUSES 2.1) and risk characterisation |
| **Water:** Marine Water (Sediment) | **Quantitative** | Quantitative exposure assessment (EUSES 2.1) and risk characterisation |
| **Water:** Fresh Water Food Chain (Predators) | **Exposure assessment and risk characterisation not required** | No potential for bioaccumulation |
| **Water:** Marine Water Food Chain (Predators) | **Exposure assessment and risk characterisation not required** | No potential for bioaccumulation |
| **Water:** Marine Water Food Chain (Top Predators) | **Exposure assessment and risk characterisation not required** | No potential for bioaccumulation |
| **Water:** Sewage Treatment Plant (Effluent) | **Quantitative** | Quantitative exposure assessment (EUSES 2.1) and risk characterisation |
| **Air** | **Quantitative exposure assessment** | |
| **Soil:** Agricultural Soil | **Quantitative** | Quantitative exposure assessment (EUSES 2.1) and risk characterisation |
| **Soil:** Terrestrial Food Chain (Predators) | **Exposure assessment and risk characterisation not required** | No PNEC oral because no potential for bioaccumulation |

### 9.0.2.2. Consumer

**Table 4. Scope and type of exposure assessment based on hazard assessment**

| Route of exposure and type of effects | Type of assessment | Explanation / Justification |
|---|---|---|
| **Inhalation:** Acute, Local | **Quantitative** | Quantitative exposure assessment and risk characterisation. See DNEL in section 5.11.2.[25] |
| **Inhalation:** Acute, Systemic | **Exposure assessment and risk characterisation not required** | No hazard identified for acute systemic effects (all routes). |
| **Inhalation:** Long term, Local | **Exposure assessment and risk characterisation not required** | No hazard identified for long term local effects (all routes). |
| **Inhalation:** Long term, | **Quantitative** | Quantitative exposure assessment and risk characterisation. See DNEL in section 5.11.2. |

[25]This section of the CSR is not reported in the appendix

| Route of exposure and type of effects | Type of assessment | Explanation / Justification |
|---|---|---|
| Systemic | | |
| **Dermal:** Acute, Local | **Qualitative risk characterisation with quantitative exposure assessment where applicable** | No-threshold effect and/or no dose-response information available |
| **Dermal:** Acute, Systemic | **Exposure assessment and risk characterisation not required** | No hazard identified for acute systemic effects (all routes). |
| **Dermal:** Long term, Local | **Exposure assessment and risk characterisation not required** | No hazard identified for long term local effects (all routes). |
| **Dermal:** Long term, Systemic | **Quantitative** | Quantitative exposure assessment and risk characterisation. See DNEL in section 5.11.2. |
| **Oral:** Acute, Systemic | **Exposure assessment and risk characterisation not required** | No hazard identified for acute systemic effects (all routes). |
| **Oral:** Long term, Systemic | **Quantitative** | Quantitative exposure assessment and risk characterisation. See DNEL in section 5.11.2. |

#### 9.0.2.3. Man via environment

**Table 5. Scope and type of exposure assessment based on hazard assessment**

| Route of exposure and type of effects | Type of assessment | Explanation / Justification |
|---|---|---|
| **Inhalation:** Long term, Systemic | **Quantitative** | Quantitative exposure assessment and risk characterisation. See DNEL in section 5.11.2. |
| **Oral:** Long term, Systemic | **Quantitative** | Quantitative exposure assessment and risk characterisation. See DNEL in section 5.11.2. |

### 9.0.3. Regional environmental exposure from the releases of all exposure scenarios covered

#### 9.0.3.1. Total releases

- **Water:** 4E4 tonnes/year
- **Air:** 4E4 tonnes/year
- **Soil:** 0 tonnes/year

#### 9.0.3.2. Regional exposure: environment

>>>**Caution:** The exposure estimates have been obtained with EUSES although the following parameter(s) is/are outside the boundaries of the EUSES model: <<<

Water Solubility, Melting Point

**Table 6. Summary of predicted regional exposure concentrations (Regional PEC)**

| Protection target | Regional PEC |
|---|---|
| Fresh Water (Pelagic) | 0.012 mg/L |
| Fresh Water (Sediment) | 0.044 mg/kg dw |
| Marine Water (Pelagic) | 0.001 mg/L |
| Marine Water (Sediment) | 0.004 mg/kg dw |
| Air | 2.33E-4 mg/m³ |
| Agricultural Soil | 8.83E-4 mg/kg dw |

**9.0.3.3. Regional exposure: man via environment**

**Regional total estimated daily intake for humans:** 4.152E-4 mg/kg bw/day

**Table 7. Summary of estimated daily human doses through intake and concentrations in food from regional exposure**

| Type of food | Estimated daily dose from regional exposure | Concentration in food from regional exposure |
|---|---|---|
| Drinking water | 3.35E-4 mg/kg bw/day | 0.012 mg/L |
| Fish | 2.72E-5 mg/kg bw/day | 0.016 mg/kg |
| Leaf crops | 4.25E-5 mg/kg bw/day | 0.002 mg/kg |
| Root crops | 1.04E-5 mg/kg bw/day | 0.002 mg/kg |
| Meat | 2.87E-9 mg/kg bw/day | 6.68E-7 mg/kg |
| Milk | 5.35E-8 mg/kg bw/day | 6.68E-6 mg/kg |

## 9.1. Consumer use of alcohol in washing and cleaning product

| | |
|---|---|
| **Environment:** | |
| Use in cleaning product as processing aids | ERC 8a |
| **Consumer** | |
| Use of laundry and dishwashing product | PC 35 |
| Use of trigger spray cleaner products | PC 35 |
| Use of liquid cleaning product for manual surface application | PC 35 |
| Use of abrasive product for manual surface application | PC 35 |
| Use of liquid cleaner for cleaning carpet | PC 35 |

## 9.1.1. Exposure scenario

### 9.1.1.1. Control of environmental exposure: Use in cleaning product as processing aids

| |
|---|
| Product characteristics |
| |
| Amounts used |
| • Daily wide dispersive use: = 0.022 tonnes/day |
| Frequency and duration of use |
| |
| Environment factors not influenced by risk management |
| • Receiving surface water flow rate: >= 1.8E4 $m^3$/d |
| Other given operational conditions affecting environmental exposure |
| |
| Conditions and measures related to municipal sewage treatment plant |
| • Municipal STP: Yes [Effectiveness Water: 87.4%] |
| • Discharge rate of STP: >= 2E3 $m^3$/d |
| • Application of the STP sludge on agricultural soil: Yes |
| Conditions and measures related to external treatment of waste for disposal |
| |
| Conditions and measures related to external recovery of waste |
| |
| Additional good practice advice beyond the REACH CSA |
| |

#### 9.1.1.2. Control of consumers exposure for "Use of laundry and dishwashing product" [PC 35]

**Further specification:** Covers use of washing product for both automated/machine and manual application according to ECETOC TRA product sub category 1

| | Inhal*) | | Derm*) | | Oral*) | |
|---|---|---|---|---|---|---|
| | Loc | Sys | Loc | Sys | Loc | Sys |
| Product characteristic | | | | | | |
| • Concentration of the substance in the product: < 50%<br>Substance not classified for eye irritancy below above mentioned concentration | | | A | | | |
| • Concentration of the substance in the product: < 15 %[26]<br>Source: Market data | A | L | | L | | L |
| Amounts used | | | | | | |
| • Product amount per task: = 50 grams<br>Source: Default ECETOC TRA for Sub Product "Laundry and dishwashing" | A | L | | | | |
| • Dilution of the product before application: = 1 times<br>ECETOC TRA assumes exposure to undiluted product | A | L | | L | | L |
| Frequency and duration of use/exposure | | | | | | |
| • Frequency: = 365 times/year<br>ECETOC TRA assumes daily use of product. | A | L | | L | | L |
| • Duration of exposure: = 60 minutes<br>Source: Default ECETOC TRA for Sub Product "Laundry and dishwashing" | A | L | | | | |
| Human factors not influenced by risk management | | | | | | |
| • Exposed body parts: two hands (Skin surface: 860 $cm^2$)<br>Source: Default ECETOC TRA for Sub Product "Laundry and dishwashing" | | | | L | | |
| Other given operational conditions affecting consumers exposure | | | | | | |
| • Room where tasks take place: Generic room (Volume: 20 $m^3$; no ventilation rate assumed)<br>ECETOC TRA assumption | A | L | | | | |
| Conditions and measures related to information and behavioural advice to consumers | | | | | | |
| | | | | | | |
| Conditions and measures related to personal protection and hygiene | | | | | | |
| | | | | | | |
| Additional good practice advice beyond the REACH CSA | | | | | | |
| | | | | | | |

*) The route of exposure (**Inhal**ation, **Derm**al, **Oral**) and type of effect (**Loc**al, **Sys**temic and **A**cute or **L**ong term) for which the determinant has been used for exposure estimation are reported.

[26]It represents the actual maximum concentration in product. Not to be confused or aggregated with the determinant above which controls the eye irritancy endpoint.

### 9.1.1.3. Control of consumers exposure for "Use of trigger spray cleaner products " [PC 35]

**Further specification:** Covers use of trigger spray cleaners such as:
- all purpose cleaners
- sanitary product
- glass cleaners

according to ECETOC TRA preduct sub category 3

| | Inhal*) | | Derm*) | | Oral*) | |
|---|---|---|---|---|---|---|
| | Loc | Sys | Loc | Sys | Loc | Sys |
| Product characteristic | | | | | | |
| • Concentration of the substance in the product: < 50%<br>Substance not classified for eye irritancy below above mentioned concentration | | | A | | | |
| • Concentration of the substance in the product: < 15 %<br>Source: Market data | A | L | | L | | L |
| Amounts used | | | | | | |
| • Product amount per task: = 35 grams<br>Source: Default ECETOC TRA for Sub Product "Trigger spray cleaners" | A | L | | | | |
| Frequency and duration of use/exposure | | | | | | |
| • Frequency: = 365 times/year<br>ECETOC TRA assumes daily use of product. | A | L | | L | | L |
| • Duration of exposure: = 240 minutes<br>Source: Default ECETOC TRA for Sub Product "Trigger spray cleaners" | A | L | | | | |
| Human factors not influenced by risk management | | | | | | |
| • Exposed body parts: two hands (Skin surface: 860 $cm^2$)<br>Source: Default ECETOC TRA for Sub Product "Trigger spray cleaners" | | | | L | | |
| Other given operational conditions affecting consumers exposure | | | | | | |
| • Room where tasks take place: Generic room (Volume: 20 $m^3$; no ventilation rate assumed)<br>ECETOC TRA assumption | A | L | | | | |
| Conditions and measures related to information and behavioural advice to consumers | | | | | | |
| | | | | | | |
| Conditions and measures related to personal protection and hygiene | | | | | | |
| | | | | | | |
| Additional good practice advice beyond the REACH CSA | | | | | | |
| | | | | | | |

*) The route of exposure (**Inhal**ation, **Derm**al, **Oral**) and type of effect (**Loc**al, **Sys**temic and **A**cute or **L**ong term) for which the determinant has been used for exposure estimation are reported.

**9.1.1.4. Control of consumers exposure for "Use of liquid cleaning product for manual surface application" [PC 35]**

**Further specification:** Sub products covered in the contributing scenario:
- floor cleaning product
- sanitary product
- all purpose cleaning product

Floor cleaning product has been used as sentinel product for exposure assessment purposes.
Product dilution in water before application has been assumed
Tasks covered:
- mixing & loading of the product with water into the bucket, where evaporation from the bottle and spills of product can occur
- manual application

General remark:
For Mixing & Loading before application: calculations made upon list of assumptions reported in RIVM report 320104003/2006 - Cleaning products fact sheet: paragraph 8.1.1 (Floor cleaning product) (except for "Concentration of substance in product" and "frequency", see Exposure scenario)

| | Inhal*) | | Derm*) | | Oral*) | |
|---|---|---|---|---|---|---|
| | Loc | Sys | Loc | Sys | Loc | Sys |
| Product characteristic | | | | | | |
| • Concentration of the substance in the product: < 50%<br>Substance not classified for eye irritancy below above mentioned concentration | A | L | | L | | L |
| • Concentration of the substance in the product: < 15 %<br>Source: Market data | | | A | | | |
| Amounts used | | | | | | |
| • Product amount per task: = 250 grams<br>Undiluted product poured into the bucket (default ConsExpo 4.1) | A | L | | | | |
| • Dilution of the product before application: = 20 times<br>Source: Default ConsExpo 4.1<br>Equivalent of 5% of product concentration in water | A | L | | L | | L |
| Frequency and duration of use/exposure | | | | | | |
| • Frequency: = 104 times/year<br>Source: Default ConsExpo 4.1 | A | L | | L | | L |
| • Duration of application: = 30 minutes<br>Source: Default ConsExpo 4.1 | A | L | | | | |
| • Duration of exposure: = 240 minutes<br>Source: Default ConsExpo 4.1 | A | L | | | | |
| Human factors not influenced by risk management | | | | | | |
| • Exposed body parts: hands and forearms (Skin surface: 1900 $cm^2$)<br>Source: Default ConsExpo 4.1 | | | | L | | |
| Other given operational conditions affecting consumers exposure | | | | | | |
| • Room where tasks take place: Living room (Volume: 58 $m^3$; ventilation rate: 0,5 1/h) | A | L | | | | |

| | | |
|---|---|---|
| • Release area: = 22 $m^2$<br>living room floor surface area (Default ConsExpo 4.1) | A | L |
| • Product cleaning solution for application: = 880 grams<br>Source: Default ConsExpo 4.1 | A | L |
| Conditions and measures related to information and behavioural advice to consumers | | |
| | | |
| Conditions and measures related to personal protection and hygiene | | |
| | | |
| Additional good practice advice beyond the REACH CSA | | |
| | | |

*) The route of exposure (**Inhal**ation, **Derm**al, **Oral**) and type of effect (**Loc**al, **Sys**temic and **A**cute or **L**ong term) for which the determinant has been used for exposure estimation are reported.

#### 9.1.1.5. Control of consumers exposure for "Use of abrasive product for manual surface application" [PC 35]

**Further specification:** Use of undiluted product has been assumed.
Activities covered:
- toilet cleaning (lavatory pan, washbasin, floor)

| | Inhal*) | | Derm*) | | Oral*) | |
|---|---|---|---|---|---|---|
| | Loc | Sys | Loc | Sys | Loc | Sys |
| Product characteristic | | | | | | |
| • Concentration of the substance in the product: < 50%<br>Substance not classified for eye irritancy below above mentioned concentration | A | L | | L | | L |
| • Concentration of the substance in the product: < 5 %<br>Source: Market data | | | A | | | |
| Amounts used | | | | | | |
| • Product amount per task: = 37 grams<br>Undiluted product to be used<br>Source: Default ConsExpo 4.1 | A | L | | | | |
| • Dilution of the product before application: = 1 times<br>Use of undiluted product assumed: Default ConsExpo 4.1 | A | L | | L | | L |
| Frequency and duration of use/exposure | | | | | | |
| • Frequency: = 156 times/year<br>Source: Default ConsExpo 4.1 | A | L | | L | | L |
| • Duration of application: = 7.6 minutes<br>Source: Default ConsExpo 4.1 | A | L | | | | |
| • Duration of exposure: = 10 minutes<br>Source: Default ConsExpo 4.1 | A | L | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Human factors not influenced by risk management | | | | | | |
| • Exposed body parts: one palm (Skin surface: 215 $cm^2$)<br>Source: Default ConsExpo 4.1 | | | | L | | |
| Other given operational conditions affecting consumers exposure | | | | | | |
| • Room where tasks take place: Toilet (Volume: 2,5 $m^3$; ventilation rate: 2 1/h)<br>Source: Default ConsExpo 4.1 | A | L | | | | |
| • Release area: = 4 $m^2$<br>toilet floor, washbasin, lavatory pan (Default ConsExpo 4.1) | A | L | | | | |
| Conditions and measures related to information and behavioural advice to consumers | | | | | | |
| | | | | | | |
| Conditions and measures related to personal protection and hygiene | | | | | | |
| | | | | | | |
| Additional good practice advice beyond the REACH CSA | | | | | | |
| | | | | | | |

*) The route of exposure (**Inhal**ation, **Derm**al, **Oral**) and type of effect (**Loc**al, **Sys**temic and **A**cute or **L**ong term) for which the determinant has been used for exposure estimation are reported.

#### 9.1.1.6. Control of consumers exposure for "Use of liquid cleaner for cleaning carpet" [PC 35]

**Further specification:** Dilution to water before application has been assumed
Activities covered:
- mixing & loading of the product with water into the bucket, where evaporation from the bottle and spills of product can occur
- carpet cleaning (brushing)

General remark:
For Mixing & Loading before application: calculations made upon list of assumptions reported in RIVM report 320104003/2006 - Cleaning product fact sheet: paragraph 8.2.1 (Carpet cleaning liquid) (except for “Concentration of substance in product” and “frequency”, see Exposure scenario)

| | Inhal*) | | Derm*) | | Oral*) | |
|---|---|---|---|---|---|---|
| | Loc | Sys | Loc | Sys | Loc | Sys |
| Product characteristic | | | | | | |
| • Concentration of the substance in the product: < 50%<br>Substance not classified for eye irritancy below above mentioned concentration | A | L | | L | | L |
| • Concentration of the substance in the product: < 30 %<br>Source: Market data | | | A | | | |
| Amounts used | | | | | | |
| • Product amount per task: = 500 grams<br>Undiluted product for carpet cleaning (default ConsExpo 4.1) | A | L | | | | |
| • Dilution of the product before application: = 200 times<br>Source: Default ConsExpo 4.1 | A | L | | L | | L |

| | | | | |
|---|---|---|---|---|
| Frequency and duration of use/exposure | | | | |
| • Frequency: = 0.5 times/year<br>Source: Default ConsExpo 4.1 | A | L | L | L |
| • Duration of application: = 110 minutes<br>Source: Default ConsExpo 4.1 | A | L | | |
| • Duration of exposure: = 110 minutes<br>Source: Default ConsExpo 4.1 | A | L | | |
| Human factors not influenced by risk management | | | | |
| • Exposed body parts: two hands (Skin surface: 860 $cm^2$)<br>Source: Default ConsExpo 4.1 | | | L | |
| Other given operational conditions affecting consumers exposure | | | | |
| • Room where tasks take place: Living room (Volume: 58 $m^3$; ventilation rate: 0,5 1/h)<br>Source: Default ConsExpo 4.1 | A | L | | |
| • Release area: = 22 $m^2$<br>carpet covering all living room surface (Default ConsExpo 4.1) | A | L | | |
| • Product cleaning solution for application: = 1E4 grams<br>Source: Default ConsExpo 4.1 | A | L | | |
| Conditions and measures related to information and behavioural advice to consumers | | | | |
| | | | | |
| Conditions and measures related to personal protection and hygiene | | | | |
| | | | | |
| Additional good practice advice beyond the REACH CSA | | | | |
| | | | | |

*) The route of exposure (**Inhal**ation, **Derm**al, **Oral**) and type of effect (**Loc**al, **Sys**temic and **A**cute or **L**ong term) for which the determinant has been used for exposure estimation are reported.

## 9.1.2. Exposure estimation for Consumer use of alcohol in washing and cleaning product

### 9.1.2.1. Exposure estimation for the environment (Use in cleaning product as processing aids)

#### 9.1.2.1.1. Environmental releases

**Table 8. Summary of the local releases to the environment**

| Compartment | Release factor estimation method | Explanation / Justification |
|---|---|---|
| **Water** | ERC<br><br>(ERC 8a) | **Release factor after on site risk management (%):** 100<br><br>**Local release rate (kg/day):** 22 |
| **Air** | ERC<br><br>(ERC 8a) | **Release factor after on site risk management (%):** 100<br><br>**Explanation/Justification:**<br>Local release rate from wide dispersive use are taken into account at the regional scale only |
| **Soil** | ERC<br><br>(ERC 8a) | **Release factor after on site risk management (%):** 0<br><br>**Explanation/Justification:**<br>Indoor use has been assumed |

**Summed releases from all life cycle stages:** see section 9.0.3.

#### 9.1.2.1.2. Environmental exposure

>>>**Caution:** The exposure estimates have been obtained with EUSES although some parameters are outside EUSES model (see section 9.0.3.2): <<<

**Table 9. Summary of exposure concentrations**

| Protection target | Exposure concentration | Explanation / Justification |
|---|---|---|
| **Water:** Fresh Water (Pelagic) | **Local PEC:** 0.151 mg/L<br><br>**Local concentration:** 0.139 mg/L | |
| **Water:** Fresh Water (Sediment) | **Local PEC:** 0.646 mg/kg dw | |
| **Water:** Marine Water (Pelagic) | **Local PEC:** 0.015 mg/L<br><br>**Local concentration:** 0.014 mg/L | |
| **Water:** Marine Water (Sediment) | **Local PEC:** 0.064 mg/kg dw | |
| **Water:** Sewage Treatment Plant (Effluent) | **Local PEC:** 1.39 mg/L | |
| **Air** | **Local PEC:** 2.39E-4 mg/m³<br><br>**Local concentration:** 5.52E-6 mg/m³ | |
| **Soil:** Agricultural Soil | **Local PEC:** 0.019 mg/kg dw<br><br>**Local concentration:** 0.018 mg/kg dw | |

**For regional PECs see section 9.0.3.2.**

**9.1.2.1.3. Indirect exposure of humans via the environment**

Exposure via inhalation

The exposure concentrations in air are reported in the Table "Summary of exposure concentrations" of the preceding section 9. x.2.1.2 "Environmental exposure".

Exposure via food consumption: Total daily intake for humans

**Table 10. Summary of estimated daily human doses and concentrations in food**

| Type of food | Daily human dose through intake | | Explanation / Justification |
|---|---|---|---|
| | **Total estimated daily intake for humans:** 0.005 mg/kg bw/day | | |
| | Estimated daily dose through intake from local exposure | Concentration in food from local exposure | |
| Drinking water | 0.004 mg/kg bw/day | 0.151 mg/L | |
| Fish | 3.49E-4 mg/kg bw/day | 0.213 mg/kg | |
| Leaf crops | 4.44E-5 mg/kg bw/day | 0.003 mg/kg | |
| Root crops | 1.01E-4 mg/kg bw/day | 0.018 mg/kg | |
| Meat | 2.9E-8 mg/kg bw/day | 6.74E-6 mg/kg | |
| Milk | 5.4E-7 mg/kg bw/day | 6.74E-5 mg/kg | |
| | **Dose from regional exposure:** see section 9.0.3.3 | | |

**9.1.2.2. Exposure estimation for Consumer for Use of laundry and dishwashing product**

**Table 11. Summary of exposure concentrations for contributing scenario: Use of laundry and dishwashing product**

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| **Inhalation:** Acute, Local | 375 mg/m³ | **Method:** External exposure estimation tool<br>**Name:** ECETOC TRA | **Representativity and reliability:**<br>ECETOC TRA: Inhalation exposure model<br>**Remark on exposure value:**<br>Event concentration |
| **Inhalation:** Long term, Systemic | 15.6 mg/m³ | **Method:** External exposure estimation tool<br>**Name:** ECETOC TRA | **Representativity and reliability:**<br>ECETOC TRA: Inhalation exposure model<br>**Remark on exposure value:**<br>Event concentration avaraged over the day |
| **Dermal:** Acute, Local | Not available | **Method:** Conditions of use (OC/RMM) | |

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| | | **Name:** Eye irritation | |
| **Dermal:** Long term, Systemic | 21.4 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA | **Representativity and reliability:**<br>ECETOC TRA: dermal exposure model<br><br>**Remark on exposure value:**<br>Dose over the day |
| **Oral:** Long term, Systemic | 0 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA | **Representativity and reliability:**<br>ECETOC TRA: oral exposure model<br><br>**Remark on exposure value:**<br>According to ECETOC TRA, oral exposure not relevant for this sub category |

**9.1.2.3. Exposure estimation for Consumer for Use of trigger spray cleaner products**

**Table 12. Summary of exposure concentrations for contributing scenario: Use of trigger spray cleaner products**

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| **Inhalation:** Acute, Local | 263 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA | **Representativity and reliability:**<br>ECETOC TRA: inhalation exposure route<br><br>**Remark on exposure value:**<br>Event concentration |
| **Inhalation:** Long term, Systemic | 43.8 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA | **Representativity and reliability:**<br>ECETOC TRA: inhalation exposure model<br><br>**Remark on exposure value:**<br>Event concentration avaraged over the day |
| **Dermal:** Acute, Local | Not available | **Method:** Conditions of use (OC/RMM)<br><br>**Name:** Eye irritation | |
| **Dermal:** Long term, Systemic | 21.4 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA | **Representativity and reliability:**<br>ECETOC TRA: dermal exposure model<br><br>**Remark on exposure value:**<br>Dose over the day |
| **Oral:** Long | 0 mg/kg | **Method:** External exposure | **Representativity and reliability:** |

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| term, Systemic | bw/day | estimation tool<br><br>**Name:** ECETOC TRA | ECETOC TRA: oral exposure model<br><br>**Remark on exposure value:**<br>According to ECETOC TRA, oral exposure not relevant for this sub category |

**9.1.2.4. Exposure estimation for Consumer for Use of liquid cleaning product for manual surface application**

**Table 13. Summary of exposure concentrations for contributing scenario: Use of liquid cleaning product for manual surface application**

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| **Inhalation:**<br>Acute, Local | 42.4 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Representativity and reliability:**<br>ConsExpo 4.1: evaporation model<br><br>**Remark on exposure value:**<br>Exposure value from “manual application” (mixing & loading not relevant)<br>Event concentration<br>The most suitable Thibaudaux equation has been used for the calculation of the mass transfer rate<br>Assumptions (Default ConsExpo 4.1):<br>- 24,1 m3/day of inhalation rate – light exercise<br>- Molecular weight matrix equal 18 g/mol, assuming that the matrix is water |
| **Inhalation:**<br>Long term, Systemic | 7.07 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Representativity and reliability:**<br>ConsExpo 4.1: evaporation model<br><br>**Remark on exposure value:**<br>Exposure value from “manual application” (mixing & loading not relevant)<br>Concentration averaged over a day<br>The most suitable Thibaudaux equation has been used for the calculation of the mass transfer rate<br>Assumptions (Default ConsExpo 4.1):<br>- 24,1 m3/day of inhalation rate – light exercise<br>- Molecular weight matrix equal 18 g/mol, assuming that the matrix is water |
| **Dermal:**<br>Acute, Local | | **Method:** External exposure estimation tool | |

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| | | **Name:** Eye irritation | |
| **Dermal:** Long term, Systemic | 2.19 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Representativity and reliability:**<br>ConsExpo 4.1: Instantaneous application model<br><br>**Remark on exposure value:**<br>Exposure value from "manual application" (mixing & loading not relevant)<br>Dose over the day |
| **Oral:** Long term, Systemic | 0 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Remark on exposure value:**<br>Oral exposure not relevant for this task |

**9.1.2.5. Exposure estimation for Consumer for Use of abrasive product for manual surface application**

**Table 14. Summary of exposure concentrations for contributing scenario: Use of abrasive product for manual surface application**

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| **Inhalation:** Acute, Local | 362 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Representativity and reliability:**<br>ConsExpo 4.1: Evaporation model<br><br>**Remark on exposure value:**<br>Event concentration<br>The most suitable Thibaudaux equation has been used for the calculation of the mass transfer rate<br>Assumptions (Default ConsExpo 4.1):<br>- 24,1 m3/day of inhalation rate – light exercise<br>- Molecular weight matrix equal 45 g/mol, assuming water in product is 40% |
| **Inhalation:** Long term, Systemic | 2.51 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Representativity and reliability:**<br>ConsExpo 4.1: Evaporation model<br><br>**Remark on exposure value:**<br>Concentration averaged over a day<br>The most suitable Thibaudaux equation has been used for the calculation of the mass transfer rate<br>Assumptions (Default ConsExpo 4.1):<br>- 24,1 m3/day of inhalation rate – light exercise<br>- Molecular weight matrix equal 45 g/mol, assuming water in product is 40% |

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| | | | |
| **Dermal:** Acute, Local | Not available | **Method:** Conditions of use (OC/RMM)<br><br>**Name:** Eye irritation | |
| **Dermal:** Long term, Systemic | 0.29 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Representativity and reliability:**<br>ConsExpo 4.1: Instantaneous application model<br><br>**Remark on exposure value:**<br>1% of the product amount is assumed to give dermal exposure<br>Dose over the day |
| **Oral:** Long term, Systemic | 0 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Remark on exposure value:**<br>Oral exposure not relevant for this task |

**9.1.2.6. Exposure estimation for Consumer for Use of liquid cleaner for cleaning carpet**

**Table 15. Summary of exposure concentrations for contributing scenario: Use of liquid cleaner for cleaning carpet**

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| **Inhalation:** Acute, Local | 284 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Representativity and reliability:**<br>ConsExpo 4.1: Evaporation model<br><br>**Remark on exposure value:**<br>Exposure value from “manual application” (mixing & loading not relevant)<br>Event concentration<br>The most suitable Thibaudaux equation has been used for the calculation of the mass transfer rate<br>Assumptions (Default ConsExpo 4.1):<br>- 24,1 $m^3$/day of inhalation rate – light exercise<br>- Molecular weight matrix equal 18 g/mol, assuming that the matrix is water |
| **Inhalation:** Long term, Systemic | 21.7 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Representativity and reliability:**<br>ConsExpo 4.1: Evaporation model<br><br>**Remark on exposure value:**<br>Exposure value from “manual application” (mixing & loading not relevant)<br>Concentration averaged over a day |

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| | | | The most suitable Thibaudaux equation has been used for the calculation of the mass transfer rate<br>Assumptions (Default ConsExpo 4.1):<br>- 24,1 $m^3$/day of inhalation rate – light exercise<br>- Molecular weight matrix equal 18 g/mol, assuming that the matrix is water |
| **Dermal:** Acute, Local | Not available | **Method:** Conditions of use (OC/RMM)<br><br>**Name:** Eye irritation | |
| **Dermal:** Long term, Systemic | 6.23 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Representativity and reliability:**<br>ConsExpo 4.1: Instantaneous application model<br><br>**Remark on exposure value:**<br>Exposure value from "manual application" (mixing & loading not relevant)<br>0.27% of the diluted product assumed to end up on the skin (default ConsExpo 4.1)<br>Dose over the day |
| **Oral:** Long term, Systemic | 0 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ConsExpo 4.1 | **Remark on exposure value:**<br>Oral exposure not relevant for this task |

# 10. RISK CHARACTERISATION

See section 9.0.2 "Scope and type of exposure assessment" as to whether a risk characterisation is required for the different target groups and exposure pathways.

## 10.1. Consumer use of alcohol in washing and cleaning product

### 10.1.1. Human health

#### 10.1.1.1. Workers

This exposure scenario does not address workers.

#### 10.1.1.2. Consumers

**Table 16. Risk characterisation: Consumer use of laundry and dishwashing product**

| **Route of exposure and type of effects** | **Risk characterisation ratio** | **Risk characterisation** |
|---|---|---|
| **Inhalation:** Acute, Local | **RCR = 0.395** | |
| **Inhalation:** Long term, Systemic | **RCR = 0.137**<br><br>**Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3):** 0.137 | |
| **Dermal:** Acute, Local | **Qualitative risk characterisation** | **Prevention of release/exposure:**<br>Eye irritancy controlled by substance concentration in product<br><br>**Expected residual exposure:**<br>Not relevant<br><br>**Conclusion on risk characterisation:**<br>Risk controlled |
| **Dermal:** Long term, Systemic | **RCR = 0.104** | |
| **Oral:** Long term, Systemic | **RCR = 0** | |
| **Combined routes:** Long term, Systemic | **RCR = 0.241**<br><br>**Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3):** 0.241 | |

**Table 17. Risk characterisation: Consumer use of trigger spray cleaner product**

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| **Inhalation:** Acute, Local | **RCR = 0.277** | |
| **Inhalation:** Long term, Systemic | **RCR = 0.384**<br><br>**Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3):** 0.384 | |
| **Dermal:** Acute, Local | **Qualitative risk characterisation** | **Prevention of release/exposure:**<br>Eye irritancy controlled by substance concentration in product<br><br>**Expected residual exposure:**<br>Not relevant<br><br>**Conclusion on risk characterisation:**<br>Risk controlled |
| **Dermal:** Long term, Systemic | **RCR = 0.104** | |
| **Oral:** Long term, Systemic | **RCR = 0** | |
| **Combined routes:** Long term, Systemic | **RCR = 0.488**<br><br>**Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3):** 0.488 | |

**Table 18. Risk characterisation: Consumer use of surface cleaning product diluted before use**

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| **Inhalation:** Acute, Local | **RCR = 0.045** | |
| **Inhalation:** Long term, Systemic | **RCR = 0.062**<br><br>**Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3):** 0.062 | |
| **Dermal:** Acute, Local | **Qualitative risk characterisation** | **Prevention of release/exposure:**<br>Eye irritancy controlled by substance concentration in product |

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| | | **Expected residual exposure:**<br>Not relevant<br>**Conclusion on risk characterisation:**<br>Risk controlled |
| **Dermal:** Long term, Systemic | **RCR = 0.011** | |
| **Oral:** Long term, Systemic | **RCR = 0** | |
| **Combined routes:** Long term, Systemic | **RCR = 0.073**<br>**Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3):** 0.073 | |

**Table 19. Risk characterisation: Consumer use of liquid abrasive product for manual surface application**

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| **Inhalation:** Acute, Local | **RCR = 0.381** | |
| **Inhalation:** Long term, Systemic | **RCR = 0.022**<br>**Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3):** 0.022 | |
| **Dermal:** Acute, Local | **Qualitative risk characterisation** | **Prevention of release/exposure:**<br>Eye irritancy controlled by substance concentration in product<br>**Expected residual exposure:**<br>Not relevant<br>**Conclusion on risk characterisation:**<br>Risk controlled |
| **Dermal:** Long term, Systemic | **RCR = 0.001** | |
| **Oral:** Long term, Systemic | **RCR = 0** | |
| **Combined routes:** | **RCR = 0.023** | |

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| Long term, Systemic | **Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3):** 0.023 | |

**Table 20. Risk characterisation: Consumer use of liquid cleaner for cleaning carpet**

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| **Inhalation:** Acute, Local | **RCR = 0.299** | |
| **Inhalation:** Long term, Systemic | **RCR = 0.19**<br><br>**Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3):** 0.19 | |
| **Dermal:** Acute, Local | **Qualitative risk characterisation** | **Prevention of release/exposure:**<br>Eye irritancy controlled by substance concentration in product<br><br>**Expected residual exposure:**<br>Not relevant<br><br>**Conclusion on risk characterisation:**<br>Risk controlled |
| **Dermal:** Long term, Systemic | **RCR = 0.03** | |
| **Oral:** Long term, Systemic | **RCR = 0** | |
| **Combined routes:** Long term, Systemic | **RCR = 0.221**<br><br>**Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3):** 0.221 | |

#### 10.1.1.3. Indirect exposure of humans via the environment

**Table 21. Risk characterisation for humans exposed via the environment**

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| **Inhalation:** Long term, Systemic | **RCR = 2.096E-6** | |
| **Oral:** Long term, Systemic | **RCR = 5.511E-5** | |

### 10.1.2. Environment

#### 10.1.2.1. Aquaticcompartment (incl. sediment)

**Table 22. Risk characterisation for the aquatic compartment (incl. sediment and secondary poisoning)**

| Protection target | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| Fresh Water (Pelagic) | **RCR = 0.157** | |
| Fresh Water (Sediment) | **RCR = 0.179** | |
| Marine Water (Pelagic) | **RCR = 0.019** | |
| Marine Water (Sediment) | **RCR = 0.022** | |

#### 10.1.2.2. Terrestrialcompartment

**Table 23. Risk characterisation for the terrestrial compartment (incl. secondary poisoning)**

| Protection target | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| Agricultural Soil | **RCR = 0.03** | |

#### 10.1.2.3. Atmospheric compartment

#### 10.1.2.4. Microbiological activity in sewage treatment systems

**Table 24. Risk characterisation for the microbiological activity in sewage treatment systems**

| Protection target | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| Sewage Treatment Plant (Effluent) | **RCR = 0.002** | |

# 10.2. Overall exposure (combined for all relevant emission/release sources)

## 10.2.1. Human health (combined for all exposure routes)

>>>NOTE: When relevant select the combinations of exposure scenarios which could result in simultaneous exposure of humans and report the outcome of the assessment here. <<<

## 10.2.2. Environment (combined for all emission sources)

### 10.2.2.1. Exposure and risks due to all wide dispersive uses

**Table 25. Risk characterisation for the exposure due to all wide dispersive uses**

| Protection target | PEC local due to all wide dispersive uses | Risk characterisation |
|---|---|---|
| **Water:** | | |
| Fresh Water (Pelagic) | **0.151 mg/L** | **RCR = 0.157** |
| Fresh Water (Sediment) | **0.646 mg/kg dw** | **RCR = 0.179** |
| Marine Water (Pelagic) | **0.015 mg/L** | **RCR = 0.019** |
| Marine Water (Sediment) | **0.064 mg/kg dw** | **RCR = 0.022** |
| Sewage Treatment Plant (Effluent) | **1.39 mg/L** | **RCR = 0.002** |
| **Soil:** | | |
| Agricultural Soil | **0.019 mg/kg dw** | **RCR = 0.03** |

# Appendix 2 – ES for Communication

The example of the exposure scenario for communication has been produced in two versions:

1. Long (full) version: More detailed information on assumptions about generic conditions of use as described in the CSR
2. Short (reduced) version: Content in section 2 limited to those conditions of use which are directly related to the product design and basic use characteristic determined by the individual manufacturer of the consumer product and the references to the full set of conditions given in section 3

The exposure scenario for communication has been generated using the Chesar version 1.2.

This exposure scenario is generated from the information in the CSR and contains:

- Section 1: The Title section. Describes the scope of the exposure scenario in a standardised way.
- Section 2: Operational Conditions and Risk Management Measures. The conditions and measures relevant for the five contributing scenarios in the ES format published by ECHA[27].
- Section 3: Exposure estimation and risk characterisation. The key information concerning the exposure estimation and/or risk characterisation.
- Section 4: a section in which key parameters from the assessment and advice on scaling could be included (section 4). This section has not been developed as explained in paragraph 2.3.

[27] Guidance on information requirements and chemical safety assessment. Exposure Scenario Format in, Part D: Exposure scenario building (version: 2, May 2010)

# ES FOR COMMUNICATION (Full information)

**Substance Name:** Alcohol

**EC Number:** xxx-xxx-x

**CAS Number:** xx-xx-x

**Registration Number:** xxxxxxxxxxxx[28]

**Date of Generation/Revision:** 2011-07-20

**Author:**

## 1. ES 1: Consumer end-use (SU 21); washing and cleaning product

| **1. Title of Exposure scenario** | |
|---|---|
| PC 35: Washing and cleaning product | |
| **Environment:** Component released during end-use | ERC 8a |
| **Consumer** | |
| Use of laundry and dishwashing product | PC 35 |
| Use of trigger spray cleaner products | PC 35 |
| Use of liquid cleaning product for manual surface application | PC 35 |
| Use of abrasive product for manual surface application | PC 35 |
| Use of liquid cleaner for cleaning carpet | PC 35 |

| **2. Conditions of use affecting exposure** |
|---|
| **2.1 Control of environmental exposure:** Component released during end use **(ERC 8a)** |
| **Conditions and measures related to municipal sewage treatment plant** |
| Waste water is to be treated by municipal STP |
| **2.2 Control of consumers exposure for** Use of laundry and dishwashing product **(PC 35)** |
| **Product characteristics** |
| Covers concentration of substance in product up to < 15 % |
| **Amount used, frequency and duration of use/exposure** |
| For each use event, covers use amount up to 50 grams<br>Covers daily use<br>Covers duration of exposure up to 60 minutes |

[28] The EC, CAS and registration numbers are artificial and are given solely for the purpose of illustration in the example

| |
|---|
| **Other operational conditions affecting consumers exposure** |
| Covers two hands exposed |
| **2.3 Control of consumers exposure for** Use of trigger spray cleaner products **(PC 35)** |
| **Product characteristics** |
| Covers concentration of substance in product up to < 15 % |
| **Amount used, frequency and duration of use/exposure** |
| For each use event, covers use amount up to 35 grams<br>Covers daily use<br>Covers duration of exposure up to 240 minutes |
| **Other operational conditions affecting consumers exposure** |
| Covers two hands exposed |
| **2.4 Control of consumers exposure for** Use of liquid cleaning product for manual surface application **(PC 35)** |
| **Product characteristics** |
| Covers concentration of substance in product up to < 15 % |
| **Amount used, frequency and duration of use/exposure** |
| For each use event, covers use amount up to 250 grams<br>Covers dilution in water greater then 20 times<br>Covers daily use<br>Covers duration of application up to 30 minutes |
| **Other operational conditions affecting consumers exposure** |
| Covers hands and forearms exposed<br>Covers use in Living room under typical ventilation and residence time<br>Covers an application area up to 22 $m^2$<br>Covers cleaning solution amount per event up to 880 grams |
| **2.5 Control of consumers exposure for** Use of abrasive product for manual surface application **(PC 35)** |
| **Product characteristics** |
| Covers concentration of substance in product up to < 5 % |
| **Amount used, frequency and duration of use/exposure** |
| For each use event, covers use amount up to 37 grams<br>Covers use of undiluted product<br>Covers daily use<br>Covers duration of application up to 7.6 minutes |
| **Other operational conditions affecting consumers exposure** |
| Covers one palm exposed |

| |
|---|
| Covers use in Toilet under typical ventilation and residence time<br>Covers an application area up to 4 $m^2$ |
| **2.6 Control of consumers exposure for** Use of liquid cleaner for cleaning carpet **(PC 35)** |
| **Product characteristics** |
| Covers concentration of substance in product up to < 30 % |
| **Amount used, frequency and duration of use/exposure** |
| For each use event, covers use amount up to 500 grams<br>Covers dilution in water greater then 200 times<br>Covers daily use<br>Covers duration of application up to 110 minutes<br>Covers duration of exposure up to 110 minutes |
| **Other operational conditions affecting consumers exposure** |
| Covers two hands exposed<br>Covers use in Living room under typical household ventilation<br>Covers an application area up to 22 $m^2$<br>Covers cleaning solution amount per event up to 1E4 grams |

| **3. Exposure estimation and reference to its source** | | |
|---|---|---|
| | | |
| **Environment** | | |
| **Release route** | **Release rate (kg/day)** | **Release estimation method** |
| **Water** | 22 | ERC - ERC 8a |
| **Air** | 0 | ERC - ERC 8a |
| **Soil** | 0 | ERC - ERC 8a |

| **Protection target** | **Exposure estimate** (based on: EUSES 2.0) | **RCR** |
|---|---|---|
| Freshwater (pelagic) | 0.151 mg/L | 0.157 |
| Freshwater (sediment) | 0.646 mg/kg dw | 0.179 |
| Freshwater (sediment) | 0.646 mg/kg dw | 0.179 |
| Marine water (pelagic) | 0.015 mg/L | 0.019 |
| Marine water (sediment) | 0.064 mg/kg dw | 0.022 |
| Freshwater food chain (predators) | | |
| Marine water food chain (predators) | | |
| Marine water food chain (top predators) | | |
| Effluent | 1.39 mg/L | 0.002 |
| Agricultural soil | 0.019 mg/kg dw | 0.03 |
| Terrestrial food chain (predator) | | |

| **Risk characterisation for man via the environment**[29] |
|---|
| Inhalation: 0<br><br>Oral: 0 |

| **Consumer exposure** | | | | | |
|---|---|---|---|---|---|
| **Long-term, systemic** | | | | | |
| **Contributing scenario** | **Inhalation** | **Dermal** | **Oral** | **Combined routes** | **Exposure estimation Method** |
| Use of laundry and dishwashing product (PC 35) | Exposure: 15.6 mg/m³<br><br>RCR: 0.137 | Exposure: 21.4 mg/kg bw/day<br><br>RCR: 0.104 | Exposure: 0 mg/kg bw/day<br><br>RCR: 0 | RCR: 0.241 | Inhal: External exposure estimation tool - ECETOC TRA<br><br>Derm: External exposure estimation tool - ECETOC TRA<br><br>Oral: External exposure estimation tool - ECETOC TRA |
| Use of trigger spray cleaner products (PC 35) | Exposure: 43.8 mg/m³<br><br>RCR: 0.384 | Exposure: 21.4 mg/kg bw/day<br><br>RCR: 0.104 | Exposure: 0 mg/kg bw/day<br><br>RCR: 0 | RCR: 0.488 | Inhal: External exposure estimation tool - ECETOC TRA<br><br>Derm: External exposure estimation tool - ECETOC TRA<br><br>Oral: External exposure estimation tool - ECETOC TRA |
| Use of liquid cleaning product for manual surface application (PC 35) | Exposure: 7.07 mg/m³<br><br>RCR: 0.062 | Exposure: 2.19 mg/kg bw/day<br><br>RCR: 0.011 | Exposure: 0 mg/kg bw/day<br><br>RCR: 0 | RCR: 0.073 | Inhal.: External exposure estimation tool - ConsExpo 4.1<br><br>Derm.: External exposure estimation tool - ConsExpo 4.1<br><br>Oral.: External exposure estimation tool - ConsExpo 4.1 |
| Use of abrasive product for manual surface application (PC 35) | Exposure: 2.51 mg/m³<br><br>RCR: 0.022 | Exposure: 0.29 mg/kg bw/day<br><br>RCR: 0.001 | Exposure: 0 mg/kg bw/day<br><br>RCR: 0 | RCR: 0.023 | Inhal.: External exposure estimation tool - ConsExpo 4.1<br><br>Derm.: External exposure estimation tool - ConsExpo 4.1<br><br>Oral.: External |

[29] The estimated dose/exposure for man via the environment was very low and it has been rounded down in Chesar 1.2 to “0”. The rounding rule will be changed in Chesar 2.0

| | | | | | |
|---|---|---|---|---|---|
| | | | | | exposure estimation tool - ConsExpo 4.1 |
| Use of liquid cleaner for cleaning carpet (PC 35) | Exposure: 21.7 mg/m³<br><br>RCR: 0.19 | Exposure: 6.23 mg/kg bw/day<br><br>RCR: 0.03 | Exposure: 0 mg/kg bw/day<br><br>RCR: 0 | RCR: 0.221 | Inhal.: External exposure estimation tool - ConsExpo 4.1<br><br>Derm.: External exposure estimation tool - ConsExpo 4.1<br><br>Oral.: External exposure estimation tool - ConsExpo 4.1 |

| **Risk characterisation for acute systemic** |
|---|
| Not required as no hazard identified |

| **Local effects via inhalation route** | | | |
|---|---|---|---|
| **Contributing scenario** | **Acute** | **Long term** | **Exposure estimation Method** |
| Use of laundry and dishwashing product (PC 35) | Exposure: 375 mg/m³<br><br>RCR: 0.395 | Not required as no hazard identified | Acute: External exposure estimation tool - ECETOC TRA |
| Use of trigger spray cleaner products (PC 35) | Exposure: 263 mg/m³<br><br>RCR: 0.277 | Not required as no hazard identified | Acute: External exposure estimation tool - ECETOC TRA |
| Use of liquid cleaning product for manual surface application (PC 35) | Exposure: 42.4 mg/m³<br><br>RCR: 0.045 | Not required as no hazard identified | Acute: External exposure estimation tool - ConsExpo 4.1 |
| Use of abrasive product for manual surface application (PC 35) | Exposure: 362 mg/m³<br><br>RCR: 0.381 | Not required as no hazard identified | Acute: External exposure estimation tool - ConsExpo 4.1 |
| Use of liquid cleaner for cleaning carpet (PC 35) | Exposure: 284 mg/m³<br><br>RCR: 0.299 | Not required as no hazard identified | Acute: External exposure estimation tool - ConsExpo 4.1 |

| Local effects via dermal route | | | |
|---|---|---|---|
| **Contributing scenario** | **Acute** | **Long term** | **Exposure estimation Method** |
| Use of laundry and dishwashing product (PC 35) | Exposure:<br><br>RCR: Not available | Not required as no hazard identified | Acute: Conditions of use (OC/RMM) |
| Use of trigger spray cleaner products (PC 35) | Exposure:<br><br>RCR: Not available | Not required as no hazard identified | Acute: Conditions of use (OC/RMM) |
| Use of liquid cleaning product for manual surface application (PC 35) | Exposure:<br><br>RCR: Not available | Not required as no hazard identified | Acute: Conditions of use (OC/RMM) |
| Use of abrasive product for manual surface application (PC 35) | Exposure:<br><br>RCR: Not available | Not required as no hazard identified | Acute: Conditions of use (OC/RMM) |
| Use of liquid cleaner for cleaning carpet (PC 35) | Exposure:<br><br>RCR: Not available | Not required as no hazard identified | Acute: Conditions of use (OC/RMM) |

| **4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES[30]** |
|---|
| |

[30] Section 4 of the current example has been left empty since “scaling advice” for consumers is still work in progress

# ES FOR COMMUNICATION (reduced information)

**Substance Name:** Alcohol

**EC Number:** xxx-xxx-x

**CAS Number:** xx-xx-x

**Registration Number:** xxxxxxxxxxxx[31]

**Date of Generation/Revision:** 2011-07-20

**Author:**

## 1. ES 0: Consumer end-use (SU 21); washing and cleaning products

| **1. Title of Exposure scenario** | |
|---|---|
| PC 35: Washing and cleaning products | |
| **Environment:** Component released during use | ERC 8a |
| **Consumer** | |
| Use of laundry and dishwashing product | PC 35 |
| Use of trigger spray cleaner products | PC 35 |
| Use of liquid cleaning product for manual surface application | PC 35 |
| Use of abrasive product for manual surface application | PC 35 |
| Use of liquid cleaner for cleaning carpet | PC 35 |

| **2. Conditions of use affecting exposure** |
|---|
| **2.1 Control of environmental exposure:** Component released during use **(ERC 8a)** |
| **Conditions and measures related to municipal sewage treatment plant** |
| Wastewater is to be treated by a municipal STP |
| **2.2 Control of consumers exposure for** Use of laundry and dishwashing product **(PC 35)** |
| **Product characteristics** |
| Covers concentration of substance in product up to < 15 % |
| **Amount used, frequency and duration of use/exposure** |
| For each use event, covers use amount up to 50 grams<br>Covers daily use |

[31] The EC, CAS and registration numbers are artificial and are given solely for the purpose of illustration in the example

| |
|---|
| **2.3 Control of consumers exposure for** Use of trigger spray cleaner products **(PC 35)** |
| **Product characteristics** |
| Covers concentration of substance in product up to < 15 % |
| **Amount used, frequency and duration of use/exposure** |
| For each use event, covers use amount up to 35 grams<br>Covers daily use |
| **2.4 Control of consumers exposure for** Use of liquid cleaning product for manual surface application **(PC 35)** |
| **Product characteristics** |
| Covers concentration of substance in product up to < 15 % |
| **Amount used, frequency and duration of use/exposure** |
| For each use event, covers use amount up to 250 grams<br>Covers dilution in water greater then 20 times<br>Covers daily use |
| **2.5 Control of consumers exposure for** Use of abrasive product for manual surface application **(PC 35)** |
| **Product characteristics** |
| Covers concentration of substance in product up to < 5 % |
| **Amount used, frequency and duration of use/exposure** |
| For each use event, covers use amount up to 37 grams<br>Covers use of undiluted product<br>Covers daily use |
| **2.6 Control of consumers exposure for** Use of liquid cleaner for cleaning carpet **(PC 35)** |
| **Product characteristics** |
| Covers concentration of substance in product up to < 30 % |
| **Amount used, frequency and duration of use/exposure** |
| For each use event, covers use amount up to 500 grams<br>Covers dilution in water greater then 200 times<br>Covers daily use |

| 3. Exposure estimation and reference to its source | | |
|---|---|---|
| | | |
| **Environment** | | |
| **Release route** | **Release rate (kg/day)** | **Release estimation method** |
| **Water** | 22 | ERC - ERC 8a |
| **Air** | 0 | ERC - ERC 8a |
| **Soil** | 0 | ERC - ERC 8a |

| **Protection target** | **Exposure estimate** (based on: EUSES 2.0) | **RCR** |
|---|---|---|
| Freshwater (pelagic) | 0.151 mg/L | 0.157 |
| Freshwater (sediment) | 0.646 mg/kg dw | 0.179 |
| Freshwater (sediment) | 0.646 mg/kg dw | 0.179 |
| Marine water (pelagic) | 0.015 mg/L | 0.019 |
| Marine water (sediment) | 0.064 mg/kg dw | 0.022 |
| Freshwater food chain (predators) | | |
| Marine water food chain (predators) | | |
| Marine water food chain (top predators) | | |
| Effluent | 1.39 mg/L | 0.002 |
| Agricultural soil | 0.019 mg/kg dw | 0.03 |
| Terrestrial food chain (predator) | | |

| **Risk characterisation for man via the environment**[32] |
|---|
| Inhalation: 0<br><br>Oral: 0 |

| **Consumer exposure** | | | | | |
|---|---|---|---|---|---|
| **Long-term, systemic** | | | | | |
| **Contributing scenario** | **Inhalation** | **Dermal** | **Oral** | **Combined routes** | **Exposure estimation Method** |
| Use of laundry and dishwashing product (PC 35) | Exposure: 15.6 mg/m³<br><br>RCR: 0.137 | Exposure: 21.4 mg/kg bw/day<br><br>RCR: 0.104 | Exposure: 0 mg/kg bw/day<br><br>RCR: 0 | RCR: 0.241 | Inhal: External exposure estimation tool - ECETOC TRA Reference to Subcategory 1 PC35[33]<br><br>Derm: External exposure estimation tool - ECETOC TRA Reference to Subcategory 1 PC35<br><br>Oral: External |

[32] The estimated dose/exposure for man via the environment was very low and it has been rounded down in Chesar 1.2 to "0". The rounding rule will be changed in Chesar 2.0

[33]References to external literature has been manually added in order to allow DU to retrieve the full set of operational conditions (OC) underlining the assessment

| | | | | | |
|---|---|---|---|---|---|
| | | | | | exposure estimation tool - ECETOC TRA Reference to Subcategory 1 PC35 |
| Use of trigger spray cleaner products (PC 35) | Exposure: 43.8 mg/m³<br><br>RCR: 0.384 | Exposure: 21.4 mg/kg bw/day<br><br>RCR: 0.104 | Exposure: 0 mg/kg bw/day<br><br>RCR: 0 | RCR: 0.488 | Inhal: External exposure estimation tool - ECETOC TRA Reference to Subcategory 3 PC35<br><br>Derm: External exposure estimation tool - ECETOC TRA Reference to Subcategory 3 PC35<br><br>Oral: External exposure estimation tool - ECETOC TRA Reference to Subcategory 3 PC35 |
| Use of liquid cleaning product for manual surface application (PC 35) | Exposure: 7.07 mg/m³<br><br>RCR: 0.062 | Exposure: 2.19 mg/kg bw/day<br><br>RCR: 0.011 | Exposure: 0 mg/kg bw/day<br><br>RCR: 0 | RCR: 0.073 | Inhal: External exposure estimation tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 8.1.1<br><br>Derm: External exposure estimation tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 8.1.1<br><br>Oral: External exposure estimation tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 8.1.1 |
| Use of abrasive product for manual surface application (PC 35) | Exposure: 2.51 mg/m³<br><br>RCR: 0.022 | Exposure: 0.29 mg/kg bw/day<br><br>RCR: 0.001 | Exposure: 0 mg/kg bw/day<br><br>RCR: 0 | RCR: 0.023 | Inhal: External exposure estimation tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 6.1<br><br>Derm: External exposure estimation tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 6.1<br><br>Oral: External exposure estimation |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 6.1 |
| Use of liquid cleaner for cleaning carpet (PC 35) | Exposure: 21.7 mg/m³<br><br>RCR: 0.19 | Exposure: 6.23 mg/kg bw/day<br><br>RCR: 0.03 | Exposure: 0 mg/kg bw/day<br><br>RCR: 0 | RCR: 0.221 | Inhal: External exposure estimation tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 8.2.1<br><br>Derm: External exposure estimation tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 8.2.1<br><br>Oral: External exposure estimation tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 8.2.1 |

| **Risk characterisation for acute systemic** |
|---|
| Not required as no hazard identified |

| **Local effects via inhalation route** | | | |
|---|---|---|---|
| **Contributing scenario** | **Acute** | **Long term** | **Exposure estimation Method** |
| Use of laundry and dishwashing product (PC 35) | Exposure: 375 mg/m³<br><br>RCR: 0.395 | Not required as no hazard identified | Acute: External exposure estimation tool - ECETOC TRA Reference to Subcategory 1 PC35 |
| Use of trigger spray cleaner products (PC 35) | Exposure: 263 mg/m³<br><br>RCR: 0.277 | Not required as no hazard identified | Acute: External exposure estimation tool - ECETOC TRA Reference to Subcategory 3 PC35 |
| Use of liquid cleaning product for manual surface application (PC 35) | Exposure: 42.4 mg/m³<br><br>RCR: 0.045 | Not required as no hazard identified | Acute: External exposure estimation tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 8.1.1 |
| Use of abrasive product for manual surface application (PC 35) | Exposure: 362 mg/m³<br><br>RCR: 0.381 | Not required as no hazard identified | Acute: External exposure estimation tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 6.1 |
| Use of liquid cleaner for cleaning carpet (PC 35) | Exposure: 284 mg/m³<br><br>RCR: 0.299 | Not required as no hazard identified | Acute: External exposure estimation tool - ConsExpo 4.1 RIVM report 320104003/2006, paragraph 8.2.1 |

| Local effects via dermal route | | | |
|---|---|---|---|
| **Contributing scenario** | **Acute** | **Long term** | **Exposure estimation Method** |
| Use of laundry and dishwashing product (PC 35) | Exposure:<br><br>RCR: Not available | Not required as no hazard identified | Acute: Conditions of use (OC/RMM) |
| Use of trigger spray cleaner products (PC 35) | Exposure:<br><br>RCR: Not available | Not required as no hazard identified | Acute: Conditions of use (OC/RMM) |
| Use of liquid cleaning product for manual surface application (PC 35) | Exposure:<br><br>RCR: Not available | Not required as no hazard identified | Acute: Conditions of use (OC/RMM) |
| Use of abrasive product for manual surface application (PC 35) | Exposure:<br><br>RCR: Not available | Not required as no hazard identified | Acute: Conditions of use (OC/RMM) |
| Use of liquid cleaner for cleaning carpet (PC 35) | Exposure:<br><br>RCR: Not available | Not required as no hazard identified | Acute: Conditions of use (OC/RMM) |

| **4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES[34]** |
|---|
| |

[34] Section 4 of the current example has been left empty since “scaling advice” for consumers is still work in progress

## Appendix 3: Acronyms and definitions[35]

AC – Article category

CHESAR - Chemical Assessment and Reporting Tool

CSR - Chemical Safety Report

DNEL - Derived No Effect Level

DU – Downstream User

ERC - Environmental Release Category

ECHA - European Chemicals Agency

ES - Exposure Scenario

EUSES – European Union System for Evaluation of Substances

OC – Operational Conditions

PC – Chemical Product Category

PNEC - Predicted No Effect Concentration

PEC - Predicted Environmental Concentration

REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals

RCR - Risk Characterisation Ratio

RMM - Risk Management Measure

SDS – Safety Data Sheet

STP - Sewage Treatment Plant

SU - Sector of Use

Derived No-Effect Level (DNEL) - the level of exposure to a substance above which humans should not be exposed, as derived from a human health hazard assessment[36].

Downstream user - User of a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.

Environmental release category - A pre-set combination of life cycle stage, distribution of emission sources, fate of substance in the technical process, level of containment, default emission factors (uncontrolled) and presence of waste water treatment , typical for an identified use.

Exposure assessment - The quantitative or qualitative estimate of the dose/concentration of the substance to which humans and/or the environment are or may be exposed. Exposure assessment under REACH consists of two steps: 1) Development of Exposure Scenarios and 2) Exposure Estimation, which have to be iterated until it can be concluded that the resulting exposure scenarios would ensure adequate control of risks upon implementation.

[35]Source, unless otherwise stated: Guidance on information requirements and chemical safety assessment Chapter R.20: Table of terms and abbreviation (2008)
[36]REACH Regulation, Annex I, 1.0.1

Exposure estimation - Quantification of exposure, related to the operational conditions and risk management measures as described in an exposure scenario. Exposure scenario building and the related exposure estimate together build the exposure assessment.

Operational conditions - Operational conditions include e.g. physical appearance of preparation, duration and frequency of use/exposure, amount of substance, room size and ventilation rate.

Predicted No-Effect Concentration (PNEC) - the concentration of a substance below which adverse effects in the environmental sphere of concern (e.g. water, soil) are not expected to occur[37].

Product category - Element of the use descriptor system characterising the type of chemical product in which the substance is (finally) used (PC).

Risk characterisation ratio (RCR): a comparison of the exposure (or concentration in the case on environmental hazards) with the appropriate DNEL (or PNEC) and taking into account the risk management measures and operational conditions described in the exposure scenario. The risk characterisation determines whether the risks to humans and the environment are adequately controlled.

Risk management measures - Measures that control the emission of a substance and/or exposure to it, thereby controlling the risks to human health or the environment. They include, for example the concentration of the substance in a product.

Sector of use - Element of the use descriptor system describing the sector of economy (industry, professional service, private) that a substance is used in, as such or in a preparation (mixture).

[37]REACH Regulation, Annex I, 3.0.1