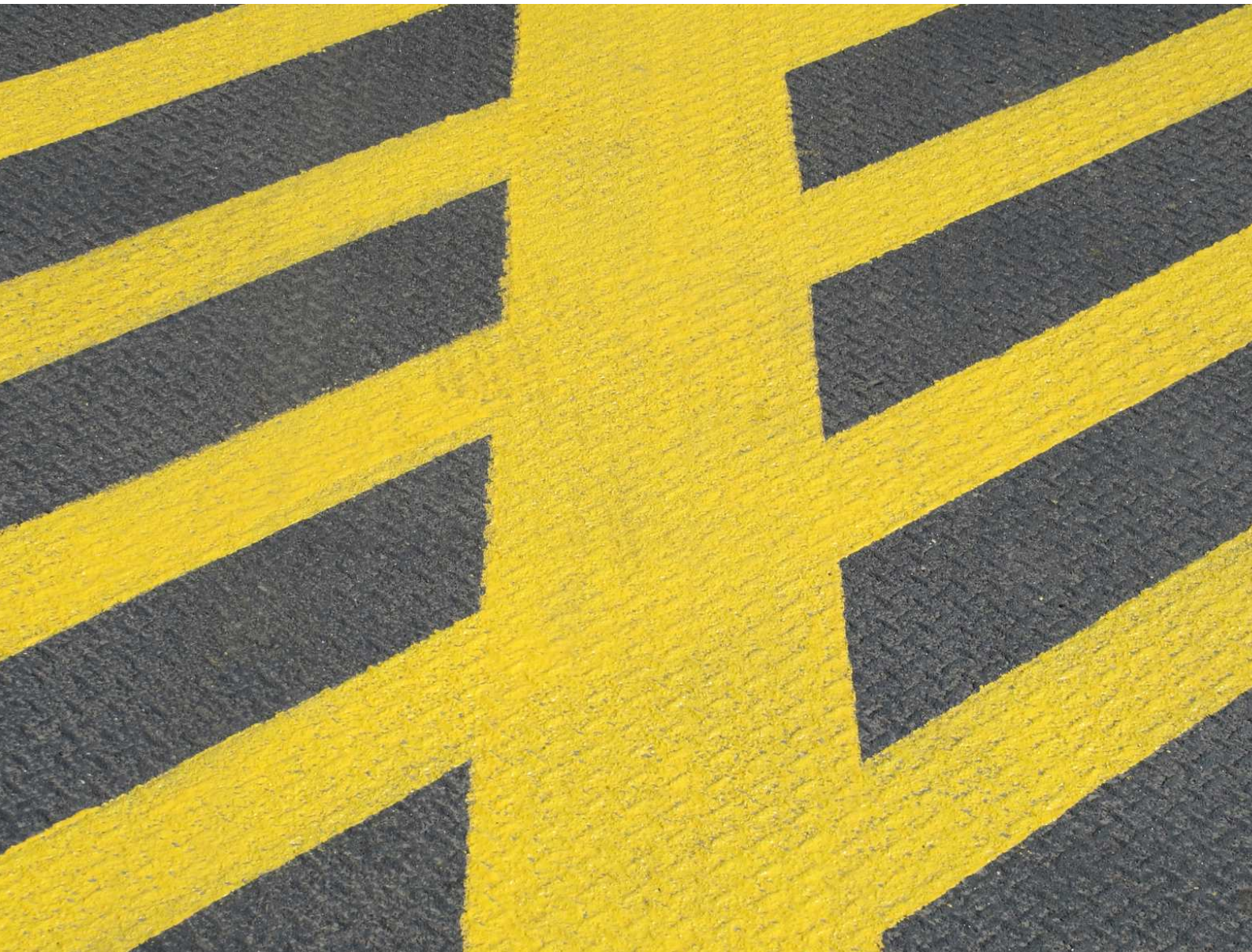
# Exposure Scenario for Chemical Safety report and Communication Example: Professional use of A substance in Floor Coatings



**EXPOSURE SCENARIO FOR CHEMICAL SAFETY REPORT AND COMMUNICATION**
**EXAMPLE: PROFESSIONAL USE OF A SUBSTANCE IN FLOOR COATINGS**

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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 worker and environment exposure to a substance which is commonly used in floor coatings 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.

Worker 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 - below the appropriate Derived No-Effect Level - DNEL), then in can be concluded that there is “no

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[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)

concern", and the risks from using the product are deemed to be controlled. If the Tier 1 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 results of exposure monitoring data, or alternatively a higher Tier model can be applied that takes into account other factors that influence the exposure result.

This example illustrates the application of the ECETOC TRA worker exposure assessment tool (Tier 1) and how to refine the assessment by introducing exposure considerations beyond the scope of the current version of the ECETOC TRA.

More detail on the estimation tools used in this project, and exposure estimation for workers in general, can be found in ECHA Guidance on information requirements and chemical safety assessment Chapter R.14. - Occupational exposure estimation (v.2, 2010). In this chapter, their core concepts, input parameters, strengths and limitations are described. An important aspect of this example is a practical demonstration of how the limitations within the TRA tool can be addressed and reflected in exposure scenarios for the chemical safety report (CSR) and for communication.

This example is 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 worker use. Physical health hazards are not considered in this example. The waste and service life stages of the life-cycle for the substance have not been addressed.[3]

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

[3] 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.

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# 1. INTRODUCTION

## *1.1. Background*

The exposure scenario is one of the new requirements of the REACH Regulation[4]. The exposure scenario (ES) is an integral part of the Chemical Safety Report (CSR) and it presents the uses of a substance together with the operational conditions and risk management measures that are necessary to achieve safe use with respect to the environment and human health. The exposure scenario also provides information for the supply chain – in this document the term "exposure scenario for communication" is used - as an annex to the safety data sheet (SDS) prepared by the manufacturer for the use of a downstream user, such as a formulator of mixtures.

In 2010, the European Chemicals Agency (ECHA) published, in cooperation with the semiconductor industry, examples of exposure scenarios for the industrial use of substances. The current example presents the ES for professional use of a (floor coating) substance in a construction sector.

The European Chemicals Agency (ECHA) established a collaboration with the construction chemicals industry to develop practical examples of how to generate exposure scenarios (ESs). The examples developed are related to the professional use of a substance contained in floor coating products used in the construction sector.

Project participants strove to achieve a high level of understanding of the typical uses of the substance through information sharing. They established a common understanding of what type of information chemical manufacturers need, and can use, to estimate exposure of the environment and of (professional) workers to the substance.

Furthermore, the example enabled ECHA to test Chesar[5], ECHA's Chemical Safety Assessment and Reporting Tool. The experience gained in the development of these ESs has been fedback to the Chesar development team and used in the refinement of the tool. The functionalities for the generation of the CSR and exposure scenario for communication were used to prepare the example presented in this document.

## *1.2. Boundaries of the project*

The objective of the project was to build an example of an exposure scenario for a CSR and for communication representing the professional use of a substance.

One of the elements crucial for the development of the CSR and ESs is cooperation between the manufacturer/importer (M/I) and downstream user (DU). While the first has at his disposal all information related to the physicochemical and toxicological properties of the substance, the latter is able to provide information on uses of the substance, including tasks descriptions, operational conditions and risk management measures (for workers and environment) and work practices typically used. An effective dialogue between these two actors in the supply chain is essential. Only then, can the reliable exposure scenarios be built, exposures to the environment and human health be assessed and the safe conditions of use identified. The example presented reflects the effect of this cooperation between the M/I and DU.

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[4] Article 14.4.(a) of the REACH Regulation
[5] http://chesar.echa.europa.eu/

The modelling tools contained within Chesar were used to derive the estimated exposure levels. For the assessment of the environmental exposure, the EUSES 2.1[6] assessment tool was used; for the estimation of workers' exposure, the ECETOC TRA v.2[7] assessment tool was used with some modifications (see section 2.3). Both tools belong to the first tier of assessment tools.

ECHA's 'Guidance on information requirements and chemical safety assessment Exposure Scenario Format in Part D: Exposure scenario building' (v.2, 2010)[8] was used as the basis for the format of the example presented in this document.

The exposure assessment follows the provisions of the guidance on the scope of the exposure assessment[9] 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.[10]

## *1.3. Project outcome*

The example presented in this document demonstrates how the risks related to the use of the substance - an organic solvent - can be evaluated, and how to select the risk management measures required to ensure its safe use.

The exposure scenario developed for the Chemical Safety Report was used as a basis for the development of the ES for communication. The latter illustrates how the information about the identified uses and the safe conditions of use for the substance may be effectively communicated to a downstream user. The exposure scenario presented is intended for communication between the registrant and his industrial customers, formulators, who produce mixtures containing this substance. It would form part of the ext-SDS. The information presented in this ES must be taken into account by the formulator when developing the ES for the final user of the mixture, for example, a construction worker.

The ESs for the CSR and for communication have been generated using Chesar 1.2 (see footnote 5). In this version, the phrases related to conditions of use contained in the Chesar tool library were developed on the basis of discussions with stakeholders. **Please note:** The exposure scenarios as generated with Chesar 1.2 have been modified manually – in section 4 of the ES for communication, information needed for scaling has been added. This modification will be considered when further developing the specifications for Chesar version 2.

## *1.4. Main findings*

A number of issues arose when developing these exposure scenarios. The lessons learnt are reported in the main text (section 2) as they will help others who need to prepare similar exposure scenarios. The main points are summarised beneath:

- Preparing the CSR and ES for communication is an obligation of the manufacturer/importer. However, to develop meaningful exposure scenarios, which present realistic conditions of use and (estimations of) exposure levels, the input from

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[6] http://ecb.jrc.ec.europa.eu/home.php
[7] http://www.ecetoc.org/tra
[8] http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_ESformat_en.pdf?vers=27-05-10
[9] Guidance on information requirements and chemical safety assessment Part B: Hazard Assessment (2008) http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_b_en.pdf?vers=20_10_08
[10] For the state of play of the consultation procedure please go to the Consultation Procedure page on the ECHA web site

the downstream users (and their organisations) is essential. The required information includes: description of uses, duration and frequency of use, concentration of the substance in products, current risk management practice (such as ventilation conditions, personal protective equipment or waste disposal practice).

- Demonstrating the safe use of a substance may require refinement of the initial exposure assessment. This process may include use of other (higher tier) tools, the use of exposure monitoring data, or further iterations based on the Tier 1 tool. Such iterations include changes to the input parameters which exist in the tool, or the introduction of additional exposure determinants. However, such additional determinants must be demonstrated to be compatible within the boundaries of applicability of the actual Tier 1 tool. The last option is illustrated in the example presented in this document: Concentration of the substance in the mixture and dermal protective equipment have been used as exposure modifying factors for the skin.

- Modelling tools, like the TRA, used for the estimation of exposure levels may have built-in assumptions. One of them is the assumption that good general ventilation conditions exist at the workplace. However this does not necessarily match the reality in the context of professional uses, in particular if they take place indoors. The requirement for the good general ventilation is therefore explicitly stated under the heading ‘Other operational conditions affecting workers’ exposure’ in section 2 of the exposure scenario for communication.

# 2. BUILDING AN EXPOSURE SCENARIO FOR PROFESSIONAL USE OF A SUBSTANCE FOR A CSR AND FOR COMMUNICATION

## *2.1 Substance selection and properties*

An organic solvent has been selected as an example reference substance. The substance has a low volatility, as indicated by its vapour pressure at 20 °C. It is also biodegradable in water (not bioaccumulative) and moderately soluble in water.

The substance is not classified for environmental adverse effects either under the provisions of the CLP Regulation[11] or via self-classification. It is classified for human health adverse effects as harmful and as an eye irritant. The properties of the substance that may affect the exposure levels together with the relevant toxicological and ecotoxicological information are summarised in the table below.

Table 1: Properties of the substance

| SUBSTANCE INFORMATION | | |
|---|---|---|
| **General properties** | | |
| 1 | Molecular weight | 108 |
| 2 | Physical state (solid, liquid, gas) at 20°C and 101.3 kPa | Liquid |
| 3 | Melting/freezing point | -15.3 °C |
| 4 | Boiling point at 1013hPa | +205.4 °C |
| 5 | Vapour pressure (Pa) at 20ºC | 22.6 |
| 6 | Water solubility | 40g/L at 20 °C |
| 7 | Octanol/Water partitioning coefficient (log Kow) | 1.1 |
| **Classification and labelling** | | |
| 8 | Substance classified as CMR PBT/vPvB | No |
| 9 | Substance classification (R phrases) | Directive 67/548/EEC:Xn 20/22 – harmful by inhalation and if swallowed<br>Regulation (EC) No 1272/2008: H302- harmful if swallowed<br>H332 – harmful if inhaled<br>H319 – Causes serious eye irritation |
| 10 | Occupational exposure limit/s | Not allocated |
| **Toxicological information** | | |
| 11 | DNEL Long-term inhalation systemic (workers) | 90 mg/m$^3$ |
| 12 | DNEL Long-term dermal systemic (workers) | 9.5 mg/kg bw/day |
| 13 | DNEL Acute inhalation systemic (workers) | 450 mg/m$^3$ |
| 14 | DNEL Acute dermal systemic (workers) | 47 mg/kg bw/day |
| 15 | DNEL Long-term oral systemic (man via environment) | 5 mg/kg bw/day |
| **Ecotoxicological information** | | |
| 16 | PNEC freshwater | 1 mg/L |
| 17 | PNEC freshwater sediment | 5.27 mg/L |
| 18 | PNEC marine water | 0.1 mg/L |
| 19 | PNEC marine water sediment | 0.527 mg/L |
| 20 | PNEC agricultural soil | 0.456 mg/kg dry weight |
| 21 | PNEC Sewage Treatment Plant (STP) | 39 mg/L |

[11] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

The toxicological and ecotoxicological information trigger the following consequences:

- A quantitative exposure assessment and risk characterisation are needed in order to evaluate the chronic systemic effect for workers exposed to the substance via dermal and inhalation routes.
- A quantitative exposure assessment and risk characterisation are needed to evaluate the acute systemic effect for workers exposed to the substance via dermal and inhalation routes.
- A quantitative assessment is needed for the human exposure via the environment – through the inhalation oral routes.
- A qualitative assessment has to be carried out for the risk of eye irritation for which it has not been possible to derive a DNEL.

These effects have been taken into account when building the exposure scenarios and when calculating exposure estimations and the risk characterisation ratio(s) for the professional use of the substance.

## *2.2 Identified uses of the substance*

The following paragraphs summarise information about the identified uses of the example reference substance and the corresponding descriptors which can be found in ECHA's use descriptor system; the use of such descriptors can help actors in the supply chain to communicate information in a consistent manner. They are also important input parameters for the ECETOC TRA and they reflect assumptions applied for generating the exposure estimations and exposure scenarios used in Chesar (see 2.3 section).

The substance has a variety of professional uses (SU 22 [12] - Professional uses: Public domain (administration, education, entertainment, services, craftsmen)), including some in the construction sector (SU 19 – building and construction work).

One use of the substance in the construction sector is in a floor coating product that can be used in both indoor and outdoor settings. The two main modes of application are spraying (PROC 11 - Non industrial spraying) and application with hand tools e.g. roller or brush. (PROC 10 - Roller application or brushing). The substance can be delivered in large containers, necessitating decanting on site (PROC 8a - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities). Then it is mixed or blended with other ingredients using a hand-operated stirrer (PROC 5 - Mixing or blending in batch processes for formulation of preparations and articles). The duration of tasks per day varies from up to1 hour for decanting (PROC 8a), through to 4 hours for spraying (PROC 11), and up to 8 hours for each of the two remaining activities, mixing (PROC 5) and application with hand-held tools (PROC 10). Typically, in the floor coating products, the substance is used at a concentration of between 5% and 25%, however the concentration of the substance delivered, used to preparation the final mixture, may also be higher than 25%. All tasks are performed at ambient temperature. As a general rule, eye protection (goggles), appropriate gloves and long-sleeved overalls are used for all tasks. In addition, for the spray application, a half-face respirator fitted with an appropriate cartridge is used. Other, higher level risk management measures, such as local exhaust ventilation (LEV), are typically not available for this construction use. The model assumes that all the application equipment and personal protective equipment (PPE) are used and maintained according to their manufacturer's instructions.

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[12] The descriptors SU (for Sector of Use) and PROC (for Process Category) are part of the use descriptor system presented in the ECHA Guidance on information requirements and chemical safety assessment Chapter R 12: Use descriptor system (version: 2 March 2010) available at: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf

From the environmental perspective, these tasks are considered to represent a 'wide dispersive use'. (ERC 8a[13] - Wide dispersive indoor use of processing aids in open systems and/or ERC 8d - Wide dispersive outdoor use of processing aids in open systems). A municipal sewage treatment plant (STP) is assumed as available to treat waste waters/effluent arising from all locations where the substance is used.

## *2.3 Exposure Assessment and Exposure Scenario for CSR*

A CSR has been generated using ECHA's Chemical Safety Assessment and Reporting Tool, Chesar. When using Chesar for exposure assessment the following terms are key: use; stage; and contributing scenario.

- **Uses** of a substance are described within a life-cycle tree structure, presented as 'stages'.
- There are eight different '**stages**' within the life-cycle: manufacturing stage, formulation stage (for production of mixtures), end-use stage of the substance as such or in a mixture for three user groups: industrial worker, professional worker and consumer) and article service life (for the three user groups). For each of these stages, one or more exposure scenarios can be built.
- Workers' or consumers' activities (= uses) carried out at each stage**,** are characterised by the corresponding operational conditions and risk management measures, related to the environment and worker or consumer. The set of operational conditions and risk management measures related to the 'use' is called the '**contributing scenario**'. One or more of these contributing scenarios form an exposure scenario.

The two (Tier 1) exposure estimation tools ECETOC TRA v.2 and EUSES 2.1, built-in to Chesar, have been used for the exposure assessment. Both tools estimated the exposure on the basis of the information on the substance properties presented in the previous section and the typical risk management measures and operational conditions, including the conditions of use set when the PROC or ERC specified are selected as the input parameter to the Chesar.

Although the substance is not classified as hazardous for environmental effects, the level of exposure to the environment was nevertheless evaluated using EUSES 2.1. The standard set of assumptions built into EUSES for wide dispersive use was applied to calculate the impact of the substance in the presence of the municipal sewage treatment plant (STP). For the purposes of this assessment, the outdoor condition (ERC 8d) was used for the exposure assessment.

### 2.3.1 Application of ECETOC TRA methodology

ECETOC TRA v.2 was used to estimate a worker's level of exposure. Even though the substance can be used in both indoor and outdoor workplace settings, the indoor conditions were taken, as the more conservative situation, to assess the exposure levels.

ECETOC TRA was designed for estimating exposure via the inhalation route in an industrial setting (previously known as the Estimation and Assessment of Substance Exposure (EASE) model). Many factors - substance properties, indoor/outdoor use, process (PROC),

[13] ERC – environmental release category – is a use descriptor presented in ECHA Guidance on information requirements and chemical safety assessment Chapter R-16 – Environmental Exposure Estimation (2010) available at:
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r16_en.pdf?vers=27_05_10

duration of tasks, concentration of a substance, certain risk management measures e.g. local exhaust ventilation and respiratory protective equipment - are taken into consideration when estimating exposure via inhalation in this model. However, the effect of some of these factors (e. g. indoor/outdoor use, duration of tasks, concentration of a substance) are not taken into consideration in the calculation method for the dermal route of exposure.

As a consequence, it was not possible to determine the safe use for some processes (or tasks) that presented a risk of dermal exposure using the ECETOC TRA.

The risk characterisation ratios (RCR) resulting from the initial ECETOC TRA exposure assessment for the relevant process categories (PROCs) are summarized in Table 2. RCRs represents the ratio between the exposure level and the relevant DNEL.

**Table 2: Risk characterisation ratios (RCRs) calculated with ECETOC TRA in the screening estimation**

| Process (Task) | RCR for long term, systemic dermal exposure |
|---|---|
| Diluting of the concentrated product - transfer for mixing (PROC 8a) | 1.44 |
| Mixing of the substance into ready-to-use product (PROC 5) | 1.44 |
| Use of hand-held tools - roller or brush application (PROC 10) | 2.887 |
| Use of product in a spray form (PROC 11) | 11.28 |

In order to further address the dermal route, an exposure assessment via an extension to ECETOC TRA has been performed. This approach introduced a number of additional determinants into the assessment of the exposure via the dermal route, as follows:

- A modification of the exposure based on the concentration of substance in the (final) product used;
- The use of personal protective equipment (PPE) for skin protection.

The algorithms used to derive the dermal exposure with these additional determinants were consistent with those used for the inhalation exposure:

- the effectiveness of the (dermal) PPE was estimated as 90%; and
- the concentration of the substance in the product (5 - 25%) resulted in a reduction of the estimated dermal exposure by 40%[14].

As a result of this iteration, the calculated exposure levels and the resulting risk characterisation ratios for dermal exposure, as well as for the combined local and systemic effects (that is, exposure through the combined routes of inhalation and dermal) indicated that the risks were adequately controlled. The use of a higher tier tool was therefore not required.

[14] In the ECETOC TRA, a non-linear relation is assumed between the concentration of the substance in a product and the inhalation exposure. For reasons of consistency, this approach has been also been applied to the dermal exposure in this example.

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

**Issue 1: Dermal exposure assessment with the ECETOC TRA v2 tool**
For the dermal exposure estimation using the ECETOC TRA v2 tool, the only variable input parameters are the process category (PROC) and the local exhaust ventilation (LEV). For uses for which LEV is not available, such as in construction, presented in this example, the TRA tool does not support the assessment of the effect of any measures to reduce dermal exposure.

**Lesson Learned**
In cases where, ECETOC TRA does not demonstrate the safe use of a substance for the dermal route of exposure, the refinement of the initial (screening) exposure assessment is necessary.
The following additional determinants may be added in the iteration:
- the effect of concentration of the substance in the product,
- the effect of the use of personal protective equipment in the form of skin protection.

Such solutions may need to be considered for each case where iterations are needed. In some situations, a single modification may be sufficient to reach an acceptable level of exposure and risk characterisation ratio and to demonstrate adequate control of risks.

If new determinants are introduced, care must be taken to the use of algorithms that will preserve a level of caution typical for the tool. Simple linear adaptations of expected exposure in relation to concentration of the substance in product may not be conservative enough. A justification should be provided for the algorithm chosen.

**Issue 2: Assumptions about the conditions of use**
Operational conditions such as general ventilation rate and general occupational hygiene conditions can impact on the level of worker exposure. However these assumptions are not explicitly stated in the ECETOC TRA tool. In the construction sector, on-site conditions under which work is done - including general ventilation - may vary significantly. For example, a coating product (used on the floor or wall) may be applied in a small room (such as storage room or office), with no or a low-level general ventilation, and where for the duration of the refurbishment activity the air-conditioning system may not be operational.

**Lesson Learned**
For indoor construction activities, the ventilation conditions may play a key role in the exposure assessment. The Tier 1 model is based on assumption, that good general ventilation is available at the workplace. However, this may not always match the reality in the context of professional use, especially if the process (or task) takes place indoors.

The registrant should make it explicit in his exposure scenario that the good general ventilation is a requirement. The DU should check if the required ventilation is available for his process(es).

In the ES for communication generated with Chesar 1.2 this requirement for general ventilation is included by default in all exposure scenarios generated using ECETOC TRA.

As an alternative to introducing new determinants, a, higher tier modelling tool can be used. Suitable and representative measured data may also be used. In this case, the data should

fulfil the criteria presented in the Guidance on information requirements and chemical safety assessment, Chapter R 14 – 'Occupational exposure estimation'(2010)[15].

A qualitative risk assessment and risk characterisation was carried out for eye irritation, since a DNEL could not be determined for that hazard. According to the classification of the substance, the cut-off concentration for adverse effects on the eye is 20% (the substance is an eye irritant at a concentration of 20% or higher). In the three tasks described in the ESs the maximum concentration used is 25%. In one task the substance is used at a concentration above 25%. Therefore to eliminate or minimise the local effect, risk management measures for eye protection have been included in all exposure scenarios.

## *2.4 Exposure Scenario for Communication*

The exposure scenario for communication is intended to be the tool for manufacturers/importers (M/I) to convey to the downstream users (DUs) the information on the conditions of uses of substances that are assessed as safe for both the environment and humans i.e. workers and the general population, including consumers. If the use of the DU is included in the ES, it is expected that he will verify whether, and ensure that, the recommended OCs and RMMs are implemented at his workplace. In addition, the information contained in the ES may also trigger some other actions, for example modifications to the product (e.g. a change of concentration or packaging) or the introduction at the workplace (on a voluntary basis) of some additional RMMs that are recommended as 'good practice'. Finally, this information may also be used as a basis for the development of a DU's own information in relation to the products that he manufactures (e.g. own extended SDSs and product labels) to convey the information on safe use to his customers / end-users In this example, these end-users are the workers using the substance on construction sites

This example presents an ES developed by the manufacturer/importer for the formulator.

The ES for communication consists of four sections:

- Section 1: The Title section
  - Contains the information allowing identification of the use of the substance, including the sector of use (SU), mode of environmental exposure (ERC) and the individual processes (PROCs) in which the substance is used
- Section 2: Conditions of use affecting exposure
  - In this section, contributing scenarios, both for the environment and (professional) workers are identified. In this part, the elements that affect the level of exposure are listed e.g. OCs and RMMs. Also included are *additional* measures that may further reduce exposure as a 'good practice'. (Ideally, information provided in this section should reflect the information that the DUs provided to the M/I when they asked for the information on the uses, OCs and RMMs recommended, when the M/I was collating his information to prepare the ES for the CSR.) In relation to the environment, due to the character of the activity (wide dispersive use) presented in this example, only very limited information needs to be communicated to the DU; the only relevant determinant is the presence of the STP.

  Assumptions on which the exposure modelling tool is based that affect the exposure level should be included in this section as well. For example, ECETOC TRA for workers was originally designed for industrial workplaces, where there is a requirement for a certain level of general ventilation. Therefore, the requirement for

15 http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r14_en.pdf?vers=27_05_10

adequate ventilation (please see also Issue 2) is specifically identified among the OCs.

**Issue 3: RMMs required for safe use and 'good practice'**
The main function of the ES for communication is to convey the information on the OC and RMMs needed as a minimum to ensure safe use of the substance. (This triggers certain obligations for the downstream users). A balance should be struck between providing sufficiently specific information to manage the risks based on the exposure assessment model applied and not introducing unnecessary, restrictive or impractical requirements for the DU.

**Lesson Learned**
All elements – OCs and RMMs - that determine the safe use of the substance have to be presented in the ES for communication. Information should be provided on the effectiveness of the RMMs required, as well as on the conditions under which this effectiveness can be achieved. For example, the effectiveness of respiratory protective equipment (RPE) is identified as 90%. Training is one of the factors that allows a worker to use RPE in an efficient and effective manner – so it should be listed as a requirement. The type of filter installed in the respirator also influences its effectiveness, therefore the correct type should be specified. However, care should be taken to use wording which also allows to use of alternative and equally effective types of filters. Similar information should be provided in relation to dermal protection: the type of gloves, the material from which they should be made, the breakthrough time, and training in relation to use and maintenance.
There may be other elements that reduce exposure but whose effect has not been included in the assessment of the exposure level. These should be listed as a 'good practice'; the implementation of this advice is not mandatory. For example, use of a specific type of tool or a general good occupational hygiene work practice.

- Section 3: Exposure estimations
  - Estimated levels of exposure and the corresponding RCRs are provided to demonstrate the safe use of the substance for both human health and the environment. The methodology used for the derivation of the exposure level is presented; the tools used for the modelling are named, and any modifications made to them in order to perform the calculations are listed.
- Section 4: Scaling advice[16]
  - The aim of scaling is to allow flexibility in checking if the uses of the DU or his customers are covered by an exposure scenario. It enables the DU?? to demonstrate that a use is covered by an exposure scenario, although not all the parameters for his use are identical to those presented in that exposure scenario. In some cases, the DU may be interested in changing some of the parameters of the tasks performed e.g. duration of the task and/or the concentration of the substance. For these reasons, advice on scaling should be provided that includes:

- the parameters affecting the exposure for each task
- and tools used to derive exposure estimations
- information on modifications made to the tool (e.g. determinants added)

[16] More information is available in the Guidance for downstream users (2008), available at: http://guidance.echa.europa.eu/docs/guidance_document/du_en.pdf?vers=29_01_08

.

The version of Chesar (version 1.2) used to develop this example of the ES for communication does not include a functionality that allows scaling information to be presented. Therefore, the information presented in the example has been added manually.

**Issue 4: Scaling options**

In some cases, the conditions (duration of use and/or concentration of the substance) under which the substance is used at a DU location may be different from those presented in the exposure scenario annexed to the SDS. The DU may wish to check whether his conditions are nevertheless safe.

**Lessons Learned**

Scaling may be used to check whether an individual DU's OCs and RMMs ensure safe conditions of use. The same modelling tool as originally applied has to be used for the re-assessment. Therefore, all elements which affect the calculated exposure level have to be reported in the ES for communication, together with the information on the modifications that have been applied to the tool and added determinants. There may be a need to obtain expert advice, for example from the manufacturer, the supplier or a sector organisation, if the tool has been modified to ensure that it is used, and the result are interpreted correctly.

# Appendix 1 – ES for CSR

Exposure scenarios, describing the conditions of use, exposure estimation and risk characterisation constitute an integral part of the CSR. They are presented in sections 9 and 10 of the CSR. Only these sections are included in this Appendix.

- Section 9.0.1: present uses and exposure scenarios.
- Section 9.0.2: Reports the scope and type of exposure assessment - route of exposure and type of effect (determined by hazard data) assessed and type of assessment - qualitative or quantitative[17].
- Section 9.1.1.x: Presents the contributing scenarios. The first one relates to the environment, then follow the contributing scenarios presenting uses and exposure conditions relevant for selected professional uses.
- 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 professional exposure).
- Section 10.1.1: The risk characterisation for human health is reported for each contributing scenario.

Assumptions made in the exposure scenario:

- volume of substance used for professional use – 18000t/year
- possibility that the substance is used in indoor and outdoor settings
    - for evaluation of human exposure – indoor use exposure values were calculated
    - for evaluation of the environmental exposure – outdoor use was considered.
- municipal STP is present – any emissions to water pass through a sewage treatment plant
- for professional use of the substance, a limited number of risk management options are available:
    - substance concentration
    - duration of exposure / task
    - PPE needed to control risks
    - sector-specific use of a substance in construction – LEV may not be available in all locations

Issues related to eye irritation are presented as a dermal local acute exposure assessment.

In the example given, the environmental exposure and the individual tasks in which the substance is used are presented as 'Contributing Scenarios'.

[17]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 - updated publication is expected in the autumn 2011. For the current state of the consultation proces please check the Consultation Procedure page on the ECHA web site

# CHEMICAL SAFETY REPORT

**Substance Name:** Organic solvent

**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 | Professional use of floor-coating substance | - Wide dispersive outdoor use of substance in coatings, release intended (ERC 8d)<br>- Diluting of the concentrated product - transfer for mixing<br>- Mixing of the substance into ready-to-use product<br>- Use of hand-held tools - roller or brush application<br>- Use of product in a spray form | PW-1 |
| *) A stage number consists of an abbreviation of the main life cycle stage followed by a consecutive number. | | | |

**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 | | | 0.0 | |
| Professional workers uses | PW-1 (IUC-1) | - Wide dispersive outdoor/indoor use of substance in coatings, release intended (ERC 8d)<br><br>- Diluting of the concentrated product - transfer for mixing (PROC 8a)<br>- Mixing of the substance into ready-to-use product (PROC 5)<br>- Use of hand-held tools - roller or brush application (PROC 10)<br>- Use of product in a spray form (PROC 11) | | | 18000.0 | 1 |
| *) A stage number consists of an abbreviation of the main life cycle stage followed by a consecutive number. | | | | | | |

| Main life cycle stage | Stage No. *) | Manufacture / Use / Subsequent service life | Related subsequent service life | Market sector | Tonnage (tonnes per year) | ES No. |
|---|---|---|---|---|---|---|
| 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. Worker

**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 | **Exposure assessment and risk characterisation not** | The substance does not meet the criteria to be classified as dangerous for respiratory acute |

| Route of exposure and type of effects | Type of assessment | Explanation / Justification |
|---|---|---|
| | **required** | local efects. |
| **Inhalation:** Acute, Systemic | **Quantitative** | Quantitative exposure assessment and risk characterisation. See DNEL in section 5.11.2. |
| **Inhalation:** Long term, Local | **Exposure assessment and risk characterisation not required** | The substance does not meet the criteria to be classified as dangerous for respiratory long term local effects. |
| **Inhalation:** Long term, Systemic | **Quantitative** | Quantitative exposure assessment and risk characterisation. See DNEL in section 5.11.2. |
| **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 | **Quantitative** | Quantitative exposure assessment and risk characterisation. See DNEL in section 5.11.2. |
| **Dermal:** Long term, Local | **Exposure assessment and risk characterisation not required** | The substance does not meet the criteria to be classified as dangerous for dermal long term local effects. |
| **Dermal:** 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:** 1.8E4 tonnes/year
- **Air:** 1.8E4 tonnes/year
- **Soil:** 3.6E3 tonnes/year

#### 9.0.3.2. Regional exposure: environment [ERC 8d]

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

| Protection target | Regional PEC |
|---|---|
| Fresh Water (Pelagic) | 0.007 mg/L |
| Fresh Water (Sediment) | 0.034 mg/kg dw |
| Marine Water (Pelagic) | 7.02E-4 mg/L |
| Marine Water (Sediment) | 0.003 mg/kg dw |
| Air | 9.55E-5 mg/m³ |
| Agricultural Soil | 0.003 mg/kg dw |

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

**Regional total estimated daily intake for humans:** 3.616E-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 | 2.11E-4 mg/kg bw/day | 0.007 mg/L |
| Fish | 1.66E-5 mg/kg bw/day | 0.01 mg/kg |
| Leaf crops | 1.15E-4 mg/kg bw/day | 0.007 mg/kg |
| Root crops | 1.89E-5 mg/kg bw/day | 0.003 mg/kg |
| Meat | 2.97E-9 mg/kg bw/day | 6.92E-7 mg/kg |
| Milk | 5.54E-8 mg/kg bw/day | 6.92E-6 mg/kg |

## 9.1. Professional end-use stage

| | |
|---|---|
| **Sector of use:** | |
| SU 19 - Building and construction work | |
| **Environment:** | |
| Wide dispersive outdoor use of substance in coatings, release intended | ERC 8d |
| **Worker** | |
| Diluting of the concentrated product - transfer for mixing | PROC 8a |
| Mixing of the substance into ready-to-use product | PROC 5 |
| Use of hand-held tools - roller or brush application | PROC 10 |
| Use of product in a spray form | PROC 11 |

### 9.1.1. Exposure scenario

#### 9.1.1.1. Control of environmental exposure: Wide dispersive outdoor use of substance in coatings, release intended [ERC 8d]

**Further specification:** Although the ES covers both indoor and outdoor use of the substance, environmental exposure has been assessed only for outdoor uses (more conservative)

| |
|---|
| Product characteristics |
| Liquid |
| Amounts used |
| • Daily wide dispersive use: = 0.01 tonnes/day |
| Frequency and duration of use |
| Not relevant |
| Environment factors not influenced by risk management |
| • Receiving surface water flow rate: >= 1.8E4 $m^3$/d |
| Other given operational conditions affecting environmental exposure |
| None |
| Technical conditions and measures at process level (source) to prevent release |
| None |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil |
| None |
| Organizational measures to prevent/limit release from site |
| None |
| Conditions and measures related to municipal sewage treatment plant |
| • Municipal STP: Yes [Effectiveness Water: 87.4%] |
| • Discharge rate of STP: < 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |

| |
|---|
| Conditions and measures related to external treatment of waste for disposal |
| None |
| Conditions and measures related to external recovery of waste |
| None |
| Additional good practice advice beyond the REACH CSA |
| None |

**9.1.1.2. Control of workers exposure for "Diluting of the concentrated product - transfer for mixing" [PROC 8a]**

| | Inhal*) | | Derm*) | |
|---|---|---|---|---|
| | Loc | Sys | Loc | Sys |
| Product characteristic | | | | |
| • Substance in preparation: Yes | | AL | | |
| • Concentration of substance in product: > 25% | | AL | | |
| Amounts used | | | | |
| Not relevant | | | | |
| Frequency and duration of use/exposure | | | | |
| • Duration of activity: 15 min. - 1 hour | | AL | | |
| Human factors not influenced by risk management | | | | |
| None | | | | |
| Other given operational conditions affecting workers exposure | | | | |
| • Temperature of the process: room temperature | | AL | | AL |
| • Ventilation conditions at workplace: Good general ventilation (e. g. 5 air exchanges per hour) | | AL | | AL |
| • Place of use: Indoors<br>Indoor exposure estimation, as more conservative, has been used for calculation. Substance can also be used outdoor. | | AL | | |
| • Surface of skin exposed: Two hands (960 $cm^2$) | | | | AL |
| Technical conditions and measures at process level (source) to prevent release | | | | |
| • Level of containment: Open substance bulk transfers (PROC 8a) | | AL | | |
| Technical conditions and measures to control dispersion from source towards the worker | | | | |
| • Local Exhaust Ventilation: No | | AL | | AL |
| Organisational measures to prevent /limit releases, dispersion and exposure | | | | |
| None | | | | |

| | | | | |
|---|---|---|---|---|
| Conditions and measures related to personal protection, hygiene and health evaluation | | | | |
| • Eye protection: Yes (Face shield, goggles or safety glasses with side shields) | | | A | |
| • Respiratory protection: Respiratory protection is not used | | AL | | |
| • Gloves: Suitable gloves [Effectiveness Dermal: 90%] (Nitrile rubber, chloroprene rubber, butyl rubber or other suitable gloves, complying with the requirements of EN 374 with a breakthrough time of 480 min.<br>Training in relation to use and maintenance of the PPE must be provided to ensure required effectiveness of protection.) | | | | AL |
| Additional good practice advice beyond the REACH CSA | | | | |
| • Good occupational hygiene practice: good practice | | AL | | AL |

*) The route of exposure (**Inhal**ation, **Derm**al) 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.

#### 9.1.1.3. Control of workers exposure for "Mixing of the substance into ready-to-use product" [PROC 5]

| | Inhal*) | | Derm*) | |
|---|---|---|---|---|
| | Loc | Sys | Loc | Sys |
| Product characteristic | | | | |
| • Substance in preparation: Yes | | AL | | |
| • Concentration of substance in product: 5 – 25% | | AL | | |
| • Concentration in product: 5-25% [Effectiveness Dermal: 40%] | | | | AL |
| Amounts used | | | | |
| Not relevant | | | | |
| Frequency and duration of use/exposure | | | | |
| • Duration of activity: >4 hours | | AL | | |
| Human factors not influenced by risk management | | | | |
| None | | | | |
| Other given operational conditions affecting workers exposure | | | | |
| • Temperature of the process: room temperature | | AL | | AL |
| • Ventilation conditions at workplace: Good general ventilation (e. g. 5 air exchanges per hour) | | AL | | AL |
| • Place of use: Indoors<br>Indoor exposure estimation, as more conservative, has been used for calculation. Substance can also be used outdoor. | | AL | | |
| • Surface of skin exposed: Two hands face (480 $cm^2$) | | | | AL |

| | | | | |
|---|---|---|---|---|
| Technical conditions and measures at process level (source) to prevent release | | | | |
| • Level of containment: Partially closed mixing and blending of chemicals (PROC 5) | | AL | | AL |
| Technical conditions and measures to control dispersion from source towards the worker | | | | |
| • Local Exhaust Ventilation: No | | AL | | AL |
| Organisational measures to prevent /limit releases, dispersion and exposure | | | | |
| None | | | | |
| Conditions and measures related to personal protection, hygiene and health evaluation | | | | |
| • Eye protection: Yes (Face shield, goggles or safety glasses with side shields) | | | AL | |
| • Respiratory protection: Respiratory protection is not used | | AL | | |
| • Gloves: Suitable gloves [Effectiveness Dermal: 90%] (Nitrile rubber, chloroprene rubber, butyl rubber or other suitable gloves, complying with requirements of the EN 374 with the breakthrough time of 480 min.<br>Training in relation to use and maintenance of the PPE must be provided to ensure required effectiveness of protection.) | | | | AL |
| Additional good practice advice beyond the REACH CSA | | | | |
| • Good occupational hygiene practice: good practice | | AL | | AL |

*) The route of exposure (**Inhal**ation, **Derm**al) 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 workers exposure for "Use of hand-held tools - roller or brush application" [PROC 10]

| | Inhal*) | | Derm*) | |
|---|---|---|---|---|
| | Loc | Sys | Loc | Sys |
| Product characteristic | | | | |
| • Substance in preparation: Yes | | AL | | |
| • Concentration of substance in product: 5 – 25% | | AL | | |
| • Concentration in product: 5-25% [Effectiveness Dermal: 40%] | | | | AL |
| Amounts used | | | | |
| Not relevant | | | | |
| Frequency and duration of use/exposure | | | | |
| • Duration of activity: >4 hours | | AL | | |
| Human factors not influenced by risk management | | | | |
| None | | | | |

| | | | |
|---|---|---|---|
| Other given operational conditions affecting workers exposure | | | |
| • Temperature of the process: room temperature | AL | | AL |
| • Ventilation conditions at workplace: Good general ventilation (e. g. 5 air exchanges per hour) | AL | | AL |
| • Place of use: Indoors<br>Indoor exposure estimation, as more conservative, has been used for calculation. Substance can also be used outdoor. | AL | | |
| • Surface of skin exposed: Two hands (960 $cm^2$) | | | AL |
| Technical conditions and measures at process level (source) to prevent release | | | |
| • Level of containment: Open manual pouring, brushing, rolling onto surface of article (PROC 10) | AL | | AL |
| Technical conditions and measures to control dispersion from source towards the worker | | | |
| • Local Exhaust Ventilation: No | AL | | AL |
| Organisational measures to prevent /limit releases, dispersion and exposure | | | |
| None | | | |
| Conditions and measures related to personal protection, hygiene and health evaluation | | | |
| • Eye protection: Yes (Face shield, goggles or safety glasses with side shields) | | A | |
| • Respiratory protection: Respiratory protection is not used | AL | | |
| • Gloves: Suitable gloves [Effectiveness Dermal: 90%] (Nitrile rubber, chloroprene rubber, butyl rubber or other suitable gloves, complying with requirements of the EN 374 with the breakthrough time of 480 min.<br>Training in relation to use and maintenance of the PPE must be provided to ensure required effectiveness of protection.) | | | AL |
| Additional good practice advice beyond the REACH CSA | | | |
| • Good occupational hygiene practice: good practice | AL | | AL |
| • Tool design: Use tools with long handles | AL | | AL |

*) The route of exposure (**Inhal**ation, **Derm**al) 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 workers exposure for "Use of product in a spray form" [PROC 11]**

| | Inhal*) | | Derm*) | |
|---|---|---|---|---|
| | Loc | Sys | Loc | Sys |
| Product characteristic | | | | |
| • Substance in preparation: Yes | | AL | | |
| • Concentration of substance in product: 5 – 25% | | AL | | |
| • Concentration in product: 5-25% [Effectiveness Dermal: 40%] | | | | AL |
| Amounts used | | | | |
| Not relevant | | | | |
| Frequency and duration of use/exposure | | | | |
| • Duration of activity: 1 - 4 hours | | AL | | |
| Human factors not influenced by risk management | | | | |
| None | | | | |
| Other given operational conditions affecting workers exposure | | | | |
| • Temperature of the process: room temperature | | AL | | AL |
| • Ventilation conditions at workplace: Good general ventilation (e. g. 5 air exchanges per hour) | | AL | | AL |
| • Place of use: Indoors<br>Indoor exposure estimation, as more conservative, has been used for calculation. Substance can also be used outdoor. | | AL | | |
| • Surface of skin exposed: Two hands and upper wrists (1500 $cm^2$) | | | | AL |
| Technical conditions and measures at process level (source) to prevent release | | | | |
| • Level of containment: Spraying and similar techniques (manual) without particular barriers (PROC 11) | | AL | | |
| Technical conditions and measures to control dispersion from source towards the worker | | | | |
| • Local Exhaust Ventilation: No | | AL | | AL |
| Organisational measures to prevent /limit releases, dispersion and exposure | | | | |
| None | | | | |
| Conditions and measures related to personal protection, hygiene and health evaluation | | | | |
| • Eye protection: Yes (Face shield, goggles or safety glasses with side shields) | | | A | |
| • Respiratory protection: Respiratory protection capable offering a 90% reduction in inhaled concentrations of the substance | | AL | | |
| • Gloves: Suitable gloves [Effectiveness Dermal: 90%] (Nitrile rubber, chloroprene rubber, butyl rubber or other suitable gloves, complying with requirements of the EN 374 with the breakthrough | | | | AL |

| | | |
|---|---|---|
| time of 480 min. Gauntlet type is required.<br>Training in relation to use and maintenance of the PPE must be provided to ensure required effectiveness of protection.) | | |
| Additional good practice advice beyond the REACH CSA | | |
| • Good occupational hygiene practice: good practice | AL | AL |

*) The route of exposure (**Inhal**ation, **Derm**al) 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 Professional use of floor-coating substance

#### 9.1.2.1. Exposure estimation for the environment (Wide dispersive outdoor/indoor use of substance in coatings, release intended [ERC 8d])

##### 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 8d) | **Release factor after on site risk management (%):** 100<br><br>**Local release rate (kg/day):** 9.9 |
| **Air** | ERC<br><br>(ERC 8d) | **Release factor after on site risk management (%):** 100 |
| **Soil** | ERC<br><br>(ERC 8d) | **Release factor after on site risk management (%):** 20 |

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

##### 9.1.2.1.2. Environmental exposure

**Table 9. Summary of exposure concentrations**

| Protection target | Exposure concentration | Explanation / Justification |
|---|---|---|
| **Water:** Fresh Water (Pelagic) | **Local PEC:** 0.07 mg/L<br><br>**Local concentration:** 0.062 mg/L | |
| **Water:** Fresh Water (Sediment) | **Local PEC:** 0.361 mg/kg dw | |
| **Water:** Marine Water (Pelagic) | **Local PEC:** 0.007 mg/L<br><br>**Local concentration:** 0.006 mg/L | |
| **Water:** Marine | **Local PEC:** 0.036 mg/kg | |

| Protection target | Exposure concentration | Explanation / Justification |
|---|---|---|
| Water (Sediment) | dw | |
| **Water:** Sewage Treatment Plant (Effluent) | **Local PEC:** 0.625 mg/L | |
| **Air** | **Local PEC:** 9.59E-5 mg/m³<br><br>**Local concentration:** 4.5E-7 mg/m³ | |
| **Soil:** Agricultural Soil | **Local PEC:** 0.023 mg/kg dw<br><br>**Local concentration:** 0.02 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:** 0.002 mg/kg bw/day | | |
| | Estimated daily dose through intake from local exposure | Concentration in food from local exposure | |
| Drinking water | 0.002 mg/kg bw/day | 0.07 mg/L | |
| Fish | 1.57E-4 mg/kg bw/day | 0.096 mg/kg | |
| Leaf crops | 1.42E-4 mg/kg bw/day | 0.008 mg/kg | |
| Root crops | 1.13E-4 mg/kg bw/day | 0.02 mg/kg | |
| Meat | 1.49E-8 mg/kg bw/day | 3.47E-6 mg/kg | |
| Milk | 2.78E-7 mg/kg bw/day | 3.47E-5 mg/kg | |
| | **Dose from regional exposure:** see section 9.0.3.3 | | |

### 9.1.2.2. Exposure estimation for Worker for Diluting of the concentrated product - transfer for mixing [PROC 8a]

**Table 11. Summary of exposure concentrations for contributing scenario: Diluting of the concentrated product - transfer for mixing**

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| **Inhalation:** Acute, Systemic | 225.2 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA extended – extrapolation from long-term exposure | **Representativity and reliability:**<br>Based on the full shift, long-term exposure value. Assessment factor 2 was used*. |
| **Inhalation:** Long term, Systemic | 22.53 mg/m³ | **Method:** Extended TRA workers<br><br>**Name:** Long term systemic exposure | |
| **Dermal:** Acute, Local | Not available | **Method:** Conditions of use (OC/RMM)<br><br>**Name:** Qualitative assessment- eye exposure | |
| **Dermal:** Acute, Systemic | 1.371 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA extended – extrapolation from long-term exposure | **Representativity and reliability:**<br>Based on the long-term exposure value. |
| **Dermal:** Long term, Systemic | 1.371 mg/kg bw/day | **Method:** Extended TRA workers<br><br>**Name:** Long term systemic exposure | |

* The severity and reversibility of potential effects should be taken into consideration when the assessment factor is decided on

### 9.1.2.3. Exposure estimation for Worker for Mixing of the substance into ready-to-use product [PROC 5]

**Table 12. Summary of exposure concentrations for contributing scenario: Mixing of the substance into ready-to-use product**

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| **Inhalation:** Acute, Systemic | 54.08 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA extended – extrapolation from long-term exposure | **Representativity and reliability:**<br>Based on the long-term exposure value. Assessment factor 2 was used*. |
| **Inhalation:** Long term, Systemic | 27.04 mg/m³ | **Method:** Extended TRA workers<br><br>**Name:** Long term systemic exposure | |
| **Dermal:** Acute, Local | Not available | **Method:** Conditions of use (OC/RMM)<br><br>**Name:** Qualitative assessment- eye exposure | |
| **Dermal:** Acute, Systemic | 0.823 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA extended – extrapolation from long-term exposure | **Representativity and reliability:**<br>Based on the long-term exposure value. |
| **Dermal:** Long term, Systemic | 0.823 mg/kg bw/day | **Method:** Extended TRA workers<br><br>**Name:** Long term systemic exposure | |

* The severity and reversibility of potential effects should be taken into consideration when the assessment factor is decided on

### 9.1.2.4. Exposure estimation for Worker for Use of hand-held tools - roller or brush application [PROC 10]

**Table 13. Summary of exposure concentrations for contributing scenario: Use of hand-held tools - roller or brush application**

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| **Inhalation:** Acute, Systemic | 135.2 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA extended – extrapolation from long-term exposure | **Representativity and reliability:**<br>Based on the long-term exposure value. Assessment factor 2 was used*. |
| **Inhalation:** Long term, Systemic | 67.59 mg/m³ | **Method:** Extended TRA workers<br><br>**Name:** Long term systemic exposure | |
| **Dermal:** Acute, Local | Not available | **Method:** Conditions of use (OC/RMM)<br><br>**Name:** Qualitative assessment- eye exposure | |
| **Dermal:** Acute, Systemic | 1.646 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA extended – extrapolation from long-term exposure | **Representativity and reliability:**<br>Based on the long-term exposure value. |
| **Dermal:** Long term, Systemic | 1.646 mg/kg bw/day | **Method:** Extended TRA workers<br><br>**Name:** Long term systemic exposure | |

* The severity and reversibility of potential effects should be taken into consideration when the assessment factor is decided on

### 9.1.2.5. Exposure estimation for Worker for Use of product in a spray form [PROC 11]

**Table 14. Summary of exposure concentrations for contributing scenario: Use of product in a spray form**

| Route of exposure and type of effects | Exposure concentration | Method / name of exposure assessment | Explanation / Justification |
|---|---|---|---|
| **Inhalation:** Acute, Systemic | 54.08 mg/m³ | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA extended – extrapolation from long-term exposure | **Representativity and reliability:**<br>Based on the full shift, long-term exposure value. Assessment factor 2 was used*. |
| **Inhalation:** Long term, Systemic | 16.22 mg/m³ | **Method:** Extended TRA workers<br><br>**Name:** Long term systemic exposure | |
| **Dermal:** Acute, Local | Not available | **Method:** Conditions of use (OC/RMM)<br><br>**Name:** Qualitative assessment- eye exposure | |
| **Dermal:** Acute, Systemic | 6.429 mg/kg bw/day | **Method:** External exposure estimation tool<br><br>**Name:** ECETOC TRA extended – extrapolation from long-term exposure | **Representativity and reliability:**<br>Based on the long-term exposure value. |
| **Dermal:** Long term, Systemic | 6.429 mg/kg bw/day | **Method:** Extended TRA workers<br><br>**Name:** Long term systemic exposure | |

* The severity and reversibility of potential effects should be taken into consideration when the assessment factor is decided on

# 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. Professional use of floor-coating substance

### 10.1.1. Human health

#### 10.1.1.1. Workers

**Table 15. Risk characterisation: Control of workers exposure for "Diluting of the concentrated product - transfer for mixing" [PROC 8a]**

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| **Inhalation:** Acute, Systemic | **RCR = 0.5** | |
| **Inhalation:** Long term, Systemic | **RCR = 0.25**<br><br>**Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3):** 0.25 | |
| **Dermal:** Acute, Local | **Qualitative risk characterisation** | **Prevention of release/exposure:**<br>Physical barrier to prevent eye exposure and injury<br><br>**Expected residual exposure:**<br>Not relevant<br><br>**Conclusion on risk characterisation:**<br>Risk effectively controlled |
| **Dermal:** Acute, Systemic | **RCR = 0.029** | |
| **Dermal:** Long term, Systemic | **RCR = 0.144** | |
| **Combined routes:** Acute, Systemic | **RCR = 0.53** | |
| **Combined routes:** Long term, Systemic | **RCR = 0.395**<br><br>Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3): **0.395** | |

**Table 16. Risk characterisation: Control of workers exposure for "Mixing of the substance into ready-to-use product" [PROC 5]**

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| **Inhalation:** Acute, Systemic | **RCR = 0.12** | |
| **Inhalation:** Long term, Systemic | **RCR = 0.3**<br><br>Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3): **0.3** | |
| **Dermal:** Acute, Local | **Qualitative risk characterisation** | **Prevention of release/exposure:**<br>Physical barrier to prevent eye exposure and injury<br><br>**Expected residual exposure:**<br>Not relevant<br><br>**Conclusion on risk characterisation:**<br>Risk effectively controlled |
| **Dermal:** Acute, Systemic | **RCR = 0.018** | |
| **Dermal:** Long term, Systemic | **RCR = 0.087** | |
| **Combined routes:** Acute, Systemic | **RCR = 0.138** | |
| **Combined routes:** Long term, Systemic | **RCR = 0.387**<br><br>Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3): **0.387** | |

**Table 17. Risk characterisation: Control of workers exposure for "Use of hand-held tools - roller or brush application" [PROC 10]**

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| **Inhalation:** Acute, Systemic | **RCR = 0.3** | |
| **Inhalation:** Long term, Systemic | **RCR = 0.751**<br><br>Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3): **0.751** | |

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| **Dermal:** Acute, Local | **Qualitative risk characterisation** | **Prevention of release/exposure:**<br>Physical barrier to prevent eye exposure and injury<br>**Expected residual exposure:**<br>Not relevant<br>**Conclusion on risk characterisation:**<br>Risk effectively controlled |
| **Dermal:** Acute, Systemic | **RCR = 0.035** | |
| **Dermal:** Long term, Systemic | **RCR = 0.173** | |
| **Combined routes:** Acute, Systemic | **RCR = 0.335** | |
| **Combined routes:** Long term, Systemic | **RCR = 0.924**<br>Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3): **0.924** | |

**Table 18. Risk characterisation: Control of workers exposure for "Use of product in a spray form" [PROC 11]**

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| **Inhalation:** Acute, Systemic | **RCR = 0.12** | |
| **Inhalation:** Long term, Systemic | **RCR = 0.18**<br>Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3): **0.18** | |
| **Dermal:** Acute, Local | **Qualitative risk characterisation** | **Prevention of release/exposure:**<br>Physical barrier to prevent eye exposure and injury<br>**Expected residual exposure:**<br>Not relevant<br>**Conclusion on risk characterisation:**<br>Risk effectively controlled |

| Route of exposure and type of effects | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| **Dermal:** Acute, Systemic | **RCR = 0.137** | |
| **Dermal:** Long term, Systemic | **RCR = 0.677** | |
| **Combined routes:** Acute, Systemic | **RCR = 0.257** | |
| **Combined routes:** Long term, Systemic | **RCR = 0.857**<br><br>Summed RCR including contribution of exposure via the environment (see section 9.x.2.1.3): **0.857** | |

#### 10.1.1.2. Consumers

This exposure scenario does not address consumers.

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

**Table 19. 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 = 1.182E-5** | |
| **Oral:** Long term, Systemic | **RCR = 4.825E-4** | |

### 10.1.2. Environment

#### 10.1.2.1. Aquatic compartment (incl. sediment)

**Table 20. Risk characterisation for the aquatic compartment (incl. sediment and secondary poisoning)**

| Protection target | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| Fresh Water (Pelagic) | **RCR = 0.07** | |
| Fresh Water (Sediment) | **RCR = 0.068** | |
| Marine Water (Pelagic) | **RCR = 0.07** | |
| Marine Water (Sediment) | **RCR = 0.068** | |

#### 10.1.2.2. Terrestrial compartment

**Table 21. Risk characterisation for the terrestrial compartment (incl. secondary poisoning)**

| Protection target | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| Agricultural Soil | **RCR = 0.051** | |

#### 10.1.2.3. Atmospheric compartment

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

**Table 22. Risk characterisation for the microbiological activity in sewage treatment systems**

| Protection target | Risk characterisation ratio | Risk characterisation |
|---|---|---|
| Sewage Treatment Plant (Effluent) | **RCR = 0.016** | |

## 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 23. 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) | **0.07 mg/L** | **RCR = 0.07** |
| Fresh Water (Sediment) | **0.361 mg/kg dw** | **RCR = 0.068** |
| Marine Water (Pelagic) | **0.007 mg/L** | **RCR = 0.07** |
| Marine Water (Sediment) | **0.036 mg/kg dw** | **RCR = 0.068** |
| Sewage Treatment Plant (Effluent) | **0.625 mg/L** | **RCR = 0.016** |
| **Soil:** | | |
| Agricultural Soil | **0.023 mg/kg dw** | **RCR = 0.051** |

# Appendix 2 – ES for Communication

The example presented in this Appendix exemplifies an ES for communication developed by the manufacturer of the substance. Its intended recipient is the first DU in the communication chain i.e. a formulator. The ES subsequently developed by the formulator, for the use by professional workers, which presents the safe conditions of use of the preparation that contains the organic solvent, may have a different content in order to take into consideration the other elements of the mixture but also considering the information needs of the end-user.

Section 1: Title section – provides information on the type of use of the substance (professional, construction, coating), environmental conditions of use (ERC) and uses in which the substance used is evaluated (PROCs)

Section 2: Conditions of use affecting exposure – only the elements affecting the calculated exposure levels are presented – OCs and RMMs required, and assumptions related to the modelling tool (e.g. ventilation)

Section 3: Exposure estimation / RCR – estimated exposure levels and resulting RCRs are presented; information in relation to modelling tool used and modifications made to compensate for effects of concentration of the substance and dermal protective equipment on skin exposure

Section 4: Scaling advice – a full set of information on parameters affecting exposure level estimated for each use (PROC) is provided, together with the information on the tools used.

# ES FOR COMMUNICATION

## Substance: organic solvent

**Substance Name:** Organic solvent

**EC Number:**

**Registration Number:**

**Version Number:** v.1.0

**Date of Generation/Revision:** 2011-06-22

# 1. ES 1: Professional end-use (SU 22) – coating of floors

| **1. Title of Exposure scenario** | |
|---|---|
| Coatings and Paints, Fillers, Putties Thinners PC 9a<br><br>SU19: Building and construction work | |
| **Environment:** Wide dispersive outdoor/indoor use of substance in coatings, release intended | ERC 8d |
| **Worker** | |
| Diluting of the concentrated product - transfer for mixing | PROC 8a |
| Mixing of the substance into ready-to-use product | PROC 5 |
| Use of hand-held tools - roller or brush application | PROC 10 |
| Use of product in a spray form | PROC 11 |

| **2. Conditions of use affecting exposure** |
|---|
| **2.1 Control of environmental exposure:** Wide dispersive outdoor/indoor use of substance in coatings, release intended **(ERC 8d)** |
| **Conditions and measures related to municipal sewage treatment plant** |
| Wastewater is to be treated by a municipal STP. Removal from water effectiveness [Effectiveness : 87.4%] |
| **2.2 Control of workers exposure for** Diluting of the concentrated product - transfer for mixing **(PROC 8a)** |
| **Product characteristics** |
| Concentration of the substance: up to 100% |
| **Amount used, frequency and duration of use/exposure** |
| Operation carried out for ≤ 1 hours |
| **Other operational conditions affecting workers exposure** |
| Process at room temperature.<br>Good general ventilation at workplace assumed.<br>Indoor use assumed. |
| **Conditions and measures related to personal protection, hygiene and health evaluation** |
| Wear face shield, goggles or safety glasses with side shield.<br>Wear nitrile rubber, chloroprene rubber, butyl rubber or other suitable gloves, complying |

| |
|---|
| with requirements of the EN 374 with the breakthrough time of 480 min. Effectiveness ≥ 90%<br>Training in relation to use and maintenance of the PPE must be provided to ensure required effectiveness of protection. |
| **Additional good practice advice beyond the REACH CSA** |
| Use good occupational hygiene practices |
| **2.3 Control of workers exposure for** Mixing of the substance into ready-to-use product **(PROC 5)** |
| **Product characteristics** |
| Concentration of substance in product 5 – 25% |
| **Amount used, frequency and duration of use/exposure** |
| Operation carried out for ≤ 8 hours. |
| **Other operational conditions affecting workers exposure** |
| Process at room temperature<br>Good general ventilation at workplace assumed.<br>Indoor use assumed. |
| **Technical and organisational conditions and measures** |
| Partially closed mixing and blending of chemicals. No open substance transfers. |
| **Conditions and measures related to personal protection, hygiene and health evaluation** |
| Wear face shield, goggles or safety glasses with side shield.<br>Wear nitrile rubber, chloroprene rubber, butyl rubber or other suitable gloves, complying with requirements of the EN 374 with the breakthrough time of 480 min. Effectiveness ≥ 90%<br>Training in relation to use and maintenance of the PPE must be provided to ensure required effectiveness of protection. |
| **Additional good practice advice beyond the REACH CSA** |
| Use good occupational hygiene practices |
| **2.4 Control of workers exposure for** Use of hand-held tools - roller or brush application **(PROC 10)** |
| **Product characteristics** |
| Concentration of substance in product 5 – 25% |
| **Amount used, frequency and duration of use/exposure** |
| Operation carried out for ≤ 8 hours. |
| **Other operational conditions affecting workers exposure** |
| Process at room temperature<br>Good general ventilation at workplace assumed.<br>Indoor use assumed. |
| **Conditions and measures related to personal protection, hygiene and health evaluation** |
| Wear face shield, goggles or safety glasses with side shield.<br>Wear nitrile rubber, chloroprene rubber, butyl rubber or other suitable gloves, complying with requirements of the EN 374 with the breakthrough time of 480 min. Effectiveness ≥ 90% |

| |
|---|
| Training in relation to use and maintenance of the PPE must be provided to ensure required effectiveness of protection. |
| **Additional good practice advice beyond the REACH CSA** |
| Use tools with long handles.<br>Use good occupational hygiene practices |
| **2.5 Control of workers exposure for** Use of product in a spray form **(PROC 11)** |
| **Product characteristics** |
| Concentration of substance in product 5 – 25% |
| **Amount used, frequency and duration of use/exposure** |
| Operation carried out for ≤ 4 hours |
| **Other operational conditions affecting workers exposure** |
| Process at room temperature<br>Good general ventilation at workplace assumed.<br>Indoor use assumed. |
| **Conditions and measures related to personal protection, hygiene and health evaluation** |
| Wear face shield, goggles or safety glasses with side shield.<br>Wear a respirator conforming to EN140 with Type A/P2 filter or better. Effectiveness ≥ 90%<br>Wear nitrile rubber, chloroprene rubber, butyl rubber or other suitable gloves, complying with requirements of the EN 374 with the breakthrough time of 480 min. Effectiveness ≥ 90%<br>Training in relation to use and maintenance of the PPE must be provided to ensure required effectiveness of protection. |
| **Additional good practice advice beyond the REACH CSA** |
| Use good occupational hygiene practices |

| **3. Exposure estimation and reference to its source** | | |
|---|---|---|
| | | |
| **Environment** | | |
| **Release route** | **Release rate (kg/day)** | **Release estimation method** |
| **Water** | 9.9 | ERC - ERC 8d |
| **Air** | 0 | ERC - ERC 8d |
| **Soil** | 0 | ERC - ERC 8d |

| **Protection target** | **Exposure estimate** (based on: EUSES 2.0) | **RCR** |
|---|---|---|
| Freshwater (pelagic) | 0.07 mg/L | 0.07 |
| Freshwater (sediment) | 0.361 mg/kg dw | 0.069 |
| Freshwater (sediment) | 0.361 mg/kg dw | 0.069 |
| Marine water (pelagic) | 0.007 mg/L | 0.07 |
| Marine water (sediment) | 0.036 mg/kg dw | 0.068 |
| Freshwater food chain (predators) | | |
| Marine water food chain (predators) | | |

| | | |
|---|---|---|
| Marine water food chain (top predators) | | |
| Effluent | 0.625 mg/L | 0.016 |
| Agricultural soil | 0.023 mg/kg dw | 0.051 |
| Terrestrial food chain (predator) | | |

| **Risk characterisation for man via the environment**[18] |
|---|
| Inhalation: 0<br><br>Oral: 0 |

| **Worker exposure** | | | | |
|---|---|---|---|---|
| **Long-term, systemic** | | | | |
| **Contributing scenario** | **Inhalation** | **Dermal** | **Combined routes** | **Exposure estimation Method** |
| Diluting of the concentrated product - transfer for mixing (PROC 8a) | Exposure: 22.53 mg/m³<br><br>RCR: 0.25 | Exposure: 1.371 mg/kg bw/day<br><br>RCR: 0.144 | RCR: 0.395 | Inhal: Extended TRA workers<br><br>Derm: Extended TRA workers |
| Mixing of the substance into ready-to-use product (PROC 5) | Exposure: 27.04 mg/m³<br><br>RCR: 0.3 | Exposure: 0.823 mg/kg bw/day<br><br>RCR: 0.087 | RCR: 0.387 | Inhal: Extended TRA workers<br><br>Derm: Extended TRA workers |
| Use of hand-held tools - roller or brush application (PROC 10) | Exposure: 67.59 mg/m³<br><br>RCR: 0.751 | Exposure: 1.646 mg/kg bw/day<br><br>RCR: 0.173 | RCR: 0.924 | Inhal: Extended TRA workers<br><br>Derm: Extended TRA workers |
| Use of product in a spray form (PROC 11) | Exposure: 16.22 mg/m³<br><br>RCR: 0.18 | Exposure: 6.429 mg/kg bw/day<br><br>RCR: 0.677 | RCR: 0.857 | Inhal: Extended TRA workers<br><br>Derm: Extended TRA workers |

[18] 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

| **Acute systemic** | | | | |
|---|---|---|---|---|
| **Contributing scenario** | **Inhalation** | **Dermal** | **Combined routes** | **Exposure estimation Method** |
| Diluting of the concentrated product - transfer for mixing (PROC 8a) | Exposure: 225.2 mg/m³<br><br>RCR: 0. 5 | Exposure: 1.371 mg/kg bw/day<br><br>RCR: 0.029 | RCR: 0.53 | Inhal: Extended TRA workers<br><br>Derm: Extended TRA workers |
| Mixing of the substance into ready-to-use product (PROC 5) | Exposure: 54.08 mg/m³<br><br>RCR: 0.12 | Exposure: 0.823 mg/kg bw/day<br><br>RCR: 0.018 | RCR: 0.138 | Inhal: Extended TRA workers<br><br>Derm: Extended TRA workers |
| Use of hand-held tools - roller or brush application (PROC 10) | Exposure: 135.2 mg/m³<br><br>RCR: 0.3 | Exposure: 1.646 mg/kg bw/day<br><br>RCR: 0.035 | RCR: 0.335 | Inhal: Extended TRA workers<br><br>Derm: Extended TRA workers |
| Use of product in a spray form (PROC 11) | Exposure: 54.08 mg/m³<br><br>RCR: 0.12 | Exposure: 6.429 mg/kg bw/day<br><br>RCR: 0.137 | RCR: 0.257 | Inhal: Extended TRA workers<br><br>Derm: Extended TRA workers |

**4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES (in relation to potential for scaling) - adapting parameters of use of substance to individual conditions**

Information relevant for scaling can be found on the following website: “www.xxx ”.
EUSES 2.0 was used for estimation of environmental exposure
ECETOC TRA v.2 (extended) was used for estimation of workers exposure. Modifications to the tool were made to allow for use of gloves for reducing dermal exposure (effectiveness – 90%), and to allow for the reduced level of dermal exposure due to the changed concentration of the substance (5-25% - effectiveness - 40%). Non-linear scaling used is in line with scaling method applied by the tool to respiratory exposure.

**Environment**

**Input parameters for scaling**

None

**Scaling advice**

Scaling can be done using the exposure estimation tool originally used (EUSES 2.0). Expert advice may be needed.

**Workers**

**Input parameters for scaling of workers assessment**

| Contributing scenario | PROC | Route of exposure affected | Duration of activity (hours/ day) | Concentra-tion of substance in mixture | LEV (min. effective-ness) | Respiratory protection (min. effective-ness) | Dermal protection (min. effectiveness) |
|---|---|---|---|---|---|---|---|
| Diluting of the concentrated product - transfer for mixing | PROC 8a | dermal inhalation | up to 1 hour | up to 100% | N/A | N/A | 90% |
| Mixing of the substance into the ready to use product | PROC 5 | dermal inhalation | up to 8 hours | up to 25% | N/A | N/A | 90% |
| Use of hand-held tools – roller or brush | PROC 10 | dermal inhalation | up to 8 hours | up to 25% | N/A | N/A | 90% |
| Use of the products in the spray form | PROC 11 | dermal inhalation | up to 4 hours | up to 25% | N/A | 90% | 90% |

**Scaling advice**

Scaling can be done using the exposure estimation tool originally used (ECETOC TRA v.2, extended). The tool has been modified to allow for impact of skin protection and concentration of the substance on the dermal exposure. Expert advice may be needed.

# Appendix 3: Acronyms and definitions[19]

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

LEV – Local exhaust ventilation

OC – Operational Conditions

PNEC - Predicted No Effect Concentration

PEC - Predicted Environmental Concentration

PPE – Personal Protective Equipment

PROC - Process Category

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[20].

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.

[19] Source, unless otherwise stated: Guidance on information requirements and chemical safety assessment Chapter R.20: Table of terms and abbreviation (2008

[20] REACH Regulation, Annex I, 1.0.1

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.

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 (OC) - 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[21].

Process category - Element of the use descriptor system describing the type of technical processes applied during manufacturing and use (PROCs).

Professional use[22] - In the context of this document, can be taken to mean: 'use of the substance or mixture by tradesmen and other non-industrial employees (e.g. certain employees of municipal authorities, hospitals etc) in the course of their work, normally not at their own industrial premises; i.e. use by persons other than industrial workers or consumers'

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 described in the exposure scenario. The risk characterisation determines whether the risks to humans and the environment are adequately controlled.

Risk management measures (RMM) - 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, e.g., containment of process, local exhaust ventilation, gloves, waste water treatment, general ventilation.

Sector of use – An element of the use descriptor system describing the sector of economy (industry, professional service, private) in which a substance is used as such or in a preparation.

[21] REACH Regulation, Annex I, 3.0.1
[22] Term not defined under REACH