ECHA
EUROPEAN CHEMICALS AGENCY

# An Illustrative Example of a CSR

## Part 2 - Complete example of a chemical safety report

June 2017

# EDITORIAL NOTE and DISCLAIMER

This illustrative example of a CSR is based on a made-up substance. It reflects the preliminary outcome of an ECHA project. The European Chemicals Agency does not accept any liability as to the completeness of this illustrative example and its compliance with the obligations imposed on registrants under the REACH Regulation. It thus cannot be used as a justification for compliance of a CSR with the legal requirements. Users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice.

For understanding the scope and the purpose of this document, please read also *Part 1 - Introductory Note with advice on preparing your chemical safety report* (see website reference beneath).

This document includes *Notes and Comments* boxes. These provide additional explanation to the reader but they are not meant to be part of the CSR itself.

This illustrative CSR (except the *Notes*) has been generated using IUCLID 6.1 and Chesar 3.2 files. The format and layout of this example reflects the output from these tools. The IUCLID 6.1 substance dataset and Chesar 3.2 data file are also available on the ECHA website at http://echa.europa.eu/support/practical-examples-of-chemical-safety-reports

The IUCLID 6.1 substance dataset is limited to the establishment of a CSR only. It is not an example of a IUCLID model data for REACH compliance with regard to completeness of the technical dossier.

**An illustrative example of a CSR. Part 2 - Complete example of a chemical safety report**

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# CHEMICAL SAFETY REPORT

**Substance Name:** ECHA Substance
**CAS Number:** 11111-11-1
**Registrant's Identity:** ECHA CSR Example

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# Part A

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**Notes and Comments**

**Re CSR – Part A**

Part A is an obligatory section in all CSRs. This section has not been exemplified in the illustrative example. Part A can be filled in section 13.1 of IUCLID and is integrated into the CSR when using the CSR plug-in; if these fields are left empty, the generated CSR shows, by default, the empty chapters as above.

# Part B

# 1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

## 1.1. Name and other identifiers of the substance

The substance ECHA Substance is a mono-constituent substance (organic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).
The following public name is used: ECHA Substance

**Table 1.1 Substance identity**

| | |
|---|---|
| **CAS number:** | 11111-11-1 |
| **CAS name:** | ECHA Substance |
| **IUPAC name:** | ECHA Substance |
| **Molecular formula:** | CxHyOz |
| **Molecular weight range:** | ca.300 |

## 1.2. Composition of the substance

**Name: ECHA Substance**

State/form: liquid
Degree of purity: >=88 - <=94 % (w/w)
Description:

**Table 1.2 Constituents (ECHA Substance)**

| Constituent | Typical concentration | Concentration range | Remarks |
|---|---|---|---|
| ECHA Substance EC no.: | 90 % (w/w) | >=88 - <=94 % (w/w) | Main constituent |

**Table 1. 1 Impurities (ECHA Substance)**

| Constituent | Typical concentration | Concentration range | Remarks |
|---|---|---|---|
| Impurity 1 EC no.: | 7 % (w/w) | >=5 - <=8 % (w/w) | Impurity |
| Impurity 2 EC no.: | 3 % (w/w) | >=1 - <=4 % (w/w) | Impurity |

## 1.3. Physicochemical properties

**Table 1.4 Physicochemical properties**

| Property | Description of key information | Value used for CSA / Discussion |
|---|---|---|
| Physical state | The substance is a liquid. | **Value used for CSA:** liquid at 20°C and 101.3 kPa |
| Melting / freezing point | Regulation (EC) no 440/2208, Test method A.1 was followed for melting point determination. Thermal analysis (Differential scanning calorimetry (DSC)) | **Value used for CSA:** 219K at 101.3 kPa The test item has a freezing point at -54ºC (219K) |

| | | |
|---|---|---|
| Boiling point | Regulation (EC) no 440/2208, Test method A.2 boiling temperature, thermal analysis, DSC. Two samples were tested. | **Value used for CSA:** 519K at 101.3 kPa |
| Relative density | Oscillating densimeter following Regulation (EC) no 440/2208, Test method A3. | **Value used for CSA:** 0.981 at 20°C |
| Vapour pressure | Regulation (EC) No 440/2008 Test methods pursuant to REACH Part A: Methods for the determination of physico-chemical properties: test method A.4. Preliminary test on thermal stability was performed. Static method was used.<br>T (ºC) P (Pa)<br>20 7.8<br>25 34<br>50 220 | **Value used for CSA:** 7.8Pa at 20°C |
| Partition coefficient n-octanol/water (log value) | Regulation (EC) no 440/2208, Test method A.8. using shake flask method. | **Value used for CSA:** Log Kow (Log Pow): 4.7 at 20°C |
| Water solubility | Determination of water solubility was performed in accordance with Regulation (EC) no 440/2208, Test method A.6 by flask method. | **Value used for CSA:** 149mg/L at 20°C<br>Water solubility was determined to be 149 ± 8 mg/L at 20ºC. |
| Surface tension | Regulation (EC) no 440/2208, Test method A.5, by ring method<br>Because of poor solubility of 149+-8 mg/L at 20°C, a 90 % solution had to be used. | **Value used for CSA:** 37 mN/m at 20°C and 134 mg/L |
| Flash point | Flash point of ECHA Substance was determined according to Regulation (EC) no 440/2208, Test method A.9, method closed crucible according to DIN ISO 2719. | **Value used for CSA:** 142°C at 1013 hPa<br>The test item was heated up in a closed crucible and at defined temperatures it was tried to ignite the gaseous phase upon the surface of the liquid with the hot surface. The flash point of the test item: 142ºC / 415.2K (101.3 kPa) |
| Autoflammability / self-ignition temperature | Regulation (EC) no 440/2208, Test method A.15 (EC, 1992) | **Value used for CSA:** 300°C at 1013 hPa<br>The test item showed an auto-ignition temperature of 300ºC. |
| Viscosity | OECD Guideline 114 “Viscosity of Liquids”. | **Value used for CSA:** Viscosity: 85mPa · s (dynamic) at 20°C |

**Data waiving**

**Information requirement:** Granulometry

**Reason:** study scientifically not necessary / other information available

**Justification:** the study does not need to be conducted because the substance is marketed or used in a non solid or granular form [study scientifically not necessary / other information available] - The submitted substance is liquid.

**Information requirement:** Flammability

**Reason:** other justification

**Justification:** see ‘Remark’ - There are no functional groups within the test item molecule that could cause pyrophoricity or flammability in contact with water. Basis: “Guidance on information requirements and chemical safety assessment”, Chapter R.7a: Endpoint specific guidance, R.7.1.10 (ECHA, November 2012).

**Information requirement:** Explosive properties

**Reason:** study scientifically not necessary / other information available

**Justification:** the study does not need to be conducted because the substance contains chemical groups associated with explosive properties which include oxygen, but the calculated oxygen balance is less than -200 [study scientifically not necessary / other information available] - The test item molecule contains ether-groups that are able to contribute to the explosive property. Therefore, according to “Guidance on information requirements and chemical safety assessment”, Chapter R.7a: Endpoint specific guidance, R.7.1.11 (ECHA, November 2012) the oxygen balance (OB) for the test item molecule (CxHyOz) was calculated with the result OB = -260. Since the oxygen balance is less than -200, the substance should not have explosive properties. This result was confirmed by differential scanning calorimetry (DSC) that showed no exothermic reactions up to 200°C.

**Information requirement:** Oxidising properties

**Reason:** study scientifically not necessary / other information available

**Justification:** the study does not need to be conducted because the organic substance contains oxygen or halogen atoms which are chemically bonded only to carbon or hydrogen and hence, the classification procedure does not need to be applied [study scientifically not necessary / other information available] - According to “Guidance on information requirements and chemical safety assessment”, Chapter R.7a: Endpoint specific guidance, R.7.1.13 (ECHA, November 2012) oxidising properties can be excluded because the oxygen in the substance is chemically bonded only to carbon. Additionally, for the test substance oxidising properties can be excluded based on long-term experience in handling and use.

**Information requirement:** Stability in organic solvents and identity of relevant degradation products

**Reason:** study scientifically not necessary / other information available

**Justification:** the study does not need to be conducted because the stability of the substance is not considered to be critical [study scientifically not necessary / other information available]

**Information requirement:** Dissociation constant

**Reason:** study technically not feasible

**Justification:** the study does not need to be conducted because the substance has no ionic structure [study technically not feasible] - The substance can be regarded as a hydrocarbon with two ether functional groups. Therefore, testing does not appear scientifically necessary for dissociation constant.

# 2. MANUFACTURE AND USES

**2.1 Quantities (in tonnes/year)**

| Year | Tonnages (tonnes per year) |
|---|---|
| 2010 | Manufactured: 150 |
| 2011 | Manufactured: 220 |
| 2012 | Manufactured: 320 |

Cumulative tonnages:

- Cumulative tonnage for uses at industrial sites: <=100 tonnes/year
- Cumulative tonnage for widespread uses by professional workers: <=50 tonnes/year
- Cumulative tonnage for consumer uses: <=50 tonnes/year
- Cumulative tonnage for service life: <=0 tonnes/year

## 2.1. Manufacture

**Table 2.2. Manufacture**

| | Manufacture |
|---|---|
| M-1 | **Manufacture**<br>Further description of manufacturing process:<br>Manufacture of the ECHA Substance takes place in closed system, including automated sampling and analysis. Final transfer of the substance into containers is also considered. Maintenance and cleaning operations require worker's manual intervention: prior to this, the system is emptied and purged.<br>Contributing activity/technique for the environment :<br>**- Manufacture in contained system, no water involved**<br>Contributing activity/technique for the workers :<br>**- Closed manufacturing process**<br>**- Transfer of substance or mixture (charging/discharging) at dedicated facilities**<br>**- Equipment cleaning and maintenance**<br>use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant<br>Tonnage of substance for that use: <=320 tonnes/year<br>Related assessment: use assessed in an own CSR |

**Notes and Comments**

**Re: Manufacture Information**

A description of the manufacturing process is not included in this illustrative example of a CSR. However, the type of information which should be provided in this section includes:

a. Type of chemical reaction
b. Type of processes and activities (e.g. batch or continuous process, if batch: multipurpose or dedicated equipment, closed or open process, etc.)
c. Pressure and temperature of the processes

d. Physical state of the substance in the different process steps
e. Cleaning processes related to the isolated raw product
f. Steps where use of water is involved.

Some information on the manufacturing conditions (operational conditions and risk management measures directly affecting release and exposure estimates) is reported in chapter 9.1 (exposure scenarios).

# 2.2. Identified uses

**Table 2.3. Formulation**

| | **Formulation** |
|---|---|
| F-1 | **Formulation of liquid mixtures**<br>Further description of the use:<br>Formulation refers to the mixing of raw materials to produce liquid mixtures, including products such as paints, coatings, inks, lubricants, and filling containers in dedicated facilities.<br>Formulation steps that require worker intervention include: receiving and charging the substance; mixing in open batch processes; non-automated transfer of the mixtures and filling small to medium sized containers. Maintenance and cleaning operations are also included.<br>Contributing activity/technique for the environment :<br>**- Formulation of mixture in closed and open systems**<br>Contributing activity/technique for the workers :<br>**- Receiving and charging of the substance**<br>**- Mixing or blending in batch processes; Closed systems**<br>**- Mixing or blending in batch processes; Open systems**<br>**- Transfer of substance or mixture (charging/discharging) at non dedicated-facilities**<br>**- Transfer of substance or mixture (charging/discharging) at dedicated facilities**<br>**- Transfer of substance or mixture into small containers (dedicated filling line, including weighing)**<br>**- Equipment cleaning and maintenance**<br>**Technical function of the substance:** defoamer ; wetting agent, co emulsifier<br>use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant<br>Tonnage of substance for that use: <=320 tonnes/year<br>Substance supplied to that use: as such<br>Related assessment: use assessed in an own CSR |

**Table 2.4. Uses at industrial sites**

| | **Uses at industrial sites** |
|---|---|
| IW-1 | **General Industrial use of coatings and inks**<br>Further description of the use:<br>This scenario covers the industrial use of coatings and inks in a range of processes. This includes closed printing processes (e.g. marking of electronic components, pharmaceutical products and medical devices) and open application to larger surface areas by spraying, dipping and roller/brush methods.<br>Also auxiliary activities are covered such as: raw material receipt and transfer; preparation of coatings, including mixing; loading of application devices; and tasks following application activities (curing/drying and cleaning/maintenance of equipment).<br>The concentration of the substance (additive) in coating is in the range of 0.5-2%.Contributing activity/technique for the environment :<br>**- Industrial application of coatings and inks involving water - Large scale**<br>**- Industrial application of coatings and inks involving water - Small scale**<br>**- Industrial application of coatings and inks. Water free** |

| | |
|---|---|
| | Contributing activity/technique for the workers :<br>**- Raw material receipt and transfer**<br>**- Mixing operations; Open systems**<br>**- Batch loading of equipment (manual, non dedicated)**<br>**- Spraying**<br>**- Printing closed automated machinery**<br>**- Roller, spreader, flow application; Printing**<br>**- Dipping, immersion and pouring**<br>**- Film formation - force drying, stoving and other technologies; Elevated temperature**<br>**- Equipment cleaning and maintenance; Manual**<br>**Product Category used:** PC 9a: Coatings and paints, thinners, paint removes<br>**Technical function of the substance:** defoamer ; wetting agent, co emulsifier<br>use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant<br>Tonnage of substance for that use: <=100 tonnes/year<br>Substance supplied to that use: in a mixture<br>Subsequent service life relevant for that use: yes<br>Related assessment: use assessed in an own CSR |

**Table 2.5. Uses by professional workers**

| | **Uses by professional workers** |
|---|---|
| PW-1 | **Professional painting**<br>Further description of the use:<br>This scenario covers the use of paints/decorative coatings by professional painters. This activity may be performed by brush/roller or by spraying.<br>Contributing activity/technique for the environment :<br>**- Use leading to inclusion into/onto matrix**<br>Contributing activity/technique for the workers :<br>**- Transfer of substance or mixture (charging/discharging) at non dedicated-facilities**<br>**- Roller application or brushing**<br>**- Spraying**<br>**Product Category used:** PC 9a: Coatings and paints, thinners, paint removes<br>**Technical function of the substance:** defoamer ; wetting agent, co emulsifier<br>use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant<br>Tonnage of substance for that use: <=50 tonnes/year<br>Subsequent service life relevant for that use: yes<br>Related assessment: use assessed in an own CSR |

**Table 2.6. Consumer uses**

| | **Consumer uses** |
|---|---|
| C-1 | **Consumer painting**<br>Further description of the use:<br>This scenario covers general exposures of consumers arising from the use of ECHA Substance in household products sold as paints/decorative coatings (PC 9a). Activities covered in this scenario are roller application and brushing. The paints may be water-borne or solvent-borne.<br>Contributing activity/technique for the environment:<br>**- Use leading to inclusion into/onto matrix**<br>Contributing activity/technique for consumers:<br>**- Waterborne paint; Roller application or brushing - Product category (PC): PC 9a**<br>**- Solvent rich paint; Roller application or brushing - Product category (PC): PC 9a**<br>**Technical function of the substance:** defoamer ; wetting agent, co emulsifier<br>use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant<br>Tonnage of substance for that use: <=50 tonnes/year<br>Subsequent service life relevant for that use: yes |

| | |
|---|---|
| | Related assessment: use assessed in an own CSR |

## Notes and Comments

**Re: Identified uses**

Please note: Sections 2.2 and 9 do not cover all the life-cycle stages and uses of the ECHA Substance. Specifically, the service life in articles resulting from use in coatings and inks is not addressed (even though it has been indicated to be relevant in IUCLID), and uses in lubricants are not included.

Also, in this example the industrial use of coatings and inks refers to industrial sites undertaking various coating and printing operations. In order to ensure appropriate advice to more specialised downstream users, a registrant may wish to provide more differentiation in the exposure scenarios and hence in the use description than is illustrated here. The same may apply for a substance with a different hazard profile, where the registrant may see the need to explain the use in more detail to be able to demonstrate control of risk in their CSR.

Registrants are also advised to make use of "use maps" developed by sector organisations and made available on the ECHA website (https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library). In this example, use maps have not been used explicitly, even if some of the contributing activities (e.g. use of coatings) were derived from a use map developed by CEPE.

# 3. CLASSIFICATION AND LABELLING

## 3.1. Classification and labelling according to CLP / GHS

**Substance: ECHA Substance**
**Implementation:** EU
**Remarks:**
Self-classification. The impurities in the ECHA Substance have no hazardous effects and thus do not affect the classification of the ECHA Substance.
Related composition: ECHA Substance
The substance is classified as follows:

**Table 3.1. Classification and labelling according to CLP / GHS for physicochemical properties**

| Hazard class | Hazard category | Hazard statement | Reason for no classification |
|---|---|---|---|
| Explosives: | | | conclusive but not sufficient for classification |
| Desensitised explosives: | | | conclusive but not sufficient for classification |
| Flammable gases and chemically unstable gases: | | | conclusive but not sufficient for classification |
| Flammable aerosols: | | | conclusive but not sufficient for classification |
| Oxidising gases: | | | conclusive but not sufficient for classification |
| Gases under pressure: | | | conclusive but not sufficient for classification |
| Flammable liquids: | | | conclusive but not sufficient for classification |
| Flammable solids: | | | conclusive but not sufficient for classification |
| Self-reactive substances and mixtures: | | | conclusive but not sufficient for classification |
| Pyrophoric liquids: | | | conclusive but not sufficient for classification |
| Pyrophoric solids: | | | conclusive but not sufficient for classification |
| Self-heating substances and mixtures: | | | conclusive but not sufficient for classification |
| Substances and mixtures which in contact with water emit flammable gases: | | | conclusive but not sufficient for classification |
| Oxidising liquids: | | | conclusive but not sufficient for classification |
| Oxidising solids: | | | conclusive but not |

| | | | |
|---|---|---|---|
| | | | sufficient for classification |
| Organic peroxides: | | | conclusive but not sufficient for classification |
| Corrosive to metals: | | | data lacking |

**Table 3.2. Classification and labelling according to CLP / GHS for health hazards**

| Hazard class | Hazard category | Hazard statement | Reason for no classification |
|---|---|---|---|
| Acute toxicity - oral: | | | conclusive but not sufficient for classification |
| Acute toxicity - dermal: | | | conclusive but not sufficient for classification |
| Acute toxicity - inhalation: | | | conclusive but not sufficient for classification |
| Skin corrosion / irritation: | Skin Irrit. 2 | H315: Causes skin irritation. | |
| Serious damage / eye irritation: | Eye Irrit. 2 | H319: Causes serious eye irritation. | |
| Respiratory sensitisation: | | | data lacking |
| Skin sensitisation: | | | conclusive but not sufficient for classification |
| Aspiration hazard: | | | data lacking |
| Reproductive Toxicity: | | | conclusive but not sufficient for classification |
| Reproductive Toxicity: Effects on or via lactation: | | | data lacking |
| Germ cell mutagenicity: | | | conclusive but not sufficient for classification |
| Carcinogenicity: | | | data lacking |
| Specific target organ toxicity – single exposure: | | | conclusive but not sufficient for classification |
| Specific target organ toxicity – repeated exposure: | | | conclusive but not sufficient for classification |

**Table 3.3. Classification and labelling according to CLP / GHS for environmental hazards**

| Hazard class | Hazard category | Hazard statement | Reason for no classification |
|---|---|---|---|
| Hazards to the aquatic environment (acute/short-term): | | | conclusive but not sufficient for classification |
| Hazards to the aquatic environment (chronic/long-term): | Aquatic Chronic 3 | H412: Harmful to aquatic life with long lasting effects. | |
| M-Factor acute: | | | |
| M-Factor chronic: | | | |
| Hazardous to the ozone layer: | | | data lacking |

**Labelling**
Signal word: Warning
Hazard pictogram:

**Figure 3.1.**

GHS07: exclamation mark

Hazard statements:

H315: Causes skin irritation.

H319: Causes serious eye irritation.

H412: Harmful to aquatic life with long lasting effects.

Precautionary statements:

P273: Avoid release to the environment.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313: If eye irritation persists: Get medical advice/attention.

P273: Avoid release to the environment.

P501: Dispose of contents/container to ... …in accordance with local/regional/national /international regulations (to be specified). Manufacturer/supplier or the competent authority to specify whether disposal requirements apply to contents, container or both.

## Notes and Comments

**Re: Classification for local dermal and eye effects**

When the substance is included in a mixture, the generic concentration limits as included in CLP (Regulation 1272/2008) are applicable. These generic concentration limits will play a role in the assessment of local effects (see section 9).

# 4. ENVIRONMENTAL FATE PROPERTIES

## 4.1. Degradation

### 4.1.1. Abiotic degradation

#### 4.1.1.1. Hydrolysis

The studies on hydrolysis are summarised in the following table:

**Table 4.1. Studies on hydrolysis**

| Method | Results | Remarks |
|---|---|---|
| according to OECD Guideline 111 (Hydrolysis as a Function of pH) | Half-life (DT50):<br>Recovery (in %):<br>pH 4: 100 at 50°C after 120 h<br>pH 7: 98 at 50°C after 120 h<br>pH 9: 100 at 50°C after 120 h<br>Transformation products: no | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 4.1.1.1 2007<br>[**Error! Bookmark not defined.**] |

**Discussion**

The following information is taken into account for any hazard / risk / persistency assessment:
Stable to hydrolysis at pH 4, 7 and 9 (OECD GL 111).
**Additional information:**
In the preliminary test, the test item was found to be stable at pH 4, 7 and 9, respectively. No further testing was deemed necessary as less than 10% has been hydrolysed after 120 hours at each of the three pH values.

#### 4.1.1.2. Phototransformation/photolysis

##### 4.1.1.2.1. Phototransformation in air

No relevant information available.
**Additional information:**
No experimental data available. As this study is not a standard information requirement in REACH and there is no indication from the CSA on the need to investigate further the fate and behaviour of the substance (Annex X requirement), no further testing is considered necessary.

##### 4.1.1.2.2. Phototransformation in water

No relevant information available.
**Additional information:**
No experimental data available. As this study is not a standard information requirement in REACH and there is

no indication from the CSA on the need to investigate further the fate and behaviour of the substance (Annex X requirement), no further testing is considered necessary.

#### 4.1.1.2.3. Phototransformation in soil

No relevant information available.
**Additional information:**
No experimental data available. As this study is not a standard information requirement in REACH and there is no indication from the CSA on the need to investigate further the fate and behaviour of the substance (Annex X requirement), no further testing is considered necessary.

## 4.1.2. Biodegradation

### 4.1.2.1. Biodegradation in water

#### 4.1.2.1.1. Screening tests

The studies on biodegradation in water (screening tests) are summarised in the following table:

**Table 4.2. Screening tests for biodegradation in water**

| Method | Results | Remarks |
|---|---|---|
| biodegradation in water: ready biodegradability:<br>activated sludge, non-adapted (aerobic)<br>according to OECD Guideline 301 B (Ready Biodegradability: CO2 Evolution Test) | inherently biodegradable<br>% Degradation of test substance:<br>56 after 28d (% degradation (CO2 evolution))<br>29 after 21d (% degradation (CO2 evolution))<br>11 after 14d (% degradation (CO2 evolution))<br>1 after 6d (% degradation (CO2 evolution)) | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 4.1.2.1.1.a 2006 [**Error! Bookmark not defined.**] |
| biodegradation in water: ready biodegradability:<br>activated sludge, domestic, non-adapted<br>according to OECD Guideline 301 A (Ready Biodegradability: DOC Die Away Test) | not readily biodegradable<br>% Degradation of test substance:<br>54 after 42d (% degradation (DOC removal)) | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**] |

| | | |
|---|---|---|
| | | **Reference**<br>Ref 4.1.2.1.1.b 2009 [**Error! Bookmark not defined.**] |

### 4.1.2.1.2. Simulation tests (water and sediments)

The studies on biodegradation in water (screening tests) are summarised in the following table:

**Table 4.3. Simulation tests for biodegradation in water and sediment**

| Method | Results | Remarks |
|---|---|---|
| biodegradation in water: sediment simulation testing:<br>Test system: natural water / sediment according to OECD Guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems) | Half-life (DT50):<br>% Degradation of test substance:<br>50 after 36d (radiochem. meas.) (marine water without sediment; at 11ºC)<br>50 after 52d (radiochem. meas.) (marine water/sediment; at 11°C)<br>50 after 81d (radiochem. meas.) (marine sediment; at 11°C)<br>Mineralization rate:<br>Transformation products: no | 2 (reliable with restrictions)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 4.1.2.1.2 1993 [**Error! Bookmark not defined.**] |

### 4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

**Discussion (screening testing)**

The following information is taken into account for any hazard / risk / persistency assessment:
Not readily biodegradable, but considered as inherently biodegradable as determined in two ready biodegradability tests 56% degradation (CO2 evolution) in 28 days (OECD TG 301B) and 54% degradation (DOC removal) in 42 days (OECD TG 301A) with activated sludge, domestic, non-adapted and activated sludge, non-adapted, respectively.

**Value used for CSA:**
Biodegradation in water: inherently biodegradable

**Additional information:**
The test item must be regarded as not readily biodegradable. However, as the substance still degraded between 40-60% in CO2 Evolution test, it is a clear indication that extensive primary biodegradation has occurred. The REACH Guidance on Information Requirements R.7b states ‘When results of ready biodegradability tests indicate that the pass level criterion is almost fulfilled (i.e. ThOD slightly below 60%) such results can be used to prove inherent biodegradability.’. Therefore the ECHA Substance is considered to be inherently biodegradable.

**Discussion (simulation testing)**

The following information is taken into account for any hazard / risk / persistency assessment:
OECD Guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems) with marine natural water / sediment: 50% degradation of test substance after 36 days (water) / 81 days (sediment) at 11ºC

**Value used for CSA:**
Half-life in water: 36d at 11°C
Half-life in sediment: 81d at 11°C

**Additional information:**
Biodegradation of 14C-labelled ECHA Substance in marine water alone, water/sediment system and sediment was estimated by collection and quantification of the formed radio-labelled CO2. A study was conducted to determine the biodegradation of ECHA Substance in a marine water/sediment simulation test. 50% of the substance was found to be degraded under aerobic conditions after 36 days and 81 days as measured by 14C determination in CO2 fraction in water and sediment compartments, respectively.

### 4.1.2.2. Biodegradation in soil

The test results are summarised in the following table:

**Table 4.4. Simulation tests for biodegradation in soil**

| Method | Results | Remarks |
|---|---|---|
| biodegradation in soil: simulation testing:<br>Test type: laboratory<br>Soil type:<br>reconstituted soil system (compost + sandstone) (#1)<br>according to OECD Guideline 307 (Aerobic and Anaerobic Transformation in Soil) | Half-life (DT50):<br>% Degradation of test substance:<br>50 after 36d (test mat. analysis - at 1000 ppm concentration) (#1)<br>Evaporation of parent compound:<br>Volatile metabolites:<br>Residues:<br>Transformation products: no | 2 (reliable with restrictions)<br>key study experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 4.1.2.2 1988<br>[**Error! Bookmark not defined.**] |

**Discussion**

The following information is taken into account for any hazard / risk / persistency assessment:
OECD Guideline 307 (Aerobic and Anaerobic Transformation in Soil) with reconstituted soil system (compost + sandstone): 50% Degradation of test substance after 36 d (Test mat. analysis (at 1000 ppm concentration))
The value used is 36 days at 20 °C, equivalent to 68 days at 12 °C.
**Value used for CSA:**
Half-life in soil: 36d at 20°C
**Additional information:**
ECHA Substance was incubated with a reconstituted soil system (compost + sandstone) in darkness for 40 d. The samples were analyzed for residual ECHA Substance at various intervals during this period. Volatilisation of the substance was also studied concurrently indicating insignificant volatilisation with only 0.22% of the substance volatilised over 40d at 1000ppm. The substance was degraded microbiologically after adaptation of microorganisms. Biodegradation was evident through the presence of a lag phase. Disappearance due to other factors via volatilization, physicochemical transformations, photodecomposition and leaching was considered insignificant based on choice of experimental conditions and stability of compound. Consistent with results obtained in screening biodegradation and water / sediment simulation studies ECHA Substance was degraded in soil to an extent of 50% after 36 days of incubation at concentrations of 1000 ppm.

## 4.1.3. Summary and discussion of degradation

**Abiotic degradation**

**Additional information:**
Based on available data from fate studies abiotic degradation (i.e hydrolysis study) is only expected to make a minor contribution to the overall environmental fate of the substance. The substance is considered to be stable to hydrolysis at pH 4, 7 and 9.

**Biotic degradation**

**Additional information:**
Results from OECD screening studies as well as results from marine water/sediment and soil simulation studies on the substance, indicate that ECHA Substance can expected to be relatively efficiently biodegraded under aerobic conditions in the aquatic and terrestrial environment where upon a significant portion of the parent compound is mineralized.

# 4.2. Environmental distribution

## 4.2.1. Adsorption/desorption

The studies on adsorption/desorption are summarised in the following table:

**Table 4.5. Studies on adsorption/desorption**

| Method | Results | Remarks |
|---|---|---|
| adsorption / desorption: screening<br>batch equilibrium method<br>according to OECD Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method) ; according to EU Method C.18 (Adsorption / Desorption Using a Batch Equilibrium Method) | Adsorption coefficient:<br>Koc - #1: clay: 942 at 20°C (Org. C (%): 3.29) (pH 5.6)<br>Koc - #2: silt loam: 502 at 20°C (Org. C (%): 2.39) (pH 7.7)<br>Koc - #3: loam: 181 at 20°C (Org. C (%): 3.32) (pH 5.4)<br>Koc - #4: silt: 221 at 20°C (Org. C (%): 1.36) (pH 6.7)<br>Koc - #5: loamy sand: 497 at 20°C (Org. C (%): 4.43) (pH 3.5)<br>Koc: 776 at 20°C (Org. C (%): 1.36 - 4.43) (mean)<br>log Koc: 2.89<br>Kd: 3 - 31 (Org. C (%): 1.36 - 4.43)<br>Partition coefficients:<br>Mass balance (in %) at end of adsorption phase:<br>96.7 after 48h (#1)<br>92.2 after 48h (#2)<br>85.9 after 48h (#3)<br>72.7 after 48h (#4)<br>95.7 after 48h (#5)<br>Mass balance (in %) at end of desorption phase:<br>20 after 48h (#1)<br>45 after 48h (#2)<br>84 after 48h (#3)<br>77 after 48h (#4)<br>53 after 48h (#5)<br>Transformation products: no | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 4.2.1 2007<br>[**Error! Bookmark not defined.**] |

**Discussion**

The following information is taken into account for any environmental exposure assessment:
OECD Guideline 106 / EU Method C.18 (Adsorption / Desorption Using a Batch Equilibrium Method): Koc =

818-942 cm3/g; Kd = 3-31 cm3/g; Mean Koc at 20°C: 776, log Koc 2.89
**Value used for CSA:**
Koc at 20°C: 776
Log Koc at 20°C: 2.89
**Additional information:**
The test item can be considered to have a medium to low mobility in soil (according to MCCALL classification scheme, a substance with Koc 150 - 500 can be classified to have a medium mobility and with Koc 500 - 2000 to have a low mobility). Adsorption of the test substance is not completely reversible, as % desorption was 20 - 84 % in the desorption kinetics and ≤ 24 % (overall mean for each soil) for desorption isotherms. No further study on adsorption/desorption is being proposed as according to Annex IX to REACH Regulation the study does not need to be conducted if based on the substance physicochemical properties the substance can be expected to have a low potential for adsorption.

## 4.2.2. Volatilisation

No relevant information available.

## 4.2.3. Distribution modelling

No relevant information available.

## 4.2.4. Summary and discussion of environmental distribution

Based on the test results the substance is not highly adsorptive that indicates that soil and sediment are not expected to be the main target compartments for exposure assessment. The assessment of those compartments is further exemplified in Section 9.
In addition, no further distribution modelling was considered necessary as this study is not a standard information requirement in REACH and the exposure assessment indicating the concentrations in all the environmental compartments is performed in Section 9 of the CSA.

# 4.3. Bioaccumulation

## 4.3.1. Aquatic bioaccumulation

The studies on aquatic bioaccumulation are summarised in the following table:

**Table 4.6. Studies on aquatic bioaccumulation**

| Method | Results | Remarks |
|---|---|---|
| bioaccumulation in aquatic species: fish<br>Danio rerio (previous name: Brachydanio rerio) [fish]<br>aqueous<br>flow-through<br>Media type: natural water: freshwater<br>Total exposure / uptake duration: 5 wk<br>Total depuration duration: 2 wk<br>Details on estimation of bioconcentration: according to OECD Guideline 305 E (Bioaccumulation: Flow-through Fish Test) [before 14 June 1996] | Bioaccumulation factor:<br>BCF: 4055 dimensionless (whole body w.w.) (kinetic) (Exposure concentration 3 µg/L - Conc.in environment / dose:3 µg/L)<br>BCF: 2530 dimensionless (whole body w.w.) (kinetic) (Exposure concentration 30 µg/L - Conc.in environment / dose:30 µg/L)<br>Elimination:<br>yes; 98-99 % of loss at the end of the depuration period.: 2wk<br>Lipid content:<br>5 %<br>Transformation products: no | 2 (reliable with restrictions)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 4.3.1 1991<br>[**Error! Bookmark not defined.**] |

## 4.3.2. Terrestrial bioaccumulation

No relevant information available.

## 4.3.3. Summary and discussion of bioaccumulation

**Aquatic bioaccumulation**

The following information is taken into account for any environmental exposure assessment:
OECD Guideline 305 E (Bioconcentration: flow-through fish test): Bioaccumulates in aquatic organisms, BCF = 2530 (at 30 µg/L) and 4055 (at 3 µg/L).
**Value used for CSA:**
BCF: 4055dimensionless
**Additional information:**
Aquatic bioaccumulation of ECHA Substance was investigated in a flow-through system set up according to OECD guideline 305 E. A BCF of 4055 (whole fish) at a concentration of µg/l was detected whereas at a concentration of 30 µg/l the BCF was 2530. After the depuration period a loss of 98 - 99 % (not known if due to metabolism, elimination or both) was demonstrated (Ref 4.3.1 1991). Therefore it can be considered that ECHA Substance bioaccumulates in organisms in a short time period. However the observed loss during depuration was still comparably fast and high.

**Terrestrial bioaccumulation**

**Additional information:**
No experimental data available. Based on the study on aquatic bioaccumulation, relatively high log Kow (log Kow 4.7) and biodegradation test, it can be assumed that the substance is potentially bioaccumulative also in terrestrial ecosystem. As this study is not a standard information requirement in REACH and there is no indication from the CSA on the need to investigate further the fate and behaviour of the substance (Annex X requirement), no further testing is considered necessary.

# 4.4. Secondary poisoning

Based on the available information the bioaccumulation potential cannot be judged (see CSR chapter 7.5 “PNEC derivation and other hazard conclusions”).

### Notes and Comments

**General considerations**

**a.** The purity of the substance in all experimental studies is the same as described in Section 1.2. The impurities are considered not to be relevant for the assessment of any experimental studies.

**b.** For tests that are not standard information requirements in REACH, no test results or further testing has been proposed because the CSA does not indicate the need to further investigate the fate and behaviour of the substance (Annex X requirement).

# 5. HUMAN HEALTH HAZARD ASSESSMENT

## 5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

### 5.1.1. Non-human information

No relevant information available.

### 5.1.2. Human information

No relevant information available.

### 5.1.3. Summary and discussion of toxicokinetics

The following information is taken into account for any hazard / risk assessment:
Experimental toxicokinetic studies are not available. The log Pow of 4.7 is suggestive of accumulation of unchanged ECHA Substance in fatty tissues subsequent to absorption from gastro-intestinal tract or from lungs. However, on the basis of the molecular structure excretion into urine as glucuronide is assumed to be a preferred route of elimination. Elimination is assumed to be rapid. Therefore, no potential for bioaccumulation is to be expected.
**Value used for CSA:**
Bioaccumulation potential: no bioaccumulation potential
Absorption rate - oral (%): 50
Absorption rate - dermal (%): 50
Absorption rate - inhalation (%): 100
**Additional information:**
Assessment of oral toxicokinetics based on the physicochemical properties of ECHA Substance:
Molecular weight 300
Water solubility 149 mg/L
Partition coefficient log Kow = 4.7
The following remarks on the toxicokinetics of ECHA Substance are based on the available studies.
Experimental toxicokinetic studies were not available.

ABSORPTION
The physicochemical characteristics of ECHA Substance (log Pow 4.7) and the molecular mass are in a range suggestive of absorption from the gastro-intestinal tract subsequent to oral ingestion. This assumption of an oral absorption is confirmed by the data subchronic oral toxicity.
N-octanol/water partition coefficient and molecular weight of ECHA Substance are in ranges which favour dermal absorption.

DISTRIBUTION and METABOLISM
As a small molecule a wide distribution is expected. This assumption is confirmed by the changes shown in the repeated dose toxicity studies following oral application. The structure of ECHA Substance suggests that it will preferably be either directly conjugated in a phase-II reaction or undergoes further oxidation in the alcohol moieties of the molecule.

ELIMINATION
The n-Octanol/water partition coefficient (log Pow of 4.7) is suggestive of accumulation of unchanged ECHA Substance in fatty tissues subsequent to absorption from gastrointestinal tract or from lungs. However, on the basis of the molecular structure excretion into urine as glucuronide is assumed to be a preferred route of elimination. Elimination is assumed to be rapid. Therefore, no potential for bioaccumulation is to be expected.

## Notes and Comments

**General considerations**

a. The information in the hazard assessment part of the CSR is to be reviewed and assessed in conjunction with the robust study summaries that form the basis of the assessment, as reported in the IUCLID technical dossier. A CSR as such would not be considered compliant with the provisions contained in Annex I of REACH, and more specifically with its sections 1.1.4 and 3.1.5, without the relevant IUCLID dossier where the study details are reported in the form of robust study summaries (RSS). Please note that the IUCLID 6.1 dataset for ECHA Substance contains only the information that is reported in the CSR (chapters 1 to 8). The details that are necessary to make the RSS complete and therefore meet the requirements pursuant Article 10(a)(vii) REACH are not reported there, as these details are not meant to be transferred to the CSR.

b. The ECHA Practical Guide 3: How to Report Robust Study Summaries (ECHA, 2012) provides guidance on what needs to be reported for the hazard assessment which is then transferred to the CSR.

c. The ECHA Practical Guide 14: How to prepare toxicological studies in IUCLID and how to derive DNELs (ECHA, 2012) provides information on how to fill in the toxicological summaries in section 7 of IUCLID and on how to derive DNELs.

d. An Information Toolkit is available which provides a roadmap with practical information and tools to help in using existing information and non-test methods (i.e. predictions). The toolkit directs the registrant to Practical Guides on how to report read-across and categories in IUCLID.

https://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf/1e8302c3-98b7-4a50-aa22-f6f02ca54352

http://echa.europa.eu/web/guest/support/information-toolkit

# 5.2. Acute toxicity

## 5.2.1. Non-human information

### 5.2.1.1. Acute toxicity: oral

The results of studies on acute toxicity after oral administration are summarised in the following table:

**Table 5.1. Studies on acute toxicity after oral administration**

| Method | Results | Remarks |
|---|---|---|
| rat [common species] (Sprague-Dawley [rat])<br>female<br>oral: gavage<br>according to OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method) ; according to EU Method B.1 tris (Acute Oral Toxicity - Acute Toxic Class | LD50: >2000 mg/kg bw (female) | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1, |

| | | |
|---|---|---|
| Method) | | Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 5.2.1.1 2005<br>[**Error! Bookmark not defined.**] |

## 5.2.1.2. Acute toxicity: inhalation

The results of studies on acute toxicity after inhalation exposure are summarised in the following table:

**Table 5.2. Studies on acute toxicity after inhalation exposure**

| Method | Results | Remarks |
|---|---|---|
| rat [common species] (Sprague-Dawley [rat])<br>male<br>inhalation: vapour (nose only)<br>equivalent or similar to OECD Guideline 403 (Acute Inhalation Toxicity) | LC50: >20 mg/L air (male) (No animals died and no clinical signs were observed.) | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 5.2.1.2 2004<br>[**Error! Bookmark not defined.**] |

## 5.2.1.3. Acute toxicity: dermal

The results of studies on acute toxicity after dermal administration are summarised in the following table:

**Table 5.3. Studies on acute toxicity after dermal administration**

| Method | Results | Remarks |
|---|---|---|
| rat [common species] (Sprague-Dawley [rat])<br>male/female<br>Coverage: semiocclusive<br>Vehicle: unchanged (no vehicle)<br>according to OECD Guideline 402 (Acute Dermal Toxicity) ; according to EU Method B.3 (Acute Toxicity (Dermal)) | LD50: >2000 mg/kg bw (male/female)<br>LD50: >2000 mg/kg bw (female)<br>LD50: >2000 mg/kg bw (male) | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark** |

| | | |
|---|---|---|
| | | **not defined.**]<br><br>**Reference**<br>Ref 5.2.1.3 2005<br>[**Error! Bookmark not defined.**] |

### 5.2.1.4. Acute toxicity: other routes

No relevant information available.

## 5.2.2. Human information

No relevant information available.

## 5.2.3. Summary and discussion of acute toxicity

The following information is taken into account for any hazard / risk assessment:
Acute oral toxicity: LD50 > 2000 mg/kg bw, OECD Guideline 423, GLP compliant
Acute inhalation toxicity: LD50 > 5000 ppm (ca. 62300 mg/m³ at 20°C; MW 300g/mol), similar to OECD Guideline 403, GLP compliant
Acute dermal toxicity: LD50 > 2000 mg/kg bw, OECD Guideline 402, GLP compliant
**Value used for CSA:**
Acute oral toxicity: no adverse effect observed (LD50) 2000mg/kg bw
Acute dermal toxicity: no adverse effect observed (LD50) 2000mg/kg bw
Acute inhalation toxicity: no adverse effect observed (LC50) 62300mg/m³
**Additional information:**
Based on the available information, the acute toxicity of the ECHA Substance is low for all three routes of administration. There are no data gaps in acute toxicity. Even though there is no information on acute toxicity in humans, there is no reason to believe that the low acute toxicity observed in experimental animals would not be relevant for human health.
**Justification for classification or non classification:**
Based on the available data, the substance is not classified.

# 5.3. Irritation

## 5.3.1. Skin

### 5.3.1.1. Non-human information

The results of studies on skin irritation are summarised in the following table:

**Table 5.4. Studies on skin irritation**

| Method | Results | Remarks |
|---|---|---|
| rabbit [common species] (New Zealand White [rabbit])<br>Coverage: semiocclusive (shaved)<br>Vehicle: undiluted<br>according to OECD Guideline 404 (Acute Dermal Irritation / Corrosion) ; according to EU Method B.4 (Acute Toxicity: Dermal Irritation / Corrosion) | Category 2 (irritant) based on GHS criteria<br>erythema score<br>3 of max. 4 (Time point: 24, 48, 72 h)<br>Reversibility: not fully reversible within: 72 hours<br>(mean of all observations)<br>2.3 of max. 4 (Time point: 24, 48, 72 h)<br>Reversibility: not fully reversible within: 72 hours<br>(mean of all observations) | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid |

| | | |
|---|---|---|
| | 1.6 of max. 4 (Time point: 24, 48, 72 h)<br>Reversibility: not fully reversible within: 72 hours<br>(mean of all observations)<br>edema score<br>2 of max. 4 (Time point: 24, 48, 72 h)<br>Reversibility: not relevant<br>(mean of all observations)<br>2 of max. 4 (Time point: 24, 48, 72 h)<br>Reversibility: fully reversible<br>(mean of all observations)<br>2 of max. 4 (Time point: 24, 48, 72 h)<br>Reversibility: fully reversible<br>(mean of all scores) | detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 5.3.1.1 2000<br>[**Error! Bookmark not defined.**] |

Studies with results indicating corrosivity to the skin are summarised in section 5.4 Corrosivity.

### 5.3.1.2. Human information

No relevant information available.

## 5.3.2. Eye

### 5.3.2.1. Non-human information

The results of studies on eye irritation are summarised in the following table:

**Table 5.5. Studies on eye irritation**

| Method | Results | Remarks |
|---|---|---|
| rabbit (New Zealand White [rabbit])<br>Vehicle: unchanged (no vehicle)<br>according to OECD Guideline 405 (Acute Eye Irritation / Corrosion) ; according to EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion) | Category 2 (irritating to eyes) based on GHS criteria<br>conjunctivae score - , conjunctival redness<br>(animal #1) 1.3 of max. 2<br>(Time point: 24, 48, 72 h)<br>fully reversible - 7 days after dosing<br>mean, observed values<br>conjunctivae score - , conjunctival redness<br>(animal #2) 1.3 of max. 2<br>(Time point: 24, 48, 72 h)<br>fully reversible - 7 days after dosing<br>mean, observed values<br>conjunctivae score - , conjunctival redness<br>(animal #3) 1.3 of max. 2<br>(Time point: 24, 48, 72 h)<br>fully reversible - 7 days after dosing<br>mean, observed values<br>chemosis score - , conjunctival chemosis<br>(animal #1) 1.3 of max. 2<br>(Time point: 24, 48, 72 h)<br>fully reversible - 7 days after dosing<br>mean, observed values<br>chemosis score - , conjunctival chemosis<br>(animal #2) 1 of max. 2<br>(Time point: 24, 48, 72 h)<br>fully reversible - 7 days after dosing<br>mean, observed values | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 5.3.2.1 1995<br>[**Error! Bookmark not defined.**] |

| | | |
|---|---|---|
| | chemosis score - , conjunctival chemosis<br>(animal #3) 1 of max. 2<br>(Time point: 24, 48, 72 h)<br>fully reversible - 7 days after dosing<br>mean, observed values<br>cornea opacity score - , corneal opacity<br>(animal #1) 1.7 of max. 3<br>(Time point: 24, 48, 72 h)<br>fully reversible - 7 days after dosing<br>cornea opacity score - , corneal opacity<br>(animal #2) 1.7 of max. 3<br>(Time point: 24, 48, 72 h)<br>fully reversible - 7 days after dosing<br>cornea opacity score - , corneal opacity<br>(animal #3) 2 of max. 3<br>(Time point: 24, 48, 72 h)<br>fully reversible - 7 days after dosing<br>iris score - , iris inflammation<br>(animal #1) 0.7 of max. 1<br>(Time point: 24, 48 h)<br>fully reversible - 7 days after dosing<br>mean, observed values<br>iris score - , iris inflammation<br>(animal #2) 0.3 of max. 1<br>(Time point: 24, 48 h)<br>fully reversible - 7 days after dosing<br>mean, observed values<br>iris score - , iris inflammation<br>(animal #3) 0.3 of max. 1<br>(Time point: 24, 48 h)<br>fully reversible - 7 days after dosing<br>mean, observed values | |

### 5.3.2.2. Human information

No relevant information available.

## 5.3.3. Respiratory tract

### 5.3.3.1. Non-human information

No relevant information available

### 5.3.3.2. Human information

No relevant information available.

## 5.3.4. Summary and discussion of irritation

The following information is taken into account for any hazard / risk assessment:
- Skin irritation: moderately irritating in rabbits (one study acc. to OECD guideline 404 and EU method B.4, GLP), applied to the intact skin for 24 hours. Two of the test animals had erythrema scores =>2.3. No reversibility 72 hours after application. No other dermal effects noted.
- Eye irritation: slightly irritating in rabbits (one study acc. to OECD guideline 405 and EU method B.5, GLP); undiluted test material applied to right eye of three animals. Slight conjunctival redness, chemosis and ocular discharges were observed in the three animals at 1 hour examination. Moderate conjunctival redness and ocular discharges, well defined chemosis, slight to moderate iris inflammation and moderate corneal opacity were

observed in the three animals at 24 hours examination. The scores obtained for the corneal opacity calculated as the mean scores following grading at 24, 48 and 72 h were 1.7, 1.7 and 2 but fully reversed within the 7 day observation period.
**Value used for CSA:**
Skin irritation / corrosion: adverse effect observed (irritating)
Eye irritation: adverse effect observed (irritating)
Respiratory irritation: no study available
**Additional information:**
Based on the available information, ECHA Substance was observed to be moderately irritating both to eyes and to skin in animal models. There are no data gaps for the endpoint irritation/corrosion. No human information is available for this endpoint. However, there is no reason to believe that these results would not be applicable to humans.
Effects on skin irritation/corrosion: moderately irritating
Effects on eye irritation: moderately irritating
**Justification for classification or non classification:**
According to the CLP Regulation, the substance is classified as:
Skin Irritant, Category 2, based on slight erythema (grade 1) which were observed in 3 of 6 rabbits.
Eye irritant, Category 2, based on the scores obtained for the corneal opacity (calculated as the mean scores following grading at 24, 48 and 72 h) which are above 1 for the three animals and which fully reverses within the observation period.

# 5.4. Corrosivity

## 5.4.1. Non-human information

No relevant information available.

## 5.4.2. Human information

No relevant information available.

## 5.4.3. Summary and discussion of corrosion

The studies with results indicating corrosivity are discussed in section 5.3.4 Summary and discussion of irritation.

# 5.5. Sensitisation

## 5.5.1. Skin

### 5.5.1.1. Non-human information

The results of studies on skin sensitisation are summarised in the following table:

**Table 5.6. Studies on skin sensitisation**

| Method | Results | Remarks |
|---|---|---|
| guinea pig (Dunkin-Hartley [guinea pig]) female<br>skin sensitisation: in vivo (non-LLNA) according to OECD Guideline 406 (Skin Sensitisation) ; according to EU Method B.6 (Skin Sensitisation) | GHS criteria not met<br>No. with positive reactions: 1st reading : 1 out of 20<br>(test group ; 24 h after challenge; dose: 100 %) (Reading: 1st reading. . Hours after challenge: 24.0. Group: test group. Dose level: 100 %. No with. + reactions: 1.0. Total no. in groups: 20.0.) | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1, |

| | | |
|---|---|---|
| | No. with positive reactions: 2nd reading : 0 out of 20<br>(test group ; 48 h after challenge; dose: 100 %) (Reading: 2nd reading. . Hours after challenge: 48.0. Group: test group. Dose level: 100 %. No with. + reactions: 0.0. Total no. in groups: 20.0.)<br>No. with positive reactions: 1st reading : 0 out of 10<br>(negative control ; 24 h after challenge; dose: 0 %) (Reading: 1st reading. . Hours after challenge: 24.0. Group: negative control. Dose level: 0 %. No with. + reactions: 0.0. Total no. in groups: 10.0.)<br>No. with positive reactions: 2nd reading : 0 out of 10<br>(negative control ; 48 h after challenge; dose: 0 %) (Reading: 2nd reading. . Hours after challenge: 48.0. Group: negative control. Dose level: 0 %. No with. + reactions: 0.0. Total no. in groups: 10.0.) | Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 5.5.1.1 1996 [**Error! Bookmark not defined.**] |

### 5.5.1.2. Human information

No relevant information available.

## 5.5.2. Respiratory system

### 5.5.2.1. Non-human information

No relevant information available.

### 5.5.2.2. Human information

No relevant information available.

## 5.5.3. Summary and discussion of sensitisation

The following information is taken into account for any hazard / risk assessment:

**Skin sensitisation**

Guinea pig maximisation test: Not sensitising (OECD guideline 406 and EU method B.6), Induction: intradermal; Challenge: topical)
**Value used for CSA:** no adverse effect observed (not sensitising)
Additional information:
ECHA substance did not show any skin sensitising properties in guinea pigs. There is no reason to believe that results obtained in guinea pigs would not be applicable to humans.

The following information is taken into account for any hazard / risk assessment:

**Respiratory sensitisation**

**Value used for CSA:** no study available
Additional information:
There is no information available for respiratory sensitisation. Therefore, there is a data gap in this respect. However, the data gap cannot be fulfilled with experimental data, since there is no internationally accepted animal model for respiratory sensitisation. In case human data for respiratory sensitisation emerges, this will be

taken into account.
**Justification for classification or non classification:**
Based on the available data, the substance is not classified.

# 5.6. Repeated dose toxicity

## 5.6.1. Non-human information

### 5.6.1.1. Repeated dose toxicity: oral

The results of studies are summarised in the following table:

**Table 5.7. Studies on repeated dose toxicity after oral administration**

| Method | Results | Remarks |
|---|---|---|
| rat [common rodent species] (Wistar [rat])<br>male/female<br>short-term repeated dose toxicity: oral<br>(oral: gavage)<br><br>Vehicle: corn oil<br>Exposure: 28 d; DRF pre-study: 14 d (daily)<br>according to OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents) | NOAEL: >=1000 mg/kg bw/day (actual dose received) (male/female) | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 5.6.1.1a 2005 [**Error! Bookmark not defined.**] |
| rat [common rodent species] (Sprague-Dawley [rat])<br>male/female<br>sub-chronic toxicity: oral<br>(oral: gavage)<br><br>Vehicle: corn oil<br>Exposure: 90 days (daily)<br>according to OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents) | NOAEL: 700 mg/kg bw/day (nominal) (male) see 'Remark' - In the 1000 mg/kg bw/day group in males, absolute and relative liver weights were increased. Among 8/10 of males in the 1000 mg/kg bw./day slight to moderate degeneration of hepatocytes in centrilobular area in liver was present. No effects were seen in females. | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 5.6.1.1b 2005 [**Error! Bookmark** |

| | | |
|---|---|---|
| | | **not defined.**] |

### 5.6.1.2. Repeated dose toxicity: inhalation

No relevant information available.

### 5.6.1.3. Repeated dose toxicity: dermal

No relevant information available.

### 5.6.1.4. Repeated dose toxicity: other routes

No relevant information available.

## 5.6.2. Human information

No relevant information available.

## 5.6.3. Summary and discussion of repeated dose toxicity

The following information is taken into account for any hazard / risk assessment:
Key Information:
Subchronic (90-day) study oral (gavage), rat (Sprague-Dawley) m/f (OECD guideline 408, GLP): NOAEL: 700 mg/kg bw/day (nominal) (male);
Subacute (28-day) study oral (gavage), rat (Wistar) m/f (OECD guideline 408, GLP): NOAEL: >1000 mg/kg bw/day (actual dose received) (male/female)
**Value used for CSA (via oral route - systemic effects):**
adverse effect observed (NOAEL): (700mg/kg bw/day) (subchronic); (rat [common rodent species])
**Value used for CSA (inhalation - systemic effects):**
no study available
**Value used for CSA (inhalation - local effects):**
no study available
**Value used for CSA (dermal - systemic effects):**
no study available
**Value used for CSA (dermal - local effects):**
no study available
Additional information:
The degeneration of hepatocytes in centrilobular area observed in the oral 90-day study in rats is probably also relevant to humans. However, since this effect was only observed in the highest dose group, the effect does not give rise to concern, even though it is clearly an adverse effect and therefore is taken into account in risk assessment. There are no data gaps in repeated dose toxicity.
Repeated dose toxicity: via oral route - systemic effects (target organ) digestive: liver
**Justification for classification or non classification:**
Based on the available data, the substance is not classified.

# 5.7. Mutagenicity

## 5.7.1. Non-human information

### 5.7.1.1. In vitro data

The results of in vitro genotoxicity studies are summarised in the following table:

**Table 5.8. The results of in vitro genotoxicity studies are summarised in the following table:**

| Method | Results | Remarks |
|---|---|---|

| | | |
|---|---|---|
| mammalian cell gene mutation assay [gene mutation] (in vitro gene mutation study in mammalian cells - Type of genotoxicity: gene mutation)<br>Chinese hamster lung fibroblasts (V79) [mammalian cell line] (Met. act.: with and without)<br>Test concentrations: Experiment I: with and without S9-mix: 43.8, 87.5, 175, 350 700, 1400 µg/ml (incubation time: 4 hours). Experiment II: with S9-mix: 43.8, 87.5, 175, 350 700, 1400 µg/ml (incubation time: 4 hours). Without S9-mix: 43.8, 87.5, 175, 350 700, 1400 µg/ml (incubation time: 24 hours)<br>Positive control substance(s): 4-nitroquinoline-N-oxide<br>Positive control substance(s): cyclophosphamide<br>according to OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test) [in vitro gene mutation study in mammalian cells] | Test results:<br>negative for Chinese hamster lung fibroblasts (V79) [mammalian cell line];<br>met. act.: with and without<br>genotoxicity: negative cytotoxicity: no - preliminary toxicity tests<br>vehicle controls valid: yes<br>negative controls valid: yes<br>positive controls valid: yes | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 5.7.1.1a 2008<br>[**Error! Bookmark not defined.**] |
| bacterial reverse mutation assay [in vitro gene mutation study in bacteria] (in vitro gene mutation study in bacteria - Type of genotoxicity: gene mutation)<br>S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 [bacteria] (Met. act.: with and without)<br>E. coli WP2 uvr A [bacteria] (Met. act.: with and without)<br>Test concentrations: Doses in the main test:0, 312.5, 625, 1250, 2500, 5000 µg/plate<br>Positive control substance(s): benzo(a)pyrene<br>Positive control substance(s): sodium azide<br>Positive control substance(s): 4-nitroquinoline-N-oxide<br>Positive control substance(s): ICR 191<br>Positive control substance(s): 4-Nitro-o-phenylendiamine<br>Positive control substance(s): Nitrofurantoine<br>Positive control substance(s): 2-Aminoanthracen<br>according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria] | Test results:<br>negative for S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2 [bacteria];<br>met. act.: with and without<br>genotoxicity: negative cytotoxicity: no - (toxicity was observed up to a concentration of 5000 µg/plate with or without metabolic activation)<br>vehicle controls valid: yes<br>negative controls valid: yes<br>positive controls valid: yes<br>Remark: all strains/cell types tested | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 5.7.1.1b 2007<br>[**Error! Bookmark not defined.**] |
| in vitro mammalian chromosome aberration test [chromosome aberration] | Test results: | 1 (reliable without restriction) |

| | | |
|---|---|---|
| (in vitro cytogenicity / chromosome aberration study in mammalian cells - Type of genotoxicity: chromosome aberration)<br>Chinese hamster lung fibroblasts (V79) [mammalian cell line] (Met. act.: with and without)<br>Test concentrations: 0, 0.34, 0.67, 1.34 mg/mL<br>Positive control substance(s): ethylmethanesulphonate<br>Positive control substance(s): cyclophosphamide<br>according to OECD Guideline 473 (In Vitro Mammalian Chromosome Aberration Test) [in vitro cytogenicity / chromosome aberration study in mammalian cells] | negative for Chinese hamster lung fibroblasts (V79) [mammalian cell line]; met. act.: with and without<br>genotoxicity: negative cytotoxicity: no<br>vehicle controls valid: yes<br>negative controls valid: yes<br>positive controls valid: yes | key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 5.7.1.1c 2007<br>[**Error! Bookmark not defined.**] |

### 5.7.1.2. In vivo data

No relevant information available.

## 5.7.2. Human information

No relevant information available.

## 5.7.3. Summary and discussion of mutagenicity

**Value used for CSA (genetic toxicity in vitro):** Genetic toxicity: no adverse effect observed (negative)
**Justification for classification or non classification**
Regulation (EC) No. 1272/2008: Based on the available data, no classification is needed.

Additional information:
All three in vitro tests in genetic toxicity showed negative results. Therefore, there is no need to carry out in vivo studies in genetic toxicity. There is no reason to believe that the negative results would not be relevant to humans.

Short description of key information:
Negative in all tests conducted:
- Ames test with S. typhimurium TA 98, TA 100, TA 1535, TA 1537, E coli WP2 uvrA (met. act.: with and without) (OECD TG 471 and GLP); no toxicity was observed up to a concentration of 5000 µg/plate.
- Mammalian cell gene mutation assay with Chinese hamster lung fibroblasts (V79) (met. act.: with and without) (OECD Guideline 476 and GLP); cytotoxicity: preliminary toxicity tests
- In vitro mammalian chromosome aberration test with Chinese Hamster Lung (CHL) cells (met. act.: with and without) (OECD Guideline 473 and GLP); cytotoxicity: no
Endpoint conclusion: No adverse effect observed (negative)

# 5.8. Carcinogenicity

## 5.8.1. Non-human information

### 5.8.1.1. Carcinogenicity: oral

No relevant information available.

### 5.8.1.2. Carcinogenicity: inhalation

No relevant information available.

### 5.8.1.3. Carcinogenicity: dermal

No relevant information available.

### 5.8.1.4. Carcinogenicity: other routes

No relevant information available.

## 5.8.2. Human information

No relevant information available.

## 5.8.3. Summary and discussion of carcinogenicity

**Value used for CSA (route: oral):**
no study available
**Value used for CSA (route: dermal):**
no study available
**Value used for CSA (route: inhalation):**
no study available
Additional information:
There is no information available on carcinogenicity of the ECHA substance. However, since all in vitro genotoxicity tests were negative and since there was no indication in the repeated dose toxicity studies that the substance would be able to induce hyperplasia or pre-neoplastic lesions, carcinogenicity study is not needed. Carcinogenicity in humans is not expected.

# 5.9. Toxicity for reproduction

## 5.9.1. Effects on fertility

### 5.9.1.1. Non-human information

The results of studies on fertility are summarised in the following table:

**Table 5.9. Studies on fertility**

| Method | Results | Remarks |
|---|---|---|
| rat (Wistar [rat])<br>male/female<br>screening for reproductive / developmental toxicity<br>oral: gavage<br>Doses / Concentrations: 200, 500, 1000 mg/kg/day Basis: nominal conc.<br>Vehicle:<br>Exposure: males: 28 days; females: 54 days (once daily)<br>according to OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test) | **First parental generation (P0)**<br>NOAEL (PO) 1000 mg/kg bw/day (nominal))<br>(male/female) based on: general and systemic toxicity | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 5.9.1.1 2007 |

| | | |
|---|---|---|
| | | [**Error! Bookmark not defined.**] |

### 5.9.1.2. Human information

No relevant information available.

## 5.9.2. Developmental toxicity

### 5.9.2.1. Non-human information

No relevant information available.

**Testing proposal**

**Information requirement:** Developmental Toxicity / teratogenicity

**Justification for testing proposal:**

**Proposed test guideline:** according to OECD Guideline 414 (Prenatal Developmental Toxicity Study)
**Principles of method if other than guideline:**

**Planned study period:** The results should be available as soon as possible after ECHA's approval.

**Test material:** ECHA Substance / 11111-11-1, Form: liquid, detailed information: [**Error! Bookmark not defined.**]

### 5.9.2.2. Human information

No relevant information available.

## 5.9.3. Summary and discussion of reproductive toxicity

**Effects on fertility**
The following information is taken into account for any hazard / risk assessment:
Reproduction / Developmental Toxicity Screening: rat (Wistar) male/female, gavage (OECD Guideline 421): NOAEL (P and F1): >= 1000 mg/kg bw/day (male/female)
**Value used for CSA (route: oral):**
no adverse effect observed (NOAEL) 1000mg/kg bw/day (rat [common rodent species])
**Value used for CSA (route: dermal):**
no study available
**Value used for CSA (route: inhalation):**
no study available
Additional information:
Higher-tier fertility study (two-generation study) is not required at this tonnage band, since there were no adverse effects observed in the repeated dose toxicity study in reproductive organs or tissues or any adverse effects in the screening study for reproductive toxicity (OECD 421). Therefore, there is no data gap in fertility. There is no reason to believe that results of the screening study would not be relevant for fertility in humans and, therefore, for risk assessment.
**Developmental toxicity**
**Value used for CSA (route: oral):**
no study available (further information necessary)
**Value used for CSA (route: dermal):**
no study available
**Value used for CSA (route: inhalation):**
no study available
Additional information:
The dossier does not currently have a pre-natal developmental toxicity study. Therefore, there is data gap for this endpoint. This the reason why the dossier contains a testing proposal for pre-natal developmental toxicity.
**Justification for classification or non classification:**
The available data with regard to fertility is conclusive, the substance is not classified for this endpoint in accordance with the CLP Regulation (EC) No 1272/2008.
For developmental toxicity the dossier includes a testing proposal for an OECD 414 study. The study shall be

performed in 2012, after the decision from ECHA.

# 5.10. Other effects

## 5.10.1. Non-human information

### 5.10.1.1. Neurotoxicity

No relevant information available.

### 5.10.1.2. Immunotoxicity

No relevant information available.

### 5.10.1.3. Specific investigations: other studies

No relevant information available.

## 5.10.2. Human information

No relevant information available. No relevant information available. No relevant information available.

## 5.10.3. Summary and discussion of other effects

**Neurotoxicity**
**Value used for CSA (route: oral):**
no study available
**Value used for CSA (route: dermal):**
no study available
**Value used for CSA (route: inhalation):**
no study available

**Immunotoxicity**
**Value used for CSA (route: oral):**
no study available
**Value used for CSA (route: dermal):**
no study available
**Value used for CSA (route: inhalation):**
no study available

# 5.11. Derivation of DNEL(s) and other hazard conclusions

## 5.11.1. Overview of typical dose descriptors for all endpoints

**Table 5.10. Available dose-descriptor(s) per endpoint as a result of its hazard assessment**

| Endpoint | Route | Dose descriptor or qualitative effect characterisation; test type |
|---|---|---|
| Acute toxicity | oral | no adverse effect observed<br>(LD50): 2000mg/kg bw |
| Acute toxicity | dermal | no adverse effect observed<br>(LD50): 2000mg/kg bw |

| | | |
|---|---|---|
| Acute toxicity | inhalation | no adverse effect observed<br>(LC50): 62300mg/m³ |
| Irritation / Corrosivity | skin | adverse effect observed (irritating) |
| Irritation / Corrosivity | eye | adverse effect observed (irritating) |
| Irritation / Corrosivity | resp. tract | no study available |
| Sensitisation | skin | no adverse effect observed (not sensitising) |
| Sensitisation | resp. tract | no study available |
| Repeated dose toxicity | oral | adverse effect observed<br>(NOAEL): 700mg/kg bw/day (subchronic; rat [common rodent species]) |
| Repeated dose toxicity | dermal (systemic effects) | no study available |
| Repeated dose toxicity | dermal (local effects) | no study available |
| Repeated dose toxicity | inhalation (systemic effects) | no study available |
| Repeated dose toxicity | inhalation (local effects) | no study available |
| Mutagenicity | in vitro / in vivo | In vitro: no adverse effect observed (negative) |
| Carcinogenicity | oral | no study available |
| Carcinogenicity | dermal | no study available |
| Carcinogenicity | inhalation | no study available |
| Reproductive toxicity: effects on fertility | oral | no adverse effect observed<br>(NOAEL): 1000mg/kg bw/day (; rat [common rodent species]) |
| Reproductive toxicity: effects on fertility | dermal | no study available |
| Reproductive toxicity: effects on fertility | inhalation | no study available |
| Reproductive toxicity: developmental toxicity | oral | no study available (further information necessary) |
| Reproductive toxicity: developmental toxicity | dermal | no study available |
| Reproductive toxicity: developmental toxicity | inhalation | no study available |

## 5.11.2. Selection of the DNEL(s) or other hazard conclusions for critical health effects

**Table 5.11. Hazard conclusions for workers**

| Route | Type of effect | Hazard conclusion | Most sensitive endpoint |
|---|---|---|---|
| Inhalation | Systemic effects - Long-term | DNEL (Derived No Effect Level) 24.7mg/m³ | repeated dose toxicity (Oral) |
| Inhalation | Systemic effects - Acute | no hazard identified | acute toxicity (By inhalation) |
| Inhalation | Local effects - Long-term | low hazard (no threshold derived) | |
| Inhalation | Local effects - Acute | low hazard (no threshold derived) | |
| Dermal | Systemic effects - Long-term | DNEL (Derived No Effect Level) 7mg/kg bw/day | repeated dose toxicity (Oral) |
| Dermal | Systemic effects - Acute | no hazard identified | acute toxicity (Dermal) |
| Dermal | Local effects - Long-term | low hazard (no threshold derived) | skin irritation/corrosion |
| Dermal | Local effects - Acute | low hazard (no threshold derived) | skin irritation/corrosion |
| Eyes | Local effects | low hazard (no threshold derived) | |

**Inhalation Systemic effects - Long-term**

DNEL derivation method: ECHA REACH Guidance

**Modified dose descriptor starting point:** NOAEC

NOAECcorr=NOAELoral*(1/0.38 m³/kg/d)*(ABSoral-rat/ABSinh-human)*(6.7 m³ (8h)/10 m³ (8h)) = 700 mg/kg/d*(1/0.38 m³/kg/d)*(0.5*1)*0.67=617 mg/m³. It is assumed that oral absorption rate is 50% of that of inhalation absorption. ABSoral/rat=oral absorption rate in rats, ABSinh./human=inhalation absorption rate in humans

**Overall Assessment Factor:** 25

**AF for difference in duration of exposure:** 2 (DNEL is based on an oral 90 day study)

**AF for interspecies differences (allometric scaling):** 1 (Allometric scaling not used for inhalation route)

**AF for other interspecies differences:** 2.5

**AF for intraspecies differences:** 5 (workers)

**Inhalation Local effects - Long-term**

Further explanation on hazard conclusions:

No data available regarding local respiratory effects; the substance is however classified for skin and eye irritation; in the absence of route specific information, a qualitative risk characterisation is to be carried out (See section 9/10).

**Inhalation Local effects - Acute**

Further explanation on hazard conclusions:

No data available regarding local respiratory effects; the substance is classified for skin and eye irritation; in the absence of route specific information, a qualitative risk characterisation is to be carried out (See section 9/10).

**Dermal Systemic effects - Long-term**

DNEL derivation method: ECHA REACH Guidance

**Modified dose descriptor starting point:** NOAEL

It is assumed that oral and dermal absorption rates are equal.

**Overall Assessment Factor:** 100

**AF for difference in duration of exposure:** 2 (based on an oral 90 day study)

**AF for interspecies differences (allometric scaling):** 4 (experimental animal was rat)

**AF for other interspecies differences:** 2.5

**AF for intraspecies differences:** 5 (workers)

**Dermal Local effects - Long-term**

Further explanation on hazard conclusions:

The substance is classified for skin irritation.

**Dermal Local effects - Acute**

Further explanation on hazard conclusions:

The substance is classified for skin irritation; low hazard assigned according to ECHA CSA Guidance Part E Table E 3-1

**Table 5.12. Hazard conclusions for the general population**

| Route | Type of effect | Hazard conclusion | Most sensitive endpoint |
|---|---|---|---|
| Inhalation | Systemic effects - Long-term | DNEL (Derived No Effect Level) 6.08mg/m³ | repeated dose toxicity (Oral) |
| Inhalation | Systemic effects - Acute | no hazard identified | acute toxicity (By inhalation) |
| Inhalation | Local effects - Long-term | low hazard (no threshold derived) | |
| Inhalation | Local effects - Acute | low hazard (no threshold derived) | |
| Dermal | Systemic effects - Long-term | DNEL (Derived No Effect Level) 3.5mg/kg bw/day | repeated dose toxicity (Oral) |
| Dermal | Systemic effects - Acute | no hazard identified | acute toxicity (Dermal) |
| Dermal | Local effects - Long-term | low hazard (no threshold derived) | skin irritation/corrosion |
| Dermal | Local effects - Acute | low hazard (no threshold derived) | skin irritation/corrosion |
| Oral | Systemic effects - Long-term | DNEL (Derived No Effect Level) 3.5mg/kg bw/day | repeated dose toxicity (Oral) |
| Oral | Systemic effects - | no hazard identified | acute toxicity |

| | | | |
|---|---|---|---|
| | Acute | | (Oral) |
| Eyes | Local effects | low hazard (no threshold derived) | |

**Inhalation Systemic effects - Long-term**

DNEL derivation method: ECHA REACH Guidance

**Modified dose descriptor starting point:** NOAEC

NOAECcorr=NOAELoral*(1/1.15 m³/kg/d)*(ABSoral-rat/ABSinh-human) = 700 mg/kg/d*(1/1.15 m³/kg/d)*(0.5*1)=304 mg/m³ It is assumed that oral absorption rate 50% of that of inhalation absorption.

**Overall Assessment Factor:** 50

**AF for difference in duration of exposure:** 2 (DNEL is based on an oral 90 day study)

**AF for other interspecies differences:** 2.5

**AF for intraspecies differences:** 10

**Inhalation Local effects - Long-term**

Further explanation on hazard conclusions:

No data available regarding local respiratory effects; the substance is however classified for skin and eye irritation; in the absence of route specific information, a qualitative risk characterisation is to be carried out (See section 9/10).

**Inhalation Local effects - Acute**

Further explanation on hazard conclusions:

No data available regarding local respiratory effects ; the substance is however classified for skin and eye irritation; in the absence of route specific information, a qualitative risk characterisation is to be carried out (See section 9/10).

**Dermal Systemic effects - Long-term**

DNEL derivation method: ECHA REACH Guidance

**Modified dose descriptor starting point:** NOAEL

It is assumed that oral and dermal absorption rates are equal.

**Overall Assessment Factor:** 200

**AF for difference in duration of exposure:** 2 (based on an oral 90 day study)

**AF for interspecies differences (allometric scaling):** 4 (experimental animal was rat)

**AF for other interspecies differences:** 2.5

**AF for intraspecies differences:** 10 (for general population)

**Dermal Local effects - Long-term**

Further explanation on hazard conclusions:

The substance is classified for skin irritation.

**Dermal Local effects - Acute**

Further explanation on hazard conclusions:

The substance is classified for skin irritation; low hazard assigned according to ECHA CSA Guidance Part E Table E 3-1

**Oral Systemic effects - Long-term**

DNEL derivation method: ECHA REACH Guidance

**Modified dose descriptor starting point:** NOAEL

**Overall Assessment Factor:** 200

**AF for difference in duration of exposure:** 2 (based on an oral 90 day study)

**AF for interspecies differences (allometric scaling):** 4 (experimental animal was rat)

**AF for other interspecies differences:** 2.5

**AF for intraspecies differences:** 10 (for general population)

# 6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

## 6.1. Explosivity

No relevant information available.
Data waiving: see CSR section 1.3 Physicochemical properties.

**Classification according to GHS**

**Name:** ECHA Substance

Related composition:

Classification: conclusive but not sufficient for classification

## 6.2. Flammability

**Flammability**

No relevant information available.
Data waiving: see CSR section 1.3 Physicochemical properties.

**Flash Point**

The available information on flash point is summarised in the following table:

**Table 6.1. Information on flash point**

<table>
<tr><th>Method</th><th>Results</th><th>Remarks</th></tr>
<tr><td>Determination of flash point<br>non-equilibrium method closed cup - closed crucible according to DIN ISO 2719 (Pensky-Martens)<br>according to EU Method A.9 (Flash-Point)</td><td>Flash point:<br>142 °C at 101.3 kPa<br>Remarks:<br>The results of the preliminary and main tests are summarized in the following table:
<table>
<tr><th>Sample no.</th><th>Start temperature (ºC)</th><th>Gradient ºC/min)</th><th>Measured Flash point (ºC)</th><th>Atmospheric Pressure(kPa)</th><th>Corrected Flash point (ºC)</th></tr>
<tr><td>Pretest</td><td>25</td><td>8.3</td><td>148.3</td><td>102.1</td><td>150.1</td></tr>
<tr><td>1</td><td>132</td><td>1.2</td><td>142.0</td><td>102.0</td><td>143.8</td></tr>
<tr><td>2</td><td>132</td><td>1.2</td><td>144.0</td><td>101.8</td><td>145.9</td></tr>
<tr><td>3</td><td>132</td><td>1.1</td><td>140.0</td><td>101.8</td><td>141.9</td></tr>
</table></td><td>1 (reliable without restriction)<br>key study<br>experimental study<br><br>Test material<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information:<br>[Error! Bookmark not defined.]<br><br>Reference<br>Ref 6.2 2012<br>[Error! Bookmark not defined.]</td></tr>
</table>

**Discussion**

The following information is taken into account for any hazard / risk assessment:
Flash point of ECHA Substance was determined according to Regulation (EC) no 440/2208, Test method A.9, method closed crucible according to DIN ISO 2719.
**Additional information:**
The test item was heated up in a closed crucible and at defined temperatures it was tried to ignite the gaseous phase upon the surface of the liquid with the hot surface. The flash point of the test item: 142ºC / 415.2K (101.3

kPa)

**Classification according to GHS**

**Name:** ECHA Substance

Related composition:

Classification (gas): conclusive but not sufficient for classification
Classification (liquid): conclusive but not sufficient for classification
Classification (solid): conclusive but not sufficient for classification

# 6.3. Oxidising potential

No relevant information available.
Data waiving: see CSR section 1.3 Physicochemical properties.

**Classification according to GHS**

**Name:** ECHA Substance

Related composition:

Classification (gas): conclusive but not sufficient for classification
Classification (liquid): conclusive but not sufficient for classification
Classification (solid): conclusive but not sufficient for classification

# 7. ENVIRONMENTAL HAZARD ASSESSMENT

## 7.1. Aquatic compartment (including sediment)

### 7.1.1. Fish

#### 7.1.1.1. Short-term toxicity to fish

The results are summarised in the following table:

**Table 7.1. Short-term effects on fish**

| Method | Results | Remarks |
|---|---|---|
| Danio rerio (previous name: Brachydanio rerio)<br>freshwater<br>short-term toxicity to fish<br>according to EU Method C.1 (Acute Toxicity for Fish) ; according to OECD Guideline 203 (Fish, Acute Toxicity Test) | LC50 (96h): 10.3 mg/L test mat. - 95% CL = 8-16 mg/l (meas. (arithm. mean)) based on: mortality | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 7.1.1.1 2007<br>[**Error! Bookmark not defined.**] |

**Discussion**

The following information is taken into account for acute fish toxicity for the derivation of PNEC:
LC50 (96h) for freshwater fish (Danio rerio): 10.3 mg/L (OECD TG 203; static)
**Value used for CSA:**
LC50 for freshwater fish: 10.3mg/L LC50 for marine water fish:
**Additional information:**
The LC50 (96 hours) was 10.3 mg/l (measured concentration) with 95% confidence limits of 8-16 mg/l. The other results were LC50 (3 h): 21.5 mg/L test mat. (measured), LC50 (24 h): 10.3 mg/L test mat. (measured), LC50 (48 h): 10.3 mg/L test mat. (measured), LC50 (72 h): 10.3 mg/L test mat. (measured).

#### 7.1.1.2. Long-term toxicity to fish

No relevant information available.

**Data waiving**

**Information requirement:** Long-term toxicity testing to aquatic vertebrates

**Reason:** other justification

**Justification:** see 'Remark' - In accordance with column 2 of REACH Annex IX, the study shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The substance has been classified with aquatic chronic 3. The substance is not poorly water soluble. Based on the fact that the substance is not persistent, no further testing is needed to

confirm that the substance is not a PBT substance. As the exposure assessment (see chapter 9) does not indicate the need to investigate further the effects on aquatic organisms (as all the RCRs to all the compartments are well below 1 and all the supported uses are therefore assessed to be safe) no further long-term testing is proposed for aquatic compartments.

# 7.1.2. Aquatic invertebrates

## 7.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

**Table 7.2. Short-term effects on aquatic invertebrates**

| Method | Results | Remarks |
|---|---|---|
| Daphnia magna<br>freshwater<br>static<br>according to OECD Guideline 202<br>(Daphnia sp. Acute Immobilisation Test) | EC50 (24h): 24.8 mg/L test mat. (meas. (initial)) based on: mobility<br>EC50 (48h): 22.1 mg/L test mat. (meas. (initial)) based on: mobility (95% CL = 18.4 - 24.3 mg/l) | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 7.1.2.1 2006<br>[**Error! Bookmark not defined.**] |

**Discussion**

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:
EC50 (48 hours) for freshwater invertebrates (Daphnia magna): 22.1 mg/L (OECD TG 202; static)
**Value used for CSA:**
EC50/LC50 for freshwater invertebrates: 22.1mg/L EC50/LC50 for marine invertebrates:
**Additional information:**
The test substance was found to be toxic to Daphnia magna after 48 h at a measured concentration of 25.0 mg/L and lower. EC50 (24 h) was 25.8 mg/L test mat. (measured) based on: mobility; the EC100 (48h) was 50 mg/l and EC50 (48 h) was 22.1 mg/L. The LOEC after 48 hours was 25 mg/L (measured concentration).

## 7.1.2.2. Long-term toxicity to aquatic invertebrates

No relevant information available.

**Data waiving**

**Information requirement:** Long-term toxicity testing on aquatic invertebrates

**Reason:** other justification

**Justification:** see 'Remark' - In accordance with column 2 of REACH Annex IX, the study shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The substance has been classified with aquatic chronic 3. The substance is not poorly water soluble. Based on the fact that the substance is not persistent, no further testing is needed to confirm that the substance is not a PBT substance. As the exposure assessment (see chapter 9) does not indicate the need to investigate further the effects on aquatic organisms (as all the RCRs to all the compartments are well below 1 and all the supported uses are therefore assessed to be safe) no further long-

term testing is proposed for aquatic compartments.

## 7.1.3. Algae and aquatic plants

The results are summarised in the following table:

**Table 7.3. Effects on algae and aquatic plants**

| Method | Results | Remarks |
|---|---|---|
| Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) (algae) freshwater<br>toxicity to aquatic algae and cyanobacteria<br>according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006] | EC50 (72h): 52.2 mg/L test mat. (meas. (geom. mean)) based on: biomass - /yield inhibition (95%CL: 48.8-61.7 mg/l)<br>EC50 (72h): 80.6 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95%CL: 78.9-82.3 mg/l)<br>EC10 (72h): 34.8 mg/L test mat. (meas. (geom. mean)) based on: biomass - /yield inhibition (95%CL: 28.5-43.9 mg/l)<br>EC10 (72h): 51.9 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95%CL: 45.2-56.2 mg/l) | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 7.1.3 2007<br>[**Error! Bookmark not defined.**] |

**Discussion**

**Effects on algae / cyanobacteria**

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:
ErC50 (72h) for freshwater algae (Desmodesmus subspicatus): 80.6 mg/L (OECD TG 201; static)
ErC10 (72h): 51.9 mg/L
**Value used for CSA:**
EC50/LC50 for freshwater algae: 80.6mg/L EC50/LC50 for marine water algae: EC10/LC10 or NOEC for freshwater algae: 51.9mg/L EC10/LC10 or NOEC for marine water algae:
**Additional information:**
The EC50 values with 95% confidence intervals for inhibition of biomass (EbC50) and specific growth rate (ErC50) after 72 h were 52.2 (48.8-61.7) and 80.6 (78.9-82.3) mg/l, respectively . The EC20 (72 h) was 41.9 mg/L test mat. (measured) based on: biomass (/ yield inhibition) and EC20 (72 h): 61.4 mg/L test mat. (measured) based on: growth rate.

## 7.1.4. Sediment organisms

No relevant information available.

**Discussion**

The following information is taken into account for sediment toxicity for the derivation of PNEC:
**Value used for CSA:**
EC50/LC50 for freshwater algae: 80.6mg/L EC50/LC50 for marine water algae: EC10/LC10 or NOEC for freshwater algae: 51.9mg/L EC10/LC10 or NOEC for marine water algae:
**Additional information:**
Toxicity to sediment organisms is not a standard information requirement in Annex IX. Moreover, as the substance is not highly adsorptive and the exposure assessment (see chapter 9) does not indicate the need to investigate further the effects on sediment organisms (as the RCRs based on PNECsediment derived via equilibrium partitioning are well below 1 and all the supported uses are therefore assessed to be safe) no further long-term testing on sediment is proposed.

### 7.1.5. Other aquatic organisms

No relevant information available.

## 7.2. Terrestrial compartment

### 7.2.1. Toxicity to soil macro-organisms

No relevant information available.

**Data waiving**

**Information requirement:** Toxicity to soil macro-organisms except arthropods

**Reason:** other justification

**Justification:** see 'Remark' - In accordance with column 2 of REACH Annex IX in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. As the substance does not indicate high adsorption (log Kow/Koc >5) and is not persistent nor very persistent; and there is no indication that the substance is very toxic (EC/LC50 <1 mg/L for algae, daphnia or fish), the substance belongs according to REACH Guidance R.7C Table R.7.11-2 to soil hazard category 1. As the exposure assessment (see Chapter 9) based on PNECsoil(screen) does not indicate the risk for terrestrial compartment (all RCRs to all compartments are well below 1 and all the supported uses are therefore assessed to be safe) no further testing is proposed for terrestrial toxicity.

### 7.2.2. Toxicity to terrestrial plants

No relevant information available.

**Data waiving**

**Information requirement:** Effects on terrestrial plants

**Reason:** other justification

**Justification:** see 'Remark' - In accordance with column 2 of REACH Annex IX in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. As the substance does not indicate high adsorption (log Kow/Koc >5) and is not persistent nor very persistent, and there is no indication that the substance is very toxic (EC/LC50 <1 mg/L for algae, daphnia or fish), the substance belongs according to REACH Guidance R.7C Table R.7.11-2 to soil hazard category 1. As the exposure assessment (see Chapter 9) based on PNECsoil(screen) does not indicate the risk for terrestrial compartment (all RCRs to all compartments are well below 1 and all the supported uses are therefore assessed to be safe) no further testing is proposed for terrestrial toxicity.

### 7.2.3. Toxicity to soil micro-organisms

No relevant information available.

**Data waiving**

**Information requirement:** Effects on soil micro-organisms

**Reason:** other justification

**Justification:** see 'Remark' - In accordance with column 2 of REACH Annex IX in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. As the substance does not indicate high adsorption (log Kow/Koc >5) and is not persistent nor very persistent, and there is no indication that the substance is very toxic (EC/LC50 <1 mg/L for algae, daphnia or fish), the substance belongs according to REACH Guidance R.7C Table R.7.11-2 to soil hazard category 1. As the exposure assessment (see Chapter 9) based on PNECsoil(screen) does not indicate the risk for terrestrial compartment (all RCRs to all compartments are well below 1 and all the supported uses are therefore assessed to be safe) no further testing is proposed for terrestrial toxicity.

### 7.2.4. Toxicity to other terrestrial organisms

No relevant information available.

# 7.3. Atmospheric compartment

No relevant information available.

# 7.4. Microbiological activity in sewage treatment systems

The results are summarised in the following table:

**Table 7.4. Effects on micro-organisms**

| Method | Results | Remarks |
|---|---|---|
| activated sludge of a predominantly domestic sewage<br>freshwater<br>static<br>according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] | EC50 (3h): >1000 mg/L test mat. (meas. (geom. mean)) based on: inhibition of total respiration - respiration rate (water solubility is only 149 mg/L) | 1 (reliable without restriction)<br>key study<br>experimental study<br><br>**Test material**<br>ECHA Substance / 11111-11-1,<br><br>Form: liquid<br><br>detailed information: [**Error! Bookmark not defined.**]<br><br>**Reference**<br>Ref 7.1.4 2007<br>[**Error! Bookmark not defined.**] |

**Discussion**

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:
Activated Sludge, Respiration Inhibition Test: EC50(3h): >1000 mg/L corrected to >149 mg/L (water solubility) (OECD TG 209; static)
**Value used for CSA:**
EC50/LC50 for aquatic micro-organisms: 149mg/L EC10/LC10 or NOEC for aquatic micro-organisms:
**Additional information:**
The inhibition ranged from 12% to 31%. The EC50 for the test substance was determined to be greater than 1000 mg/l. However, as the substance has a water solubility of 149 mg/L, the EC50 for the test substance has been considered to be 149 mg/l.

# 7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

## 7.5.1. Toxicity to birds

No relevant information available.

**Discussion**

**Additional information:**
No information on toxicity to birds available. Toxicity to birds is not a standard information requirement in Annex IX. Moreover, as the substance is not toxic to mammals (not classified for toxicity) no further toxicity testing on birds is proposed.

## 7.5.2. Toxicity to mammals

No relevant information available.

**Discussion**

**Additional information:**
No experimental data in addition to those presented under CSR Chapter 5 is available. This is not a standard information requirement for environment in REACH. Data from CSR Chapter 5 on Human Health Hazard Assessment shows that ECHA substance is not classified nor for repeated dose toxicity or reproductive toxicity. Substance is only classified as an eye and skin irritant. The dataset is not complete and testing proposals have been presented. The need of secondary poisoning assessment will be re-evaluated based on the outcome of the proposed studies.

# 7.6. PNEC derivation and other hazard conclusions

**Table 7.5. Hazard assessment conclusion for the environment**

| Compartment | Hazard conclusion | Remarks/Justification |
|---|---|---|
| Freshwater | PNEC aqua (freshwater): 0.01mg/L<br>Intermittent releases: | Assessment factor: 1000<br>Extrapolation method: assessment factor<br>PNEC aqua (freshwater)<br>Since the three taxonomic groups (fish, invertebrates, algae) are covered but only short-term toxicity data are available for fish and invertebrates, an assessment factor of 1000 is applied on the lowest L(E)C50 of the relevant available toxicity data (fish LC50 = 10.3 mg/l). |
| Marine water | PNEC aqua (marine water): 0.001mg/L<br>Intermittent releases: | Assessment factor: 10000<br>Extrapolation method: assessment factor<br>PNEC aqua (marine water)<br>Since the three taxonomic groups (fish, invertebrates, algae) are covered but only short-term toxicity data are available for fish and invertebrates and there is no additional data on marine taxonomic groups (e.g. echinoderms, molluscs), an assessment factor of 10000 is applied on the lowest L(E)C50 of the relevant available toxicity data (fish LC50 = 10.3 mg/l). |
| Sediments (freshwater) | PNEC sediment (freshwater): 0.837mg/kg sediment dw | Extrapolation method: equilibrium partitioning method<br>PNEC sediment (freshwater)<br>Reference to equations in Guidance Part B, Version 2.1 (December 2011), paragraph B.7.2.4 - Derivation of PNEC for sediment and soil where PNECwater [mg/l]: 0.0103; Koc [cm3/g]: 776; PNECsed [mg/kg of wet sediment]: 0.182 mg/kg wet sediment = 0.837 mg/kg sediment dw |
| Sediments (marine water) | PNEC sediment (marine water): 0.084mg/kg sediment dw | Extrapolation method: equilibrium partitioning method<br>PNEC sediment (marine water)<br>Reference to equations in Guidance Part B, Version 2.1 (December 2011), paragraph B.7.2.4 - Derivation of PNEC for sediment and soil Where: PNECwater [mg/l]: 0.00103; Koc [cm3/g]: 776; PNECsed [mg/kg of wet sediment]: 0.0182 mg/kg wet sediment = 0.0837 mg/kg sediment dw |
| Sewage treatment plant | PNEC STP: 1.49mg/L | Assessment factor: 100<br>Extrapolation method: assessment factor<br>PNEC STP |

| | | |
|---|---|---|
| | | The EC50 microorganisms was determined to be greater than 1000 mg/l. As the substance has a water solubility of 149 mg/L, the EC50 for the test substance has been considered to be 149 mg/l. Applying an assessment factor of 100, the PNEC STP is 1.49 mg/l. |
| Soil | PNEC soil: 0.161mg/kg soil dw | Extrapolation method: equilibrium partitioning method PNEC soil<br>Reference to equations in Guidance Part B, Version 2.1 (December 2011), paragraph B.7.2.4 - Derivation of PNEC for sediment and soil where PNECwater [mg/l]: 0.0103; Koc [cm3/g]: 776; PNECsoil [mg/kg ww]: 0.142 mg/kg wet weight = 0.161 mg/kg soil dw |
| Air | no hazard identified: | No experimental data available. As this study is not a standard information requirement in REACH and there is no indication from the CSA on the need to investigate further the atmospheric compartment (Annex X requirement), no further testing is considered necessary. |
| Secondary poisoning | no potential to cause toxic effects if accumulated (in higher organisms) via the food chain: | The substance does not have any of the classifications for human health H373, H372, H360, H361, H362 (as mentioned in the Scope of Exposure Assessment Guidance). Therefore it can be concluded that there is no potential to cause toxic effects in the food chain. |

Conclusion on environmental classification

The results from the aquatic toxicity studies are as follows:
LC50 (96 h) fish = 10.3 mg/l (measured concentration) with 95% confidence limits of 8 -16 mg/l.
EC50 (48 h) Daphnia = 22.1 mg/l (measured concentration) with 95% confidence limits of 18.4 - 24.3 mg/l.
ErC50 (72 h) algae = 80.6 mg/l (measured concentration) with 95% confidence limits of 78.9-82.3 mg/l.
EC50 microorganisms was determined to be greater than 1000 mg/l.
No information on long-term toxicity to fish or invertebrates is available to be used for classification.
Based on the results from the short-term aquatic toxicity tests (values in the range 10 -100 mg/l) and since the substance is not readily biodegradable and has a log Kow of > 4, the substance is classified as Aquatic Chronic 3 (Hazard statement: H412) according to the CLP Regulation 1272/2008.
Based on the lowest L(E)C50 value (10.3 mg/l), the substance does not match the criteria for classification for acute aquatic hazard.

## Notes and Comments

a) According to REACH Guidance R.7b the ErC50 should always be used over EbC50 in toxicity to algae studies.

b) Details regarding the derivation methods for PNECs can be found in dedicated sections in REACH Guidance R.10.

c) If phrases for human health listed below are assigned, exposure assessment regarding secondary poisoning may be required if the substance has a log Kow ≥ 3 or BCF ≥ 100 and is not readily biodegradable.

a. H373: Causes damage to organs through prolonged or repeated exposure (cat 2)
b. H372: Causes damage to organs through prolonged or repeated exposure (cat 1)
c. H360: May damage fertility or the unborn child (cat 1A or 1B)
d. H361: Suspected of damaging fertility or the unborn child (cat 2)
e. H362: May cause harm to breast-fed child

ECHA Substance does not meet the above classification criteria. Hence, the assessment of secondary poisoning does not need to be covered.

# 8. PBT AND vPvB ASSESSMENT

## 8.1. Assessment of PBT/vPvB Properties

### 8.1.1. PBT/vPvB criteria and justification

#### 8.1.1.1. Assessed substance: substance itself

ECHA Substance

##### 8.1.1.1.1. Persistence assessment

**Evidence of non-P / non-vP properties**

**Screening criteria**
- Not P / vP based on ready biodegradability: The results of the hydrolysis study (According to OECD Guideline 111, see Chapter 4.1.1.1) revealed that the substance is stable under the test conditions. The Biodegradation DOC Die Away Test (OECD Guideline 301A, see Chapter 4.1.2.1.2) demonstrated that, although ECHA Substance did not reach the threshold of 70% degradation for being considered as "Ready Biodegradable", there was substantial microbial metabolism of ECHA Substance. Moreover, the CO2 Evolution Test (OECD Guideline 301B) confirmed that even though the substance is not readily biodegradable; it can be considered as inherently biodegradable.

Criteria based on Annex XIII of REACH
- Not P / vP based on criteria laid down in Annex XIII of REACH:
    - T1/2<=60 days in marine water: Simulation studies on water/sediment (OECD Guideline 308, see Chapter 4.1.2.1.3) revealed that ECHA Substance does not meet the 60-days degradation half-life criteria to be identified as a PBT substance in the marine environment. Half-life times for marine water (36 days at 11°C) is below the criteria for the substance to be regarded as persistent or very persistent (T1/2 <= 60 days in marine water). T1/2<=40 days in fresh- or estuarine water: No simulation data is available for fresh water/sediment compartments. However, as the degradation of chemicals in seawater is generally considered to be slower than that in freshwater tests, the available marine water/sediment simulation test is considered to cover fresh surface water and sediment as well. Therefore, based on the marine water/sediment simulation test the degradation half-life for fresh water and fresh water sediment is expected to be lower than the criteria in Annex XIII to REACH Regulation (T1/2 <= 40 days in fresh- or estuarine water, T1/2 <= 120 days in fresh- or estuarine sediment). T1/2<=180 days in marine sediment: The T1/2 for marine sediment compartment is 81 days at 11°C being well below the criteria for considering the substance as persistent in sediment (T1/2 <= 180 days).
    - T1/2<=120 days in fresh- or estuarine sediment: See Remark on "T1/2 <= 40 days in fresh- or estuarine water" T1/2<=120 days in soil: Further simulation study on soil (OECD Guideline 307, see Chapter 4.1.2.2) revealed that ECHA Substance does not meet the 120-days degradation half-life criteria to be identified as a PBT in terrestrial environment as the half-life time for soil (50 % degradation in 68 days at 12 °C) is well below the criteria for the substance to be regarded as persistent or very persistent (T1/2 <= 120 days in soil). Moreover, the substance is not very adsorptive (log Koc <3) revealing that soil is not the target compartment for ECHA Substance. That is also supported by the exposure assessment where the RCRs for soil compartment are all below 1 (highest RCR for soil: 0.239).

**Conclusion on P / vP properties:**

not P/vP.
It can be concluded that based on the criteria mentioned above the substance is not persistent (not P) and not very persistent (not vP) in the environment.

##### 8.1.1.1.2. Bioaccumulation assessment

**Conclusion on B / vB properties:**

Not assessed.

As the substance does not meet the criteria for being persistent or very persistent, no further assessment on bioaccumulation and toxicity is needed.

#### 8.1.1.1.3. Toxicity assessment

**Conclusion on T properties:**

Not assessed.
As the substance does not meet the criteria for being persistent or very persistent, no further assessment on bioaccumulation and toxicity is needed.

## 8.1.2. Summary and overall conclusions on PBT or vPvB properties

**Overall conclusion:** Based on the assessment described in the subsections above the submission substance is not a PBT / vPvB substance.
**Justification:**
The ECHA Substance is not P / vP based on criteria laid down in Annex XIII of REACH.

# 9. EXPOSURE ASSESSMENT (and related risk characterisation)

The sections 9 and 10 of this CSR have been generated with Chesar 3.2.

## 9.0. Introduction

### 9.0.1. Overview on uses

See the description of the various uses in section 2 of the CSR.
ECHA Substance is used as an additive for inks and coatings. It functions as a co-emulsifier, antifoamer and wetting agent. Mixtures for industrial and professional applications contain ECHA Substance in concentrations up to 2%. Formulated products for consumer uses contain up to 1% of ECHA Substance.
The substance is manufactured in a closed system. It is formulated into coatings and inks in batch processes. The products are used in a wide variety of industrial applications, both open and closed, such as component labelling, spraying of larger pieces in spray booths, application by roller//brush or dipping. The Substance is also present in paints used both by professionals and by consumers.

### 9.0.2. Assessment entity groups

Not applicable

### 9.0.3. Introduction to the assessment for the environment

#### 9.0.3.1. Tonnage

Assessed tonnage: 320 tonnes/year based on:

- 320 tonnes/year manufactured

Tonnage supplied per market sector:

Coatings and Inks: 200 tonnes/year

**Notes and Comments**

**Re: Overview of uses**

a) Exposure scenarios for the lubricant products have not been included in this illustrative example CSR (they account for the remaining 120 manufactured tonnes). These would normally be included in the table below and in section 9.

b) Where appropriate, exposure scenarios should address article service life. The article service life, while pertinent to the ECHA Substance, is not exemplified in this illustrative CSR.

The following table provides the tonnage per use and the local tonnages used in the assessment for each environmental contributing activity. The local tonnage corresponds to a tonnage at the site for uses taking place at industrial sites and to a tonnage assumed for a town of 10 000 inhabitants for widespread uses.

**Table 9.1. Tonnage for assessment**

| ES# | Exposure scenario (ES) name and related environmental contributing scenarios | Tonnage per use (t/year) | Daily local tonnage (t/day) | Annual local tonnage (t/year) |
|---|---|---|---|---|
| ES1 (M) | Manufacture | 320 | | |
| | - Manufacture in contained system, no water involved (ERC 1) | | 16 | 320 |
| ES2 (F) | Formulation of liquid mixtures | 320 | | |
| | - Formulation of mixture in closed and open systems (ERC 2) | | 0.5 | 100 |
| ES3 (IS) | General Industrial use of coatings and inks | 100 | | |
| | - Industrial application of coatings and inks involving water - Large scale (ERC 5) | | 0.1 | 30 |
| | - Industrial application of coatings and inks involving water - Small scale (ERC 5) | | 0.01 | 2.25 |
| | - Industrial application of coatings and inks. Water free (ERC 5) | | 0.1 | 30 |
| ES4 (PW) | Professional painting | 50 | | |
| | - Use leading to inclusion into/onto matrix (ERC 8f) | | 2.75E-5 | - |
| ES5 (C) | Consumer painting | 50 | | |
| | - Use leading to inclusion into/onto matrix (ERC 8f) | | 2.75E-5 | - |

## 9.0.3.2. Scope and type of assessment for the environment

The scope of exposure assessment and type of risk characterisation required for the environment are described in the following table based on the hazard conclusions presented in section 7.

**Table 9.2. Type of risk characterisation required for the environment**

| Protection target | Risk characterisation type | Hazard conclusion (see section 7) |
|---|---|---|
| Fresh water | Quantitative | PNEC aqua (freshwater) = 0.01 mg/L |
| Sediment (freshwater) | Quantitative | PNEC sediment (freshwater) = 0.837 mg/kg sediment dw |
| Marine water | Quantitative | PNEC aqua (marine water) = 1.03E-3 mg/L |
| Sediment (marine water) | Quantitative | PNEC sediment (marine water) = 0.084 mg/kg sediment dw |
| Sewage Treatment Plant | Quantitative | PNEC STP = 1.49 mg/L |
| Air | Not needed | No hazard identified |
| Agricultural soil | Quantitative | PNEC soil = 0.161 mg/kg soil dw |
| Predator’s prey (freshwater) | Not needed | No potential to cause toxic effects if accumulated (in higher organisms) via the food chain |
| Predator’s prey (marine water) | Not needed | No potential to cause toxic effects if accumulated (in higher organisms) via the food chain |
| Top predator’s prey (marine water) | Not needed | No potential to cause toxic effects if accumulated (in higher organisms) via the food chain |
| Predator’s prey (terrestial) | Not needed | No potential to cause toxic effects if accumulated (in higher organisms) via the food chain |

## 9.0.3.3. Fate and distribution parameters

**Physicochemical properties used for exposure estimation**

The following substance properties are used in the fate estimation done by EUSES. They correspond to the "value used for CSA" reported in sections 1 and 4.

**Table 9.3. Substance key phys-chem and fate properties**

| Substance property | Value |
|---|---|
| Molecular weight | ≥ 300 |
| Molecular weight used for the assessment | 300 |
| Melting point at 101 325 Pa | 219 K |
| Vapour pressure | 7.8 Pa at 20 °C |
| Partition coefficient (Log Kow) | 4.7 at 20 °C |
| Water solubility | 149 mg/L at 20 °C |
| Biodegradation in water: screening tests | inherently biodegradable |
| Half-life in water | 36 d at 11 °C |
| Half-life in sediment | 81 d at 11 °C |
| Half-life in soil | 36 d at 20 °C |
| Bioaccumulation: BCF (aquatic species) | 4.06E3 dimensionless |
| Adsorption/Desorption: Koc at 20 °C | 776 |

**Fate (release percentage) in the modelled biological sewage treatment plant**

In a standard (modelled) biological STP, the emissions are distributed in the following way:

| | |
|---|---|
| Release to water | 77.84% |
| Release to air | 13.64% |
| Release to sludge | 8.514% |
| Release degraded | 0% |

The above fractions are calculated by the SIMPLETREAT model integrated in EUSES.

## 9.0.3.4. Comments on assessment approach for the environment

The regional concentrations are reported in section 10.2.1.1. The local Predicted Exposure Concentrations (PECs) reported for each contributing scenario correspond to the sum of the local concentrations (Clocal) and the regional concentrations (PEC regional).
A quantitative assessment was carried out for all environmental protection targets except for air and for predators, for which no hazard had been identified.
The release estimation for the industrial scenarios is based on the following methods:

- Site related information (see manufacturing ES);Literature sources (OECD Emission Scenario Documents) (see formulation ES);
- Specific Environmental Release Categories (SPERCs) (see general industrial use of coatings and inks ES).
- Release estimation for widespread use (namely professional and consumer uses) were based on default ERC release factors.

Potential risks to environmental compartments were evaluated using fate and transport model EUSES 2.1 and release module.
The relevant OC and RMM (reported in the ES) driving the release factors (reported in corresponding exposure estimation section) reflect typical conditions of use applied at manufacturing site or by downstream users.

## Notes and Comments

**Re: Environment risk assessment**

a) The hazard identified for aquatic organisms, based on short-term toxicity studies, is extrapolated to sediments and soil with the equilibrium partitioning method. Exposure assessment is therefore carried out for water, soil and sediments (see also ECHA Guidance on Information Requirements and Chemical Safety Assessment Part D Chapter D.2.3 (Hazard conclusions determining the scope of assessment, Figure D-4).

b) Assessment on secondary poisoning is not requested, as the substance does not have any of the classifications for human health mentioned in the Scope of Exposure Assessment Guidance to trigger the detailed assessment on secondary poisoning.

c) The substance is not readily biodegradable and the PNEC is low/medium. Safe use cannot be demonstrated using default ERC release factors for release rate estimation, except for widespread uses. Consequently more appropriate release factors were used. A suitable SPERC may become available in future from the relevant downstream user organisation. Until then, the emission factors and the related conditions of use reported in this example for the industrial use of coatings are reported as if a SPERC exists, for the purpose of exemplification. They may need to be refined once the corresponding suitable SPERCs become available.

d) The substance is not regarded as PBT or vPvB. Consequently no emission minimisation is required.

e) Regarding waste, the minimum information expected to be reported in the CSR related to waste are particular considerations on waste treatment operation and the fraction of substance becoming waste.

f) See ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.16 for details on environmental exposure assessment.

### 9.0.3.5. Scope and type of assessment for man via environment

The scope of exposure assessment and type of risk characterisation required for man via the environment are described in the following table based on the hazard conclusions presented in section 5.11.

**Table 9.4. Type of risk characterisation required for man via the environment**

| Route of exposure and type of effects | Risk characterisation type | Hazard conclusion (see section 5.11) |
|---|---|---|
| **Inhalation:** Long term, Systemic | Quantitative | DNEL (Derived No Effect Level) = 6.08 mg/m³ |
| **Oral:** Long term, Systemic | Quantitative | DNEL (Derived No Effect Level) = 3.5 mg/kg bw/day |

## Notes and Comments

**Re: Man Via Environment – Scope of the exposure**

According to R.16 on Environmental Exposure Assessment:

"An assessment of indirect exposure of humans via the environment is generally only conducted if: a) the tonnage >1 000 t/y or b) the tonnage >100 t/y **and** the substance is classified b1) as STOT RE 1; or b2) as a carcinogen or mutagen (any category); or b3) as toxic to reproduction (categories 1A or 1B). "

The ECHA Substance is manufactured between 100 and 1000 t/y and not classified with any of the mentioned hazard categories, therefore the risk assessment for humans via the environment can be omitted. However, it is reported here for illustration purposes.

# 9.0.4. Introduction to the assessment for workers

## 9.0.4.1. Scope and type of assessment for workers

The scope of exposure assessment and type of risk characterisation required for workers are described in the following table based on the hazard conclusions presented in section 5.11.

**Table 9.5. Type of risk characterisation required for workers**

| Route | Type of effect | Risk characterisation type | Hazard conclusion (see section 5.11) |
|---|---|---|---|
| **Inhalation** | Systemic effects - long term | Quantitative | DNEL (Derived No Effect Level) = 24.7 mg/m³ |
| | Systemic effects - acute | Not needed | No hazard identified |
| | Local effects - long term | Qualitative | Low hazard (no threshold derived) |
| | Local effects - acute | Qualitative | Low hazard (no threshold derived) |
| **Dermal** | Systemic effects - long term | Quantitative | DNEL (Derived No Effect Level) = 7 mg/kg bw/day |
| | Systemic effects - acute | Not needed | No hazard identified |
| | Local effects - long term | Qualitative | Low hazard (no threshold derived) |
| | Local effects - acute | Qualitative | Low hazard (no threshold derived) |
| **Eye** | Local effects | Qualitative | Low hazard (no threshold derived) |

## 9.0.4.2. Comments on assessment approach for workers

**Concentration limits for uses in mixture**

The following concentration limits are set for use in mixture. If the substance is in a mixture below those concentrations, qualitative risks are assumed to be controlled for the respective route and type of effects:
• Dermal local effect: 10%
Explanation:
The generic concentration triggering mixture classification for skin irritation category 2 is 10%. It is therefore assumed that no skin irritation occurs on exposure to the substance in mixtures below this concentration. Note: This assumption applies, if risk characterisation against a DNEL or observation from human data do not

conclude differently.
• Eye effect: 10%
Explanation:
The generic concentration triggering mixture classification for eye irritation category 2 is 10%. It is therefore assumed that no eye irritation occurs on exposure to the substance in mixtures below this concentration. Note: This assumption applies, if risk characterisation against a DNEL or observation from human data do not conclude differently.

**Assessment approach related to toxicological hazard:**

A **quantitative** assessment was carried out for long term systemic hazards via skin and inhalation. The exposure of workers was estimated primarily using the ECETOC TRA (April 2012 version 3) modelling tool. However, for some of the contributing activities complementary or alternative approaches were taken:

1. For industrial use of spray coating and the related exposure in form of aerosols, measured exposure data were used to support the exposure estimation from ECETOC TRA. The TRA only predicts exposure in vapour form, however the vapour pressure of the ECHA substance is relatively low and thus the contribution of the aerosol to the overall exposure via inhalation is high; the measured exposure information reduces the uncertainty around the modelled exposure. It was, however, not possible to base the assessment on measured data only, as the available measured data set was too small.

2. For professional uses of coating by spraying and by roller/brush application it was not possible to demonstrate safe use with ECETOC TRA tool, and thus the Stoffenmanager and ART exposure estimation tools were used.

For systemic hazards, short-term and peak exposures were not quantitatively assessed because the substance is not classified regarding acute systemic toxicity.
A qualitative assessment was carried out to assess irritation for all routes. For this endpoint the “low hazard” band was assigned for skin and for eye irritation, following the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Part E, Table E.3-1. With a view to the irritation effects on skin and eyes and in the absence of data from an inhalation study, it is assumed (as reasonable worst case) that the substance may also cause irritation in the respiratory tract; however, there are no alerts of particular strong effects (substance neither corrosive nor reactive). The qualitative assessment differentiates between uses in concentrations of 10% or more (1) and uses where the concentration in the mixture is lower than 10% (2):

(1) The OC/RMMs for safe use determined in the quantitative assessment for systemic effects were evaluated as to whether they provide sufficient protection against irritation effects, or whether additional measures are needed.
- The risk is characterised by comparing the estimated exposure with the COSHH Essentials benchmark range for the Hazard Group B (5-50 ppm) (HSE: The technical basis for COSHH essentials: Easy steps to control chemicals; Table 3, http://www.coshh-essentials.org.uk/assets/live/CETB.pdf). For ECHA Substance, this corresponds to a range of 60 to 600 mg/m3. This is well above the DNEL of 24.7 mg/m3 derived for long-term systemic effects. It can therefore be assumed that the likelihood of adverse effects with respect to respiratory tract irritation is low, when the conditions of use are protective for long-term systemic effects. For a few scenarios the calculated short-term exposure value exceeds the threshold for long-term systemic effects (with 8h TWA remaining below the DNEL value), however it is still below 60 mg/m3. Consequently also in such situation the likelihood of respiratory irritation is low.
- For dermal and eye exposure, the qualitative assessment considers whether there is potential for exposure during the activity. If this is considered to be probable, PPE is required.

(2) For use in mixtures with concentration < 10% (generic concentration cut off for classification of mixtures regarding irritating components), the hazard is considered negligible and thus risk management measures with respect to irritation effects are not required for any of the exposure routes. This is based on the “low hazard” categorisation for the pure substance (see above), and the low vapour pressure (< 500 Pa), which allows to apply the concentration cut-off also for the respiratory route (irritation through vapours released from presence in diluted mixture is unlikely).

The criteria for selection of OC/RMM are summarized here below:

1. The minimum RMMs necessary to ensure the exposure levels are safe (covering all relevant endpoints, and the combined risk) were applied, taking into account uncertainty of exposure estimation and knowledge of good practice in the industry.

2. If technically feasible, engineering controls such as LEV have been recommended as preferred RMM option to reduce risk for industrial (and professional – where possible) workers in accordance with good occupational

hygiene practice.

3. Limiting the duration of an activity has not been used as a risk management measure. Where durations shorter than 8 hours have been applied in the assessment, it is based on the assumption that the activity/task within a shift is short by nature.

**General information on risk management related to toxicological hazard:**

The main specifications for personal protective equipment (PPE) appropriate for ECHA Substance are as follows:

• Respiratory Protective Equipment: Filter type A. To be combined with particulate filter when there is potential for exposure to aerosol, for example, in spraying operations

• Gloves: Butyl rubber gloves conforming to EN374, with thickness of > 0.7mm. Breakthrough time to be greater than task duration. Gloves should be worn when there is potential for dermal exposure.

## Notes and Comments

**Re: Worker Risk Assessment**

a) The ECETOC TRA tool does not support estimation of exposure where the aerosol or mist of a liquid substance is the dominating form of exposure. Thus for the paint spraying scenario supporting measurements or alternative exposure estimation tools were used.

b) Exposure estimates under REACH refer to single substances and are carried out for each single activity [task] contributing to a use. The minimum OC/RMMs per task necessary for safe use were specified, considering normal good practice within industry. Limiting the duration of an activity has not been used to refine the exposure assessment. Consequently for most contributing scenarios a full shift exposure is assumed, in order to avoid that demonstrating control of risk depends on assumptions about which contributing activities are carried out by a single worker over a shift (combined risk across tasks). For some contributing activities it has however been assumed that they are short by nature, and the corresponding risk characterisation ratio is low. The safety assessment by the REACH registrant usually cannot replace the site based risk assessment in accordance with occupational health and safety regulations. Additional or modified RMMs may be required due to the combination of tasks and/or substances that the worker is exposed to.

c) The current CSR example is not based on the "Use map" of the coating industry, as this was not published yet when the current example was updated. Registrants are nevertheless advised to make use of them while undertaking the CSA for their substances. Updated sectors used maps can be found in ECHA's use map library (https://echa.europa.eu/csr-es-roadmap/use-maps/use-map-library).

d) Regarding respiratory PPE, the mask-type (or effectiveness) and the filter-types have been specified; for dermal protection, information on the glove material, its thickness and the expected breakthrough time have been included into the CSR. In the ECETOC TRA assessment, the assumed effectiveness of the gloves is dependent on the type of instruction and training in working with gloves. Three levels of training can be chosen with corresponding effectiveness values. However the further details of glove handling (such as frequency of changing gloves, maintenance, storing, recording) are not included in the CSR but left to the local risk assessment. The same applies to handling details regarding respiratory equipment. Dermal protection may go beyond gloves (which is the only dermal PPE foreseen in ECETOC TRA), for example, protective clothing, gauntlets, aprons, face shields etc. Where obviously required such additional measures have been included in the CSR. When PPE is recommended in the exposure scenario, it is meant to be generally worn

during the time of the identified tasks. If there are phases of no potential exposure during a task, where PPE is not needed, is again of local assessment and not covered in the CSR.

e) PPE was used to protect against dermal and eye irritancy when dealing with the concentrated substance, whenever there was potential for exposure (based on the qualitative assessment). In the formulated product, the substance is diluted to below the cut-off limits for eye and dermal irritancy classification. Consequently PPE was not recommended further down the supply chain except if required to protect against long term systemic health effects.

f) The assumption on the system in place for occupational health and safety (OSH), including housekeeping, significantly impacts on the expectable effectiveness of risk management and exposure estimates. The ECETOC TRA for example offers two choices: basic system [= professional setting = good occupational hygiene practice] and advanced [industrial setting]. Advanced system and practices include effective instruction, training and supervision of workers and effective regular maintenance of equipment.

g) See ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R14 for details on occupational exposure assessment.

h) See Practical Guide 15 "How to undertake a qualitative human health assessment and document it in a Chemical Safety Report" for details on qualitative assessments.

## 9.0.5. Introduction to the assessment for consumers

### 9.0.5.1. Scope and type of assessment for consumers

The scope of exposure assessment and type of risk characterisation required for consumers are described in the following table based on the hazard conclusions reported and justified in section 5.11.

**Table 9.6. Type of risk characterisation required for consumers**

| Route | Type of effect | Risk characterisation type | Hazard conclusion (see section 5.11) |
|---|---|---|---|
| **Inhalation** | Systemic effects - long term | Quantitative | DNEL (Derived No Effect Level) = 6.08 mg/m³ |
| | Systemic effects - acute | Not needed | No hazard identified |
| | Local effects - long term | Qualitative | Low hazard (no threshold derived) |
| | Local effects - acute | Qualitative | Low hazard (no threshold derived) |
| **Dermal** | Systemic effects - long term | Quantitative | DNEL (Derived No Effect Level) = 3.5 mg/kg bw/day |
| | Systemic effects - acute | Not needed | No hazard identified |
| | Local effects - long term | Qualitative | Low hazard (no threshold derived) |
| | Local effects - acute | Qualitative | Low hazard (no threshold derived) |
| **Oral** | Systemic effects - long term | Quantitative | DNEL (Derived No Effect Level) = 3.5 mg/kg bw/day |
| **Eye** | Local effects | Qualitative | Low hazard (no threshold derived) |

### 9.0.5.2. Comments on assessment approach for consumers

**Concentration limits for uses in mixture**

The following concentration limits are set for use in mixture. If the substance is in a mixture below those concentrations, qualitative risks are assumed to be controlled for the respective route and type of effects:
• Dermal local effect: 10%
Explanation:
The generic concentration triggering mixture classification for skin irritation category 2 is 10%. It is therefore assumed that no skin irritation occurs on exposure to the substance in mixtures below this concentration. Note: This assumption applies, if risk characterisation against a DNEL or observation from human data do not conclude differently.
• Eye effect: 10%
Explanation:
The generic concentration triggering mixture classification for eye irritation category 2 is 10%. It is therefore assumed that no eye irritation occurs on exposure to the substance in mixtures below this concentration. Note: This assumption applies, if risk characterisation against a DNEL or observation from human data do not conclude differently.

**Further information on assessment approach for consumers:**

Consumer exposure was assessed using Tier 2 tool (ConsExpo Web), since Tier 1 (ECETOC TRA, Consumers v.3) tools were not able to demonstrate the safe use of the substance for consumer use of paints. ConsExpo Web has been used in connection with relevant RIVM fact sheet to describe consumer use of different products (water based and solvent rich).
ECHA Substance is used in consumer products at concentrations well below 10% (generic concentration cut off for classification of mixtures regarding irritating components). Therefore, the hazard is considered negligible and thus risk management measures with respect to irritation effects are not required for any of the exposure routes. This is based on the “low hazard” categorisation for the pure substance (see above), and the low vapour pressure (< 500 Pa), which allows to apply the concentration cut-off also for the respiratory route (irritation through vapours released from presence in diluted mixture is unlikely).

## Notes and Comments

**Re: Consumer Risk Assessment**

a) ConsExpo Web, a Tier II tool based on an evaporation model exposure estimation tool was used for consumer exposure. The RCR determined using the exposure estimation based on the ECETOC TRA Consumer v.3 model was > 1. This is mainly due to the fact that, despite the low volatility of ECHA Substance, it falls into one of the upper volatility bands of the TRA tool. Consequently a Tier II tool, ConsExpo Web, in which a broader range of input parameters is used, was used to demonstrate safe use of the substance.

b) Tier II tools like ConsExpo generally have more input parameters than ECETOC TRA that can more precisely describe use conditions. All input parameters should be reported so that the calculation can be reproduced.

c) See ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R15 for details on consumer exposure assessment

# 9.1. Exposure scenario 1: Manufacture - Manufacture

| | | |
|---|---|---|
| **Environment contributing scenario(s):** | | |
| CS 1 | Manufacture in contained system, no water involved | ERC 1 |
| **Worker contributing scenario(s):** | | |
| CS 2 | Closed manufacturing process | PROC 1 |
| CS 3 | Transfer of substance or mixture (charging/discharging) at dedicated facilities | PROC 8b |
| CS 4 | Equipment cleaning and maintenance | PROC 28 |

**Further description of the use:**

Manufacture of the ECHA Substance takes place in closed system, including automated sampling and analysis. Final transfer of the substance into containers is also considered. Maintenance and cleaning operations require worker's manual intervention: prior to this, the system is emptied and purged.

**Explanation on the approach taken for the ES**

The substance is manufactured in a closed continuous process (PROC 1).
Releases to environmental compartments are based on both site information and ERC - specific release factors, taking into account the following assumptions:

- No water releases occur since water is not used in the process or for cleaning / maintenance operations; solvents used for such activities are collected and treated as hazardous waste
- Exhaust air from the process is collected and sent to an on-site incineration unit. An initial release, before RMMs, has been estimated using ERC1 default release factor.
- Wastes collected during cleaning and maintenance operations are also incinerated on-site.

The main opportunity for worker exposure is during maintenance and cleaning operations, which involve opening the system for access. For estimating the exposure during such maintenance and cleaning operations (PROC 28) with the available lower Tier modelling tools, a conservative assumption had to be made: the exposure potential is similar to the exposure potential occurring during transfer of substance from/to vessels at non-dedicated facilities, because there is a potential for a direct contact with the substance, and there is no particular process design / engineering measures to control the exposure (except for emptying and purging before opening). Consequently, when applying the ECETOC TRA workers for exposure estimation, the exposure corresponding to PROC 8a in TRA was used.

## Notes and Comments

**Re: Content of the Introductory section to exposure assessments**

This section should:

- provide a clear and concise description of the activities/processes covered in the exposure scenario;
- highlight where methodology applied deviates from standard methodology described previously;
- identify main events where exposure to humans and environment occurs;
- provide any additional information to assist the reader in correctly interpreting the exposure scenarios.

**Re: Maintenance and cleaning activities**

There is a specific process category (PROC 28) now available suitable to describe

periodic (but not necessarily daily) cleaning and maintenance, if such activities are not already covered in one or more of the other contributing scenarios. This includes, for example, interventions into closed systems and cleaning of machinery and vessels between batches. It may also include changing of filters, maintenance of reservoirs of processing fluids and similar tasks. The exposure assessment should include a contributing scenario describing conditions for this. Repair due to accidental malfunction or renovation/reconstruction of production plants is however out of scope of the REACH safety assessment. The ECETOC TRA does not associate any (initial) exposure estimation to this PROC. Nevertheless the TRA-based exposure estimation, with PROC 8a (transfer of substance at non-dedicated facility) has been considered appropriate in this scenario to describe the potential for contact with the substance during maintenance. Should maintenance tasks be preceded by automated washing / purging of the system conducted to eliminate / minimise the residue of the substance in the system, the expected exposure during the task may be much lower (potentially to be determined by other modelling tools or measured data). Note: The practical approaches for building contributing scenarios related to cleaning and maintenance and how purging/washing are still under development, and it is expected that industry come up with a range of valid solution. There is a standard phrase available in the ESCom catalogue "Drain down and flush system prior to equipment break-in or maintenance". Some registrants associate this measure with an efficiency of 90% or more in relation to a PROC 8a exposure estimate in the TRA.

## 9.1.1. Env CS 1: Manufacture in contained system, no water involved (ERC 1)

### 9.1.1.1. Conditions of use

| Amount used, frequency and duration of use (or from service life) |
|---|
| • Daily use amount at site: <= 16.0 tonnes/day |
| • Annual use amount at site: <= 320.0 tonnes/year |
| Technical and organisational conditions and measures |
| • No water used in process or maintenance (cleaning) operation |
| • Exhaust air incineration (on site) [Effectiveness Air: 99%] |
| Conditions and measures related to biological sewage treatment plant |
| • Biological STP: None [Effectiveness Water: 0%] |
| Conditions and measures related to external treatment of waste (including article waste) |
| • Particular considerations on the waste treatment operations: Other<br>*Waste is incinerated on site by incineration conforming to standard as laid down in 2000/76/EC Directive. When incinerated on site full decomposition is expected and thus releases are negligible* |
| Other conditions affecting environmental exposure |
| • Receiving surface water flow rate: >= 18000 m3/day |
| • Discharge rate of effluent: >= 2000 m3/day |

### 9.1.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

**Table 9.7. Local releases to the environment**

| Release | Release estimation method | Explanations |
|---|---|---|
| Water | Estimated release factor (Manufacturing site specific) | **Release factor before on site RMM:** 0%<br>**Release factor after on site RMM:** 0%<br>**Local release rate:** 0 kg/day<br>**Explanation:**<br>No water used in the process or for cleaning equipment/maintenance operation. |
| Air | ERC | **Release factor before on site RMM:** 5%<br>**Release factor after on site RMM:** 0.05%<br>**Local release rate:** 8 kg/day |
| Non agricultural soil | Estimated release factor (Manufacturing site specific) | **Release factor after on site RMM:** 0%<br>**Explanation:**<br>Closed system. No release to soil. |

**Releases to waste**

**Release factor to external waste:** 0 %
Waste containing substance is incinerated on site. No waste containing ECHA Substance is expected to be generated from incineration process. Therefore, the release factor to "external" waste treatment facilities is set to 0.

**Notes and Comments**

**Re: Release Estimation Refinement**

Release estimation from the manufacturing stage exemplifies the case where no measured data is available but information on processes and RMM driving the release to the environment are well known.

- Release to water has been assumed to be 0 since the process is water free (cleaning operation included). For release to air, the initial release is based on the ERC release factor of 5%.
- Exhaust air is incinerated on-site, which is assumed to reduce the emissions by a factor of 100.
- There is no direct release to soil.
- The fraction of substance going to waste from the process can be conservatively set to 6% (assuming that potential release to water, described by the ERC release factor, is transferred to waste). However, since the collected waste is incinerated on site, release to external waste is set to 0. Release to waste (or a mass balance indicating the fraction of substance going to waste) is the minimum information to be reported in the CSR for the waste stage.

These OC/RMM for reducing or avoiding releases are reported in the environmental contributing scenario (CS), section 9.1.1.

### 9.1.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

**Table 9.8. Exposure concentrations and risks for the environment and man via the environment**

| Protection target | Exposure concentration | Risk quantification |
|---|---|---|
| Fresh water | **Local PEC:** 1.16E-5 mg/L | RCR < 0.01 |
| Sediment (freshwater) | **Local PEC:** 9.41E-4 mg/kg dw | RCR < 0.01 |
| Marine water | **Local PEC:** 1.08E-6 mg/L | RCR < 0.01 |
| Sediment (marine water) | **Local PEC:** 8.75E-5 mg/kg dw | RCR < 0.01 |
| Sewage Treatment Plant | **Local PEC:** 0 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 5.05E-5 mg/kg dw | RCR < 0.01 |
| Man via environment - Inhalation | **Concentration in air:** 1.23E-4 mg/m³ | RCR < 0.01 |
| Man via environment - Oral | **Exposure via food consumption:** 2.99E-4 mg/kg bw/day | RCR < 0.01 |
| Man via environment - combined routes | | RCR < 0.01 |

# 9.1.2. Worker CS 2: Closed manufacturing process (PROC 1)

## 9.1.2.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 100.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Closed process without likelihood of exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

## 9.1.2.2. Exposure and risks for workers

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

**Table 9.9. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 0.125 mg/m³ (TRA Workers) | RCR < 0.01 |
| Inhalation, local, long term | 0.125 mg/m³ (TRA Workers) | |

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, local, acute | 0.5 mg/m³ (TRA Workers) | |
| Dermal, systemic, long term | 0.034 mg/kg bw/day (TRA Workers) | RCR < 0.01 |
| Combined routes, systemic, long-term | | RCR < 0.01 |

**Risk characterisation**

Qualitative risk characterisation:
The exposure by inhalation is well below the long-term DNEL. This indicates at the same time that the likelihood of adverse effects due to irritancy on the respiratory tract is also low, for short-term and for long-term exposure (explanation see section 9.0.4.2).
No contact to skin or eyes is expected (local dermal effects), as the manufacturing process is a closed system. Under these use conditions, no local effects on respiratory tract, skin and eyes are expected.

# 9.1.3. Worker CS 3: Transfer of substance or mixture (charging/discharging) at dedicated facilities (PROC 8b)

## 9.1.3.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 100.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Local exhaust ventilation: Yes [Effectiveness Inhalation: 95%, Dermal: 0%] | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with basic employee training) and (other) appropriate dermal protection [Effectiveness Dermal: 90%] | TRA Workers 3.0 |
| • Use of eye protection: Yes | |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

## 9.1.3.2. Exposure and risks for workers

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

**Table 9.10. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 3.125 mg/m³ (TRA Workers) | RCR = 0.127 |

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, local, long term | 3.125 mg/m³ (TRA Workers) | |
| Inhalation, local, acute | 12.5 mg/m³ (TRA Workers) | |
| Dermal, systemic, long term | 1.371 mg/kg bw/day (TRA Workers) | RCR = 0.196 |
| Combined routes, systemic, long-term | | RCR = 0.322 |

**Risk characterisation**

Qualitative risk characterisation:
The exposure by inhalation is well below the long-term DNEL. This indicates at the same time that the likelihood of adverse effects due to irritancy on the respiratory tract is also low, for short-term and for long-term exposure (explanation see section 9.0.4.2).
Skin irritancy is controlled by using suitable dermal protection equipment, while eye irritancy is controlled by using of face shield or goggles. Under these use conditions, no local effects on respiratory tract, skin and eyes are expected.

## 9.1.4. Worker CS 4: Equipment cleaning and maintenance (PROC 28)

Scheduled maintenance and cleaning operation, including manual cleaning of open vessels.

### 9.1.4.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 100.0 % | TRA based on PROC 8a 3.0 |
| • Physical form of the used product: Liquid | TRA based on PROC 8a 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 4.0 h/day | TRA based on PROC 8a 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA based on PROC 8a 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA based on PROC 8a 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA based on PROC 8a 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with basic employee training) and (other) appropriate dermal protection [Effectiveness Dermal: 90%] | TRA based on PROC 8a 3.0 |
| • Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhalation: 90%] | TRA based on PROC 8a 3.0 |
| • Use of eye protection: Yes | |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA based on PROC 8a 3.0 |
| • Operating temperature: <= 40.0 °C | TRA based on PROC 8a 3.0 |

## 9.1.4.2. Exposure and risks for workers

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

**Table 9.11. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 7.5 mg/m³ (TRA based on PROC 8a 3.0) | RCR = 0.304 |
| Inhalation, local, long term | 7.5 mg/m³ (TRA based on PROC 8a 3.0) | |
| Inhalation, local, acute | 50 mg/m³ (TRA based on PROC 8a 3.0) | |
| Dermal, systemic, long term | 1.371 mg/kg bw/day (TRA based on PROC 8a 3.0) | RCR = 0.196 |
| Combined routes, systemic, long-term | | RCR = 0.499 |

**Remarks on exposure data from external estimation tools:**

TRA based on PROC 8a 3.0
Explanation: PROC 8a has been used for exposure estimation since it assumes direct contact with the substance and no particular design control to limit exposure.

**Risk characterisation**

Qualitative risk characterisation:
The daily average exposure by inhalation is well below the long-term DNEL. This indicates at the same time that the likelihood of adverse effect due to irritancy on the respiratory tract is also low (explanation see section 9.0.4.2). Also for short-term exposure situations the calculated exposure is still below the COSSH benchmark. (i.e. 60 mg/m3 for the ECHA substance).
Skin irritancy is controlled by using suitable dermal protection equipment, while eye irritancy is controlled by using of face shield or goggles. Under these use conditions, no local effects on respiratory tract, skin and eyes are expected.

# 9.2. Exposure scenario 2: Formulation or re-packing - Formulation of liquid mixtures

| | | |
|---|---|---|
| **Environment contributing scenario(s):** | | |
| CS 1 | Formulation of mixture in closed and open systems | ERC 2 |
| **Worker contributing scenario(s):** | | |
| CS 2 | Receiving and charging of the substance | PROC 8b |
| CS 3 | Mixing or blending in batch processes; Closed systems | PROC 3 |
| CS 4 | Mixing or blending in batch processes; Open systems | PROC 5 |
| CS 5 | Transfer of substance or mixture (charging/discharging) at non dedicated-facilities | PROC 8a |
| CS 6 | Transfer of substance or mixture (charging/discharging) at dedicated facilities | PROC 8b |
| CS 7 | Transfer of substance or mixture into small containers (dedicated filling line, including weighing) | PROC 9 |
| CS 8 | Equipment cleaning and maintenance | PROC 28 |

**Further description of the use:**

Formulation refers to the mixing of raw materials to produce liquid mixtures, including products such as paints, coatings, inks, lubricants, and filling containers in dedicated facilities.
Formulation steps that require worker intervention include: receiving and charging the substance; mixing in open batch processes; non-automated transfer of the mixtures and filling small to medium sized containers. Maintenance and cleaning operations are also included.

**Explanation on the approach taken for the ES**

The environmental emission estimates for coatings and inks are based on emission scenarios developed by OECD by the UK Environment Protection Agency (2009).
The main opportunity for worker exposure arises from open process and maintenance cleaning operations.

## 9.2.1. Env CS 1: Formulation of mixture in closed and open systems (ERC 2)

### 9.2.1.1. Conditions of use

| |
|---|
| Amount used, frequency and duration of use (or from service life) |
| • Daily use amount at site: <= 0.5 tonnes/day |
| • Annual use amount at site: <= 100.0 tonnes/year |
| Technical and organisational conditions and measures |
| • Collect water from equipment/container cleaning as waste |
| Conditions and measures related to biological sewage treatment plant |
| • Application of the STP sludge on agricultural soil: Yes |
| • Biological STP: Standard [Effectiveness Water: 22.16%] |
| • Discharge rate of STP: >= 2000 m3/day |
| Conditions and measures related to external treatment of waste (including article waste) |
| • Particular considerations on the waste treatment operations: Other<br>*Off site incineration of waste containing ECHA substance in accordance with 2000/76/EC Directive. When disposed of via incineration complete decomposition is expected and thus releases are negligible* |
| Other conditions affecting environmental exposure |
| • Receiving surface water flow rate: >= 18000 m3/day |

### 9.2.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

**Table 9.12. Local releases to the environment**

| Release | Release estimation method | Explanations |
|---|---|---|
| Water | Estimated release factor (OECD ESD coatings) | **Release factor before on site RMM:** 0.05%<br>**Release factor after on site RMM:** 0.05%<br>**Local release rate:** 0.25 kg/day<br>**Explanation:**<br>Adapted from the EMISSION SCENARIO DOCUMENT ON COATINGS INDUSTRY (PAINTS, LACQUERS AND VARNISHES), OECD, July 2009.<br>Release for liquid substances to waste or wastewater is possible only via equipment and/or packaging cleaning and workshop cleaning (OECD 2009).<br>Fluids used for cleaning equipment or packaging containing ECHA substance should be collected as waste and sent to external waste treatment, so that release to wastewater has been set equal to 0.05%, equal to the substance fraction unintentionally spread within the workshop (OECD 2009) |
| Air | Estimated release factor (OECD ESD coatings) | **Release factor before on site RMM:** 0.6%<br>**Release factor after on site RMM:** 0.6%<br>**Local release rate:** 3 kg/day<br>**Explanation:**<br>Taken from the EMISSION SCENARIO DOCUMENT ON COATINGS INDUSTRY (PAINTS, LACQUERS AND VARNISHES), OECD, July 2009. It is based on worst case release factor for low volatility substance (<1000 Pa) and high boiling point (> 120°C) |
| Non agricultural soil | Estimated release factor (OECD ESD coatings) | **Release factor after on site RMM:** 0%<br>**Explanation:**<br>No release to soil |

**Releases to waste**

**Release factor to external waste:** 1 %
Substance in waste comes from packaging material and cleaning fluids (ref. OECD, 2009)
No RMM assumed

**Notes and Comments**

**Re: Release Estimation Refinement**

a) Releases to water are possible only via the cleaning operation (including floor cleaning). OECD ESD (Emission Scenario Documents) on Coating Industry (Paints, Lacquers and Varnishes) 2009, was used as supportive source to refine the release estimation for water. The same source was used to establish the release factor to air, according to vapour pressure and boiling point.

b) There is no potential for direct release to soil, based on both the OECD ESD and from

knowledge of the process.

c) Justification and explanation on the release factors are reported in the exposure table above, while conditions of use driving the release factor (e.g. collecting water for equipment or container cleaning as waste) are clearly reported in the contributing scenarios for environment.

### 9.2.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

**Table 9.13. Exposure concentrations and risks for the environment and man via the environment**

| Protection target | Exposure concentration | Risk quantification |
|---|---|---|
| Fresh water | **Local PEC:** 9.73E-3 mg/L | RCR = 0.945 |
| Sediment (freshwater) | **Local PEC:** 0.79 mg/kg dw | RCR = 0.944 |
| Marine water | **Local PEC:** 9.73E-4 mg/L | RCR = 0.945 |
| Sediment (marine water) | **Local PEC:** 0.079 mg/kg dw | RCR = 0.944 |
| Sewage Treatment Plant | **Local PEC:** 0.097 mg/L | RCR = 0.065 |
| Agricultural soil | **Local PEC:** 0.038 mg/kg dw | RCR = 0.239 |
| Man via environment - Inhalation | **Concentration in air:** 4.58E-4 mg/m³ | RCR < 0.01 |
| Man via environment - Oral | **Exposure via food consumption:** 0.039 mg/kg bw/day | RCR = 0.011 |
| Man via environment - combined routes | | RCR = 0.011 |

## 9.2.2. Worker CS 2: Receiving and charging of the substance (PROC 8b)

### 9.2.2.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 100.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: Yes [Effectiveness Inhalation: 95%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Use of eye protection: Yes | |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |

| | Method |
|---|---|
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

### 9.2.2.2. Exposure and risks for workers

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

**Table 9.14. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 3.125 mg/m³ (TRA Workers) | RCR = 0.127 |
| Inhalation, local, long term | 3.125 mg/m³ (TRA Workers) | |
| Inhalation, local, acute | 12.5 mg/m³ (TRA Workers) | |
| Dermal, systemic, long term | 2.742 mg/kg bw/day (TRA Workers) | RCR = 0.392 |
| Combined routes, systemic, long-term | | RCR = 0.518 |

**Risk characterisation**

Qualitative risk characterisation:
The exposure by inhalation is well below the long-term DNEL. This indicates at the same time that the likelihood of adverse effects due to irritancy on the respiratory tract is also low, for short-term and for long-term exposure (explanation see section 9.0.4.2).
Skin irritancy is controlled by using suitable dermal protection equipment, while eye irritancy is controlled by using of face shield or goggles. Under these use conditions, no local effects on respiratory tract, skin and eyes are expected.

## 9.2.3. Worker CS 3: Mixing or blending in batch processes; Closed systems (PROC 3)

### 9.2.3.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 100.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Closed batch process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%]<br>*Dermal protection to be used only when there potential for exposure (e.g. sampling).* | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Use of eye protection: Yes | |

| | Method |
|---|---|
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

### 9.2.3.2. Exposure and risks for workers

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

**Table 9.15. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 3.75 mg/m³ (TRA Workers) | RCR = 0.152 |
| Inhalation, local, long term | 3.75 mg/m³ (TRA Workers) | |
| Inhalation, local, acute | 15 mg/m³ (TRA Workers) | |
| Dermal, systemic, long term | 0.138 mg/kg bw/day (TRA Workers) | RCR = 0.02 |
| Combined routes, systemic, long-term | | RCR = 0.172 |

**Risk characterisation**

Qualitative risk characterisation:
The exposure by inhalation is well below the long-term DNEL. This indicates at the same time that the likelihood of adverse effects due to irritancy on the respiratory tract is also low, for short-term and for long-term exposure (explanation see section 9.0.4.2).
Skin irritancy is controlled by using suitable dermal protection equipment, while eye irritancy is controlled by using of face shield or goggles. Under these use conditions, no local effects on respiratory tract, skin and eyes are expected.

## 9.2.4. Worker CS 4: Mixing or blending in batch processes; Open systems (PROC 5)

### 9.2.4.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 100.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Use of eye protection: Yes | |

| | Method |
|---|---|
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

### 9.2.4.2. Exposure and risks for workers

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

**Table 9.16. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 6.25 mg/m³ (TRA Workers) | RCR = 0.253 |
| Inhalation, local, long term | 6.25 mg/m³ (TRA Workers) | |
| Inhalation, local, acute | 25 mg/m³ (TRA Workers) | |
| Dermal, systemic, long term | 2.742 mg/kg bw/day (TRA Workers) | RCR = 0.392 |
| Combined routes, systemic, long-term | | RCR = 0.645 |

**Risk characterisation**

Qualitative risk characterisation:
The daily average exposure by inhalation is well below the long-term DNEL. This indicates at the same time that the likelihood of adverse effect due to irritancy on the respiratory tract is also low (explanation see section 9.0.4.2). Also for short-term exposure situations the calculated exposure is still below the COSSH benchmark. (i.e. 60 mg/m3 for the ECHA substance).
Skin irritancy is controlled by using suitable dermal protection equipment, while eye irritancy is controlled by using of face shield or goggles. Under these use conditions, no local effects on respiratory tract, skin and eyes are expected.

## 9.2.5. Worker CS 5: Transfer of substance or mixture (charging/discharging) at non dedicated-facilities (PROC 8a)

### 9.2.5.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |

| | Method |
|---|---|
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

### 9.2.5.2. Exposure and risks for workers

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

**Table 9.17. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 2.5 mg/m³ (TRA Workers) | RCR = 0.101 |
| Dermal, systemic, long term | 2.742 mg/kg bw/day (TRA Workers) | RCR = 0.392 |
| Combined routes, systemic, long-term | | RCR = 0.493 |

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## 9.2.6. Worker CS 6: Transfer of substance or mixture (charging/discharging) at dedicated facilities (PROC 8b)

Covers also transfer of process waste to storage containers

### 9.2.6.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

### 9.2.6.2. Exposure and risks for workers

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

**Table 9.18. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 12.5 mg/m³ (TRA Workers) | RCR = 0.506 |
| Dermal, systemic, long term | 2.742 mg/kg bw/day (TRA Workers) | RCR = 0.392 |
| Combined routes, systemic, long-term | | RCR = 0.898 |

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## 9.2.7. Worker CS 7: Transfer of substance or mixture into small containers (dedicated filling line, including weighing) (PROC 9)

### 9.2.7.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

### 9.2.7.2. Exposure and risks for workers

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

**Table 9.19. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 12.5 mg/m³ (TRA Workers) | RCR = 0.506 |
| Dermal, systemic, long term | 1.372 mg/kg bw/day (TRA Workers) | RCR = 0.196 |
| Combined routes, systemic, long-term | | RCR = 0.702 |

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## 9.2.8. Worker CS 8: Equipment cleaning and maintenance (PROC 28)

Covers maintenance and cleaning operation of equipment where undiluted substance is used

### 9.2.8.1. Conditions of use

| | **Method** |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 100.0 % | TRA based on PROC 8a 3.0 |
| • Physical form of the used product: Liquid | TRA based on PROC 8a 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 4.0 h/day | TRA based on PROC 8a 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA based on PROC 8a 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA based on PROC 8a 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA based on PROC 8a 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%] | TRA based on PROC 8a 3.0 |
| • Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhalation: 90%] | TRA based on PROC 8a 3.0 |
| • Use of eye protection: Yes | |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA based on PROC 8a 3.0 |
| • Operating temperature: <= 40.0 °C | TRA based on PROC 8a 3.0 |

### 9.2.8.2. Exposure and risks for workers

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

**Table 9.20. Exposure concentrations and risks for workers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk quantification** |
|---|---|---|
| Inhalation, systemic, long term | 7.5 mg/m³ (TRA based on PROC 8a 3.0) | RCR = 0.304 |
| Inhalation, local, long term | 7.5 mg/m³ (TRA based on PROC 8a 3.0) | |
| Inhalation, local, acute | 50 mg/m³ (TRA based on PROC 8a 3.0) | |
| Dermal, systemic, long term | 2.742 mg/kg bw/day (TRA based on PROC 8a 3.0) | RCR = 0.392 |

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Combined routes, systemic, long-term | | RCR = 0.695 |

**Remarks on exposure data from external estimation tools:**

TRA based on PROC 8a 3.0
Explanation: PROC 8a has been used for exposure estimation since it assumes direct contact with the substance and no particular design control to limit exposure

**Risk characterisation**

Qualitative risk characterisation:
The daily average exposure by inhalation is well below the long-term DNEL. This indicates at the same time that the likelihood of adverse effect due to irritancy on the respiratory tract is also low (explanation see section 9.0.4.2). Also for short-term exposure situations the calculated exposure is still below the COSHH benchmark. (i.e. 60 mg/m3 for the ECHA substance).
Skin irritancy is controlled by using suitable dermal protection equipment, while eye irritancy is controlled by using of face shield or goggles. Under these use conditions, no local effects on respiratory tract, skin and eyes are expected.

# 9.3. Exposure scenario 3: Use at industrial sites - General Industrial use of coatings and inks

**Market sector:** Coatings and Inks
**Product category used:** PC 9a: Coatings and Paints, Thinners, paint removers

| | | |
|---|---|---|
| **Environment contributing scenario(s):** | | |
| CS 1 | Industrial application of coatings and inks involving water - Large scale | ERC 5 |
| CS 2 | Industrial application of coatings and inks involving water - Small scale | ERC 5 |
| CS 3 | Industrial application of coatings and inks. Water free | ERC 5 |
| **Worker contributing scenario(s):** | | |
| CS 4 | Raw material receipt and transfer | PROC 8b |
| CS 5 | Mixing operations; Open systems | PROC 5 |
| CS 6 | Batch loading of equipment (manual, non dedicated) | PROC 8a |
| CS 7 | Spraying | PROC 7 |
| CS 8 | Printing closed automated machinery | PROC 10 |
| CS 9 | Roller, spreader, flow application; Printing | PROC 10 |
| CS 10 | Dipping, immersion and pouring | PROC 13 |
| CS 11 | Film formation - force drying, stoving and other technologies; Elevated temperature | PROC 2 |
| CS 12 | Equipment cleaning and maintenance; Manual | PROC 28 |

**Further description of the use:**

This scenario covers the industrial use of coatings and inks in a range of processes. This includes closed printing processes (e.g. marking of electronic components, pharmaceutical products and medical devices) and open application to larger surface areas by spraying, dipping and roller/brush methods.
Also auxiliary activities are covered such as: raw material receipt and transfer; preparation of coatings, including mixing; loading of application devices; and tasks following application activities (curing/drying and cleaning/maintenance of equipment).
The concentration of the substance (additive) in coating is in the range of 0.5-2%.

**Explanation on the approach taken for the ES**

Based on its technical function, the concentration of the substance in mixtures has been set to a maximum of 2%.
Releases to the environment have been calculated using SPERC XYZ IULS, covering industrial use of coatings involving water for large scale application, SPERC XYZ IUSS for small scale coating application and SPERC XYZ IUWF for coatings applications where water is not used, either in the process or for cleaning and maintenance. Each SPERC is associated with a specific environmental contributing activity. The SPERCs contain subSPERCs and the ones matching the ECHA substance properties (i.e. non-volatile, with boiling point > 250 °C) have been selected for the assessment.
With respect to worker exposure, the contributing scenarios which pose the greatest potential for exposure are coating tasks themselves, especially spraying, and maintenance and cleaning.

## Notes and Comments

**Re: Risk Management Measures**

PPE such as respirator and gloves are often worn during coating tasks due to the presence of many hazardous components in the coating. It is worn especially during tasks involving high aerosol emissions such as spraying operations. If the quantitative and qualitative risk assessments have not identified that PPE is essential to ensure safe use, consider including it as a recommended good practice measure beyond the scope of REACH rather than as a required measure. Local risk assessments by downstream users should address the overall risk of all chemicals used on site, based on the actual operational conditions and the known effectiveness of risk management measures. Engineering measures to prevent exposure are preferred to PPE.

**Re: SPERC**

The hypothetical SPERCs used in this example are built on information contained in the OECD ESD on coatings and paints (EMISSION SCENARIO DOCUMENT ON COATINGS INDUSTRY (PAINTS, LACQUERS AND VARNISHES), OECD, July 2009). SPERCs proposed for the current example are generic and cover industrial use of coatings within several sectors. They do not cover specific use conditions, e.g. when overspray is collected by means of wet scrubbing, and the water phase is discharged with the wastewater stream. The SPERCs are based on the improved factsheet concept and template developed by sector organisations.

In general, if the SPERC factsheet does not contain sufficient information (e.g. missing justification for release estimation), do not use the SPERC and contact the developer of the SPERC (usually an industry association).

## 9.3.1. Env CS 1: Industrial application of coatings and inks involving water - Large scale (ERC 5)

Covers uses where water is used, including in cleaning of equipment

### 9.3.1.1. Conditions of use

| Amount used, frequency and duration of use (or from service life) |
|---|
| • Daily use amount at site: <= 0.1 tonnes/day<br>*From DU survey: maximum amount of product used is 5 tonnes/day, corresponding to 0.1 tonne/day of ECHA substance (substance concentration in mixture is 2%)* |
| • Annual use amount at site: <= 30.0 tonnes/year |
| Technical and organisational conditions and measures |
| • Overspray collected and disposed of as waste<br>*This condition indicates that discharge of water phase from wet scrubber is not covered in this contributing scenario* |
| • On-site physico-chemical treatment of wastewater [Effectiveness Water: 90%]<br>*Risk Management Measure effective only on non volatile substances (BP>250 C) being part of the mixture. Examples of treatment option are described in the background document (BD)* |
| • On site air thermal oxidation/incineration [Effectiveness Air: 99%]<br>*Risk Management Measure effective only on volatile substances (BP<250 C) being part of the mixture.* |

| |
|---|
| *Examples of treatment option are described in the background document (BD)* |
| Conditions and measures related to biological sewage treatment plant |
| • Biological STP: Standard [Effectiveness Water: 22.16%] |
| • Discharge rate of STP: >= 2000 m3/day |
| • Application of the STP sludge on agricultural soil: Yes |
| Conditions and measures related to external treatment of waste (including article waste) |
| • Particular considerations on the waste treatment operations: No (low concentration)<br>*Particular risks from waste treatment unlikely due low concentration of substance in waste stream. Waste disposal according to national/local legislation is sufficient.* |
| Other conditions affecting environmental exposure |
| • Place of use: Indoor |
| • Receiving surface water flow rate: >= 18000 m3/day |

### 9.3.1.2. Releases

The releases have been estimated on the basis of SPERC XYZ IULS: Industrial use of coatings involving water: large scale

Description of activities/processes covered by the SPERC

This SPERC covers all possible industrial applications of coatings, including manual application (roller and brushing), spraying, electro coating, dipping, curtain coating. Is also includes preparation / loading of the product and curing/drying activities. Maintenance and cleaning operations are also taken into account for the release estimation. RMMs are assumed to reduce releases to air and to water from the site.
Sectors covered by the SPERC include: Furniture coating, Automotive coating and refinishing, Metal packaging coating, Coil coating, Aerospace coating, Rail vehicle coating.

Product/substance domain:

Covers use of all ranges of coating products, including solvent borne, water borne and powder coatings. Cover volatile and non volatile substances, liquid or solids.
Volatile substances (liquid) are defined by a boiling point below 250°C, while non-volatile substances (liquids or solids) by boiling point above 250°C.
This SPERC addresses large sites.
**Sub-SPERC XYZ IULS_NVOL**: Industrial use of coatings involving water: large scale (non volatile):

Applicability domain:

Boiling point > 250 C
The local releases to the environment are reported in the following table.

**Table 9.21. Local releases to the environment**

| **Release** | **Explanations** |
|---|---|
| Water | **Release factor:** 0.19%<br>**Local release rate:** 0.19 kg/day<br>**Explanation:**<br>Losses to wastewater comes for cleaning of equipment. Releases of non volatile are further reduced by on site RMM (90% of effectiveness for non volatile). The release estimation (before on site RMM) is based on OECD ESD Number 22: EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes). The rational for the release derivation is described in the background document (BD) |
| Air | **Release factor:** 1.5%<br>**Local release rate:** 1.5 kg/day<br>**Explanation:**<br>Only a minimum fraction of a solid or non volatile substance expected to be emitted to air; non volatile substances are not necessarily collected by air RMM system. This is based on OECD ESD Number 22: EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes). The rational for the derivation is described in |

| Release | Explanations |
|---|---|
| | the background document (BD) |
| Non agricultural soil | **Release factor:** 0%<br>**Local release rate:** - kg/day<br>**Explanation:**<br>No releases to soil from large sites. This is based on OECD ESD Number 22: EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes). The rational for the derivation is described in the background document (BD) |

**Releases to waste**

**Release factor to external waste:** 60.4 %
This correspond to the maximum fraction of non volatile substance in waste. This is based on OECD ESD Number 22: EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes). The rational for the derivation is described in the background document (BD)

**Notes and Comments**

**Re: Release Estimation Refinement/water based, large scale application**

a) The SPERC used covers the large-scale application where water is involved. A subSPERC matching the ECHA substance properties is selected for the assessment.

b) The release factor to water from the subSPERC is based on the ESD on coatings and assumes the following OC/RMM (reported in the related Contributing Scenario):

- Water used for cleaning operations (might be) sent to wastewater stream
- Overspray (if any) is collected as waste (potentially including the water from wet scrubbing)
- Physico-chemical wastewater treatment of the water stream with an expected effectiveness of 90%
- Exhaust air is treated in a thermal oxidation/incineration unit. This particular RMM is not effective to non-volatile substances such as ECHA substance. The SPERC in fact contains all RMM relevant for mixture. Some of them are relevant for ECHA substance (water treatment) and some not (air treatment). All RMM in the SPERC are anyway reported in the CSR

c) The release factors to air and waste are based on OECD ESD factors (worst case across different sectors)

d) Supporting information (e.g. for derivation of the release factors for OECD ESD and for typical waste water / air treatment plant to achieve the requested effectiveness) is reported in the Background Document supporting the SPERC factsheets.

### 9.3.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

**Table 9.22. Exposure concentrations and risks for the environment and man via the environment**

| Protection target | Exposure concentration | Risk quantification |
|---|---|---|
| Fresh water | **Local PEC:** 7.4E-3 mg/L | RCR = 0.718 |
| Sediment (freshwater) | **Local PEC:** 0.601 mg/kg dw | RCR = 0.718 |
| Marine water | **Local PEC:** 7.4E-4 mg/L | RCR = 0.718 |
| Sediment (marine water) | **Local PEC:** 0.06 mg/kg dw | RCR = 0.718 |
| Sewage Treatment Plant | **Local PEC:** 0.074 mg/L | RCR = 0.05 |
| Agricultural soil | **Local PEC:** 0.029 mg/kg dw | RCR = 0.182 |
| Man via environment - Inhalation | **Concentration in air:** 3.43E-4 mg/m³ | RCR < 0.01 |
| Man via environment - Oral | **Exposure via food consumption:** 0.043 mg/kg bw/day | RCR = 0.012 |
| Man via environment - combined routes | | RCR = 0.012 |

# 9.3.2. Env CS 2: Industrial application of coatings and inks involving water - Small scale (ERC 5)

Covers uses where water is used, including in cleaning of equipment

## 9.3.2.1. Conditions of use

| Amount used, frequency and duration of use (or from service life) |
|---|
| • Daily use amount at site: <= 0.01 tonnes/day<br>*Maximum amount of product used is 0.5 tonnes/day (from SPERC), which corresponds to 0.01 tonne/day of substance (substance concentration in mixture is 2%)* |
| • Annual use amount at site: <= 2.2 tonnes/year |
| Technical and organisational conditions and measures |
| • Overspray collected and disposed of as waste<br>*This condition indicates that discharge of water phase from wet scrubber is not covered in this contributing scenario* |
| Conditions and measures related to biological sewage treatment plant |
| • Biological STP: Standard [Effectiveness Water: 22.16%] |
| • Discharge rate of STP: >= 2000 m3/day |
| • Application of the STP sludge on agricultural soil: Yes |
| Conditions and measures related to external treatment of waste (including article waste) |
| • Particular considerations on the waste treatment operations: No (low concentration)<br>*Particular risks from waste treatment unlikely due low concentration of substance in waste stream. Waste disposal according to national/local legislation is sufficient.* |
| Other conditions affecting environmental exposure |
| • Place of use: Indoor |
| • Receiving surface water flow rate: >= 18000 m3/day |

## 9.3.2.2. Releases

The releases have been estimated on the basis of SPERC XYZ IUSS: Industrial use of coatings involving water: small/medium scale

Description of activities/processes covered by the SPERC

This SPERC covers all possible industrial applications of coatings, including manual application (roller and

brushing), spraying, electro coating, dipping, curtain coating. Is also includes preparation / loading of the product and curing/drying activities. Maintenance and cleaning operations are also taken into account for the release estimation. No particular RMMs are assumed to reduce releases to air and to water from the site. Sectors covered by the SPERC include: Furniture coating, Automotive coating and refinishing, Metal packaging coating, Coil coating, Aerospace coating, Rail vehicle coating.

Product/substance domain:

Covers use of all ranges of coating products, including solvent borne, water borne and powder coatings. Covers volatile and non-volatile substances, liquids or solids.
Volatile substances (liquid) are defined by a boiling point below 250°C, while non-volatile substances (liquid or solids) by boiling point above 250°C.
This SPERC addresses medium/small sites, where not more than 500 kg/day of coatings products are used.
**Sub-SPERC XYZ IUSS NVOL**: Industrial use of coatings involving water: small/medium scale (non volatile):

Applicability domain:

Boiling point > 250 C
The local releases to the environment are reported in the following table.

**Table 9.23. Local releases to the environment**

| Release | Explanations |
|---|---|
| Water | **Release factor:** 1.9%<br>**Local release rate:** 0.19 kg/day<br>**Explanation:**<br>Losses to wastewater comes for cleaning of equipment. The release estimation is based on OECD ESD Number 22: EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes). The rational for the derivation is described in the background document (BD) |
| Air | **Release factor:** 1.5%<br>**Local release rate:** 0.15 kg/day<br>**Explanation:**<br>Only a minimum fraction of a solid or non volatile substance expected to emitted to air. This is based on OECD ESD Number 22: EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes). The rational for the derivation is described in the background document (BD) |
| Non agricultural soil | **Release factor:** 0%<br>**Local release rate:** - kg/day<br>**Explanation:**<br>This is based on OECD ESD Number 22: EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes). The rational for the derivation is described in the background document (BD) |

**Releases to waste**

**Release factor to external waste:** 60.4 %
This correspond to the maximum fraction of non volatile substance in waste. This is based on OECD ESD Number 22: EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes). The rational for the derivation is described in the background document (BD)

## Notes and Comments

**Re: Release Estimation Refinement/water based, small scale application**

a) The SPERC used covers the small-scale application where water is involved. Information on maximum site tonnage (related to the product) is reported under "Product/substance domain". The registrant is expected to adapt the site tonnage taking into account DUs or SPERC information (as in the example) and concentration of the substance in mixtures.

b) The release factor to water from the subSPERC is based on the ESD on coatings and assumes the same OC as "large scale". RMMs (air/water treatment units) are not possible for small-scale applications.

c) The release factors to air and waste are based on OECD ESD factors (worst case across different sectors).

d) Supporting information (e.g. for derivation of the release factors for OECD ESD) is reported in the Background Document supporting the SPERC factsheets.

### 9.3.2.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

**Table 9.24. Exposure concentrations and risks for the environment and man via the environment**

| Protection target | Exposure concentration | Risk quantification |
|---|---|---|
| Fresh water | **Local PEC:** 7.4E-3 mg/L | RCR = 0.718 |
| Sediment (freshwater) | **Local PEC:** 0.601 mg/kg dw | RCR = 0.718 |
| Marine water | **Local PEC:** 7.4E-4 mg/L | RCR = 0.718 |
| Sediment (marine water) | **Local PEC:** 0.06 mg/kg dw | RCR = 0.718 |
| Sewage Treatment Plant | **Local PEC:** 0.074 mg/L | RCR = 0.05 |
| Agricultural soil | **Local PEC:** 0.029 mg/kg dw | RCR = 0.181 |
| Man via environment - Inhalation | **Concentration in air:** 2.64E-5 mg/m³ | RCR < 0.01 |
| Man via environment - Oral | **Exposure via food consumption:** 0.033 mg/kg bw/day | RCR < 0.01 |
| Man via environment - combined routes | | RCR < 0.01 |

## 9.3.3. Env CS 3: Industrial application of coatings and inks. Water free (ERC 5)

Covers all dry processes where water is not used in any part of the process (in the product, after application, or for cleaning purposes)

### 9.3.3.1. Conditions of use

| Amount used, frequency and duration of use (or from service life) |
|---|
| • Daily use amount at site: <= 0.1 tonnes/day<br>*From DU survey: maximum amount of product used is 5 tonnes/day, corresponding to 0.1 tonne/day of ECHA substance (substance concentration in mixture is 2%)* |
| • Annual use amount at site: <= 30.0 tonnes/year |
| Technical and organisational conditions and measures |
| • No water used for equipment cleaning |
| • Residues from equipment cleaning disposed of as waste |
| • Overspray collected and disposed of as waste<br>*This condition indicates that discharge of water phase from wet scrubber is not covered in this contributing scenario* |
| Conditions and measures related to biological sewage treatment plant |
| • Biological STP: None [Effectiveness Water: 0%] |
| Conditions and measures related to external treatment of waste (including article waste) |
| • Particular considerations on the waste treatment operations: No (low concentration)<br>*Particular risks from waste treatment unlikely due low concentration of substance in waste stream. Waste disposal according to national/local legislation is sufficient.* |
| Other conditions affecting environmental exposure |
| • Place of use: Indoor |
| • Discharge rate of effluent: >= 2000 m3/day |
| • Receiving surface water flow rate: >= 18000 m3/day |

### 9.3.3.2. Releases

The releases have been estimated on the basis of SPERC XYZ IUWF: Industrial use of coatings water free

Description of activities/processes covered by the SPERC

This SPERC covers all possible industrial applications of coatings, including manual application (roller and brushing), spraying, electro coating, dipping, curtain coating. Is also includes preparation / loading of the product and curing/drying activities. Maintenance and cleaning operations are also taken into account for the release estimation. Cover both large and small sites. No RMMs assumed in this SPERC. No water used in process or as cleaning agent.
Sectors covered by the SPERC include: Furniture coating, Automotive coating and refinishing, Metal packaging coating, Coil coating, Aerospace coating, Rail vehicle coating.

Product/substance domain:

Covers use of all ranges of coating products, including solvent borne, water borne and powder coatings. Cover volatile and non-volatile substances, liquid or solids.
Volatile substances (liquid) are defined by a boiling point below 250°C, while non-volatile substances (liquid or solids) by boiling point above 250°C.
**Sub-SPERC XYZ IUWF NVOL**: Industrial use of coatings water free (non volatile):

Applicability domain:

Boiling point > 250 C
The local releases to the environment are reported in the following table.

**Table 9.25. Local releases to the environment**

| Release | Explanations |
|---|---|
| Water | **Release factor:** 0%<br>**Local release rate:** 0 kg/day<br>**Explanation:**<br>No water used in the process or as cleaning agent (see also background document (BD)). |

| Release | Explanations |
|---|---|
| Air | **Release factor:** 1.5%<br>**Local release rate:** 1.5 kg/day<br>**Explanation:**<br>Only a minimum fraction of a solid or non volatile substance expected to emitted to air. This is based on OECD ESD Number 22: EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes). The rational for the derivation is described in the background document (BD) |
| Non agricultural soil | **Release factor:** 0%<br>**Local release rate:** - kg/day<br>**Explanation:**<br>This figure is based on OECD ESD Number 22: EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes). The rational for the derivation is described in the background document (BD) |

**Releases to waste**

**Release factor to external waste:** 60.4 %
This correspond to the maximum fraction of non volatile substance in waste. This is based on OECD ESD Number 22: EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes). The rational for the derivation is described in the background document (BD)

**Notes and Comments**

**Re: Release Estimation Refinement, water free application**

a) The SPERC used covers the application at any scale where water is not involved, either in the process or in cleaning operations.

b) The release factor to water from the subSPERC is based on absence of water in both process and cleaning, which is reflected in the following OC (reported in the related Contributing Scenario):

- Solvents are used for equipment cleaning (no water)
- Residues for cleaning are treated as waste
- Overspray (if any) is collected as waste (e.g. as for dry collection)

c) The release factors to air and waste are based on OECD ESD factors (worst case across different sectors).

d) Supporting information is reported in the Background Document supporting the SPERC factsheets.

### 9.3.3.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

**Table 9.26. Exposure concentrations and risks for the environment and man via the environment**

| Protection target | Exposure concentration | Risk quantification |
|---|---|---|
| Fresh water | **Local PEC:** 1.16E-5 mg/L | RCR < 0.01 |

| Protection target | Exposure concentration | Risk quantification |
|---|---|---|
| Sediment (freshwater) | **Local PEC:** 9.41E-4 mg/kg dw | RCR < 0.01 |
| Marine water | **Local PEC:** 1.08E-6 mg/L | RCR < 0.01 |
| Sediment (marine water) | **Local PEC:** 8.75E-5 mg/kg dw | RCR < 0.01 |
| Sewage Treatment Plant | **Local PEC:** 0 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 1.4E-4 mg/kg dw | RCR < 0.01 |
| Man via environment - Inhalation | **Concentration in air:** 3.43E-4 mg/m³ | RCR < 0.01 |
| Man via environment - Oral | **Exposure via food consumption:** 7E-4 mg/kg bw/day | RCR < 0.01 |
| Man via environment - combined routes | | RCR < 0.01 |

## 9.3.4. Worker CS 4: Raw material receipt and transfer (PROC 8b)

### 9.3.4.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 1.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

### 9.3.4.2. Exposure and risks for workers

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

**Table 9.27. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 2.5 mg/m³ (TRA Workers) | RCR = 0.101 |
| Dermal, systemic, long term | 2.742 mg/kg bw/day (TRA Workers) | RCR = 0.392 |
| Combined routes, systemic, long-term | | RCR = 0.493 |

**Risk characterisation**

Qualitative risk characterisation:

Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## 9.3.5. Worker CS 5: Mixing operations; Open systems (PROC 5)

### 9.3.5.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 1.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

### 9.3.5.2. Exposure and risks for workers

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

**Table 9.28. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 2.5 mg/m³ (TRA Workers) | RCR = 0.101 |
| Dermal, systemic, long term | 2.742 mg/kg bw/day (TRA Workers) | RCR = 0.392 |
| Combined routes, systemic, long-term | | RCR = 0.493 |

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## 9.3.6. Worker CS 6: Batch loading of equipment (manual, non dedicated) (PROC 8a)

### 9.3.6.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |

| | Method |
|---|---|
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 1.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

### 9.3.6.2. Exposure and risks for workers

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

**Table 9.29. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 5 mg/m³ (TRA Workers) | RCR = 0.202 |
| Dermal, systemic, long term | 2.742 mg/kg bw/day (TRA Workers) | RCR = 0.392 |
| Combined routes, systemic, long-term | | RCR = 0.594 |

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## 9.3.7. Worker CS 7: Spraying (PROC 7)

For manual spraying, spray gun preparation and daily cleaning of equipment is covered in this contributing scenario.

### 9.3.7.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: Yes [Effectiveness Inhalation: 95%, Dermal: 0%] | TRA Workers 3.0 |

| | Method |
|---|---|
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |
| Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply | |
| • Respiratory protection equipment if exposure to aerosol may occur | |
| • Chemical Protective Clothing (CPC) (overall and boots recommended to prevent skin contact) | |
| • Use of eye protection: Yes | |

## Notes and Comments

**Re: LEV effectiveness**

The default LEV effectiveness for industrial spraying in the ECETOC TRA v.3 is 95% and has been used for the assessment. This is appropriate for well-designed and well-maintained coating lines and spray booths and where workers are sufficiently instructed, trained and supervised (advanced OSH system). If the LEV effectiveness is likely to be poorer, consider using another assessment tool (including manual adaptation of the assumed effectiveness in the TRA).

For manual spraying, loading and daily cleaning of spraying equipment is covered in this contributing scenario, i.e. these activities are to be carried out under the same risk management as the spraying itself. If the scenario would refer to closed, automated spraying lines only (and the corresponding exposure), a separate contributing scenario for the cleaning and maintenance of equipment would be needed.

### 9.3.7.2. Exposure and risks for workers

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

**Table 9.30. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 12.5 mg/m³ (TRA Workers)<br>**Supportive exposure (not used for RC):**<br>7 mg/m³ (Measured data: Internal report ref 12345) | RCR = 0.506 |
| Dermal, systemic, long term | 1.714 mg/kg bw/day (TRA Workers) | RCR = 0.245 |

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Combined routes, systemic, long-term | | RCR = 0.751 |

**Remarks on measured exposure:**

**Internal report ref 12345**
Identity of the substance used: ECHA substance
Inhalation exposure, long term concentration: Number of measured data points: 9; GSD: 2
Explanation: The complete dataset is reported in Annex 3, attached to the present CSR
Personal exposure measurements at 1 location, (3 operators on 3 days), 2011
Measurements taken during spraying with conventional high pressure spray guns in dedicated paint booth, Local Exhaust Ventilation in operation and workers without RPE; loading and routine cleaning operations after spraying also included in the measurements.
8 hour TWA (mean) = 2.4 mg/m3,
8 hour TWA (90th percentile) = 7 mg/m3; this value is used as supportive evidence for the exposure estimation
Average measurement duration 160 mins.

**Notes and Comments**

**Re: Measured data**

Measured data are used here as supporting evidence only, to show that the modelled estimation can be seen as valid in such a case: The TRA predicts exposure to substance in vapour form but not in aerosol form. As the ECHA substance has no high vapour pressure, a significant fraction will occur as aerosol and thus there is some uncertainty on whether the TRA estimate is still valid. This uncertainty is reduced by a complementary data from exposure measurements. However, this measured data set alone would not be robust enough (see Guidance R.14). Therefore, data from both sources have been combined in a weight of evidence approach.

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## 9.3.8. Worker CS 8: Printing closed automated machinery (PROC 10)

### 9.3.8.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA based on PROC 2 3.0 |
| • Physical form of the used product: Liquid | TRA based on PROC 2 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA based on PROC 2 3.0 |
| Technical and organisational conditions and measures | |

| | Method |
|---|---|
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA based on PROC 2 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA based on PROC 2 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA based on PROC 2 3.0 |
| • Closed application process with occasional exposure | |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA based on PROC 2 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA based on PROC 2 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA based on PROC 2 3.0 |
| • Operating temperature: <= 40.0 °C | TRA based on PROC 2 3.0 |

## 9.3.8.2. Exposure and risks for workers

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

**Table 9.31. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 2.5 mg/m³ (TRA based on PROC 2 3.0)<br>**Supportive exposure (not used for RC):**<br>0.25 mg/m³ (Measured data: Measured dataset xyz1) | RCR = 0.101 |
| Dermal, systemic, long term | 0.274 mg/kg bw/day (TRA based on PROC 2 3.0) | RCR = 0.039 |
| Combined routes, systemic, long-term | | RCR = 0.14 |

**Remarks on exposure data from external estimation tools:**

TRA based on PROC 2 3.0
Explanation: PROC 2 has been used for exposure estimation since it assumes closed system with controlled occasional exposure.

**Remarks on measured exposure:**

**Measured dataset xyz1**
Identity of the substance used: ECHA Substance
Inhalation exposure, long term concentration: Number of measured data points: 6; GSD: 2
Explanation: The complete dataset is reported in Annex 3, attached to the present CSR
Number of measured data points: 6 for one site
Measurements taken from operators of printing machine in closed systems
Average measurement duration 240 mins.
Sampling methodology: Personal sampling
Limit of detection (LoD) for ECHA substance; 0.01 mg/m3
Concentration (mg/m3): 0.25; 0.11; 0.02; 0.01; <0.01 (LD); <0.01 (LD).
The highest value is used as supportive evidence for the exposure estimation

**Notes and Comments**

**Re: Supporting data when using PROC based assessment for closed systems other than in Chemical Production**

In sectors other than chemical production and refineries a measured data set is needed to claim a closed system and validate the use of PROCs 1-3 based assessment (see Guidance R14). Evidence of a personal sampling exercise to assess the effectiveness of the controls that ensure the closed system is operating effectively may be provided. Data from static monitoring may also be included in the CSR, for example, with measurements taken adjacent to the closed process and the context of the measurements clearly described.

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## 9.3.9. Worker CS 9: Roller, spreader, flow application; Printing (PROC 10)

### 9.3.9.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |
| Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply | |
| • Chemically resistant gloves conforming to EN374 | |
| • Use of eye protection: Yes | |

### 9.3.9.2. Exposure and risks for workers

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

**Table 9.32. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 2.5 mg/m³ (TRA Workers) | RCR = 0.101 |
| Dermal, systemic, long term | 5.486 mg/kg bw/day (TRA Workers) | RCR = 0.784 |
| Combined routes, systemic, long-term | | RCR = 0.885 |

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## 9.3.10. Worker CS 10: Dipping, immersion and pouring (PROC 13)

Covers also after drying of the coating

### 9.3.10.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |
| Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply | |
| • Chemically resistant gloves conforming to EN374 | |
| • Use of eye protection: Yes | |

### 9.3.10.2. Exposure and risks for workers

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

**Table 9.33. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 2.5 mg/m³ (TRA Workers) | RCR = 0.101 |
| Dermal, systemic, long term | 2.742 mg/kg bw/day (TRA Workers) | RCR = 0.392 |
| Combined routes, systemic, long-term | | RCR = 0.493 |

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

# 9.3.11. Worker CS 11: Film formation - force drying, stoving and other technologies; Elevated temperature (PROC 2)

## 9.3.11.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| • Closed drying tunnel with extract ventilation | |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 70.0 °C | TRA Workers 3.0 |

## 9.3.11.2. Exposure and risks for workers

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

**Table 9.34. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 2.5 mg/m³ (TRA Workers)<br>**Supportive exposure (not used for RC):**<br>0.5 mg/m³ (Measured data: Measured dataset xyz2) | RCR = 0.101 |
| Dermal, systemic, long term | 0.274 mg/kg bw/day (TRA Workers) | RCR = 0.039 |
| Combined routes, systemic, long- | | RCR = 0.14 |

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| term | | |

**Remarks on exposure dataset obtained with ECETOC TRA**

Explanation: Use of PROC 2, even if not ideal, has been considered reasonable in this case to describe closed oven/tunnel for drying.
The vapour pressure at operating temperature used for the calculation has been set by the assessor to 300 Pa.

**Remarks on measured exposure:**

**Measured dataset xyz2**
Identity of the substance used: ECHA Substance
Inhalation exposure, long term concentration: Number of measured data points: 6; GSD: 2
Explanation: The complete dataset is reported in Annex 3, attached to the present CSR
Measurements taken from operators of closed oven operating at controlled temperature (not more than 70 C); during measurements, operators stayed in the rooms where drying in the oven takes place the full shift
Number of measured data points: 6; 1 site
Average measurement duration 240 mins.
Sampling methodology: Personal sampling
Limit of detection (LD) for ECHA substance; 0.01 mg/m3
Concentration (mg/m3): 0.5; 0.2; 0.05; 0.01; <0.01 (LD); <0.01 (LD).
The highest value is used as supportive evidence for the exposure estimation

**Notes and Comments**

**Re: PROC-based assessment for a technical process, for which no suitable PROC exists and which is carried out under closed conditions**

The technical nature of a tunnel dryer is hardly properly reflected in any PROC, and thus ideally a PROC 0 should be assigned. However in this example, PROC 2 has been assigned to this contributing activity to illustrate the impact of elevated temperature when using ECETOC TRA in Chesar. The same principles regarding supportive datasets as listed in the annotation for CS4 (paragraph 9.3.8) apply here.

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## 9.3.12. Worker CS 12: Equipment cleaning and maintenance; Manual (PROC 28)

Covers also waste collection and transfers

### 9.3.12.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA based on PROC 8a 3.0 |

| | **Method** |
|---|---|
| • Physical form of the used product: Liquid | TRA based on PROC 8a 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 4.0 h/day | TRA based on PROC 8a 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA based on PROC 8a 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA based on PROC 8a 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA based on PROC 8a 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%] | TRA based on PROC 8a 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA based on PROC 8a 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA based on PROC 8a 3.0 |
| • Operating temperature: <= 40.0 °C | TRA based on PROC 8a 3.0 |

## 9.3.12.2. Exposure and risks for workers

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

**Table 9.35. Exposure concentrations and risks for workers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk quantification** |
|---|---|---|
| Inhalation, systemic, long term | 15 mg/m³ (TRA based on PROC 8a 3.0) | RCR = 0.607 |
| Dermal, systemic, long term | 0.548 mg/kg bw/day (TRA based on PROC 8a 3.0) | RCR = 0.078 |
| Combined routes, systemic, long-term | | RCR = 0.686 |

**Remarks on exposure data from external estimation tools:**

TRA based on PROC 8a 3.0
Explanation: PROC 8a has been used for exposure estimation since it assumes direct contact with the substance and no particular design control to limit exposure.

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

# 9.4. Exposure scenario 4: Widespread use by professional workers - Professional painting

**Market sector:** Coatings and Inks
**Product category used:** PC 9a: Coatings and Paints, Thinners, paint removers

| | | |
|---|---|---|
| **Environment contributing scenario(s):** | | |
| CS 1 | Use leading to inclusion into/onto matrix | ERC 8f |
| **Worker contributing scenario(s):** | | |
| CS 2 | Transfer of substance or mixture (charging/discharging) at non dedicated-facilities | PROC 8a |
| CS 3 | Roller application or brushing | PROC 10 |
| CS 4 | Spraying | PROC 11 |

**Further description of the use:**

This scenario covers the use of paints/decorative coatings by professional painters. This activity may be performed by brush/roller or by spraying.

**Explanation on the approach taken for the ES**

Based on its technical function, the concentration of the substance in products has been set to a maximum of 2%.
Environmental exposure assessment is based on an ERC 8f release factor (outdoor use leading to inclusion into matrix), covering also ERC 8c (indoor use leading to inclusion into matrix).
Regarding worker exposure, Stoffenmanager 4.5 and ART 1.5 modelling tools were used to derive inhalation exposure estimates for spraying and brushing operations, since Tier I model (TRA) did not indicate safe use under realistic OC/RMMs. Spraying (PROC 11) was described in a Stoffenmanager based assessment as "handling of liquids at high pressure resulting in substantial generation of mist or spray/haze", while roller and brushing (PROC 10) was described in an ART based assessment as "Spreading of liquid products". Indoor use has been assumed for assessment purposes as the worst case scenario. Outdoor use is also covered by this assessment.

## Notes and Comments

**Re: Merging Exposure Scenarios**

Although use of paints by professionals occurs both indoors and outdoors, only one ES was used. The assessment has assumed the worst case for environment (namely outdoor painting) and the worst case for human health (namely indoor painting). This reduces the number of scenarios needed without influencing the outcome. While this approach has the advantage of reducing the number of scenarios, care should be taken to ensure that it is technically valid to do so and that the assumptions are clear to readers.

**Re: Risk Management Measures**

The comments regarding the role of local risk assessments in determining the most appropriate PPE in Section 9.3 also apply here.

**Re: ART/Stoffenmanager and TRA determinants**

TRA (supporting dermal exposure) and ART/Stoffenmanager (supporting inhalation exposure) conditions of use are consolidated in Contributing Scenarios (CS) number 2 (paragraph 9.4.3.1) and 3 (paragraph 9.4.4.1). No consolidation was possible e.g. among the LEV in TRA and the Engineering Controls in Stoffenmanager: they are present

at the same time in the CSs, although covering the same conditions of use (Local Exhaust Ventilation). This is due to the fact that the tools work with different definitions and efficiencies for the local exhaust ventilations. In the ES for communication, this condition of use, if relevant, is only mentioned once, in order to avoid confusion.

## 9.4.1. Env CS 1: Use leading to inclusion into/onto matrix (ERC 8f)

Covers also ERC 8c (indoor application)

### 9.4.1.1. Conditions of use

| |
|---|
| Amount used, frequency and duration of use (or from service life) |
| • Daily local widespread use amount: <= 0.000028 tonnes/day |
| Conditions and measures related to biological sewage treatment plant |
| • Biological STP: Standard [Effectiveness Water: 22.16%] |
| Conditions and measures related to external treatment of waste (including article waste) |
| • Particular considerations on the waste treatment operations: No (low risk)<br>*ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.* |

### 9.4.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

**Table 9.36. Local releases to the environment**

| Release | Release estimation method | Explanations |
|---|---|---|
| Water | ERC | **Release factor before on site RMM:** 5%<br>**Release factor after on site RMM:** 5%<br>**Local release rate:** 1.37E-3 kg/day |
| Air | ERC | **Release factor before on site RMM:** 15%<br>**Release factor after on site RMM:** 15% |
| Non agricultural soil | ERC | **Release factor after on site RMM:** 0.5% |

### 9.4.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

**Table 9.37. Exposure concentrations and risks for the environment and man via the environment**

| Protection target | Exposure concentration | Risk quantification |
|---|---|---|
| Fresh water | **Local PEC:** 6.5E-5 mg/L | RCR < 0.01 |
| Sediment (freshwater) | **Local PEC:** 5.28E-3 mg/kg dw | RCR < 0.01 |
| Marine water | **Local PEC:** 6.42E-6 mg/L | RCR < 0.01 |
| Sediment (marine water) | **Local PEC:** 5.22E-4 mg/kg dw | RCR < 0.01 |
| Sewage Treatment Plant | **Local PEC:** 5.35E-4 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 2.12E-4 mg/kg dw | RCR < 0.01 |
| Man via environment - | **Concentration in air:** 7.13E-7 mg/m³ | RCR < 0.01 |

| Protection target | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation | | |
| Man via environment - Oral | **Exposure via food consumption:** 4.51E-4 mg/kg bw/day | RCR < 0.01 |
| Man via environment - combined routes | | RCR < 0.01 |

# 9.4.2. Worker CS 2: Transfer of substance or mixture (charging/discharging) at non dedicated-facilities (PROC 8a)

Covers also waste collection and transfer

## 9.4.2.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0 |
| • Physical form of the used product: Liquid | TRA Workers 3.0 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 0.25 h/day | TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA Workers 3.0 |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Basic | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: No [Effectiveness Dermal: 0%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhalation: 0%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Operating temperature: <= 40.0 °C | TRA Workers 3.0 |

## 9.4.2.2. Exposure and risks for workers

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

**Table 9.38. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 6.25 mg/m³ (TRA Workers) | RCR = 0.253 |
| Dermal, systemic, long term | 2.742 mg/kg bw/day (TRA Workers) | RCR = 0.392 |
| Combined routes, systemic, long-term | | RCR = 0.645 |

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

# 9.4.3. Worker CS 3: Roller application or brushing (PROC 10)

## 9.4.3.1. Conditions of use

| | Method |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | TRA Workers 3.0<br>ART 1.5 |
| • Physical form of the used product: Liquid | TRA Workers 3.0<br>ART 1.5 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | TRA Workers 3.0<br>ART 1.5 |
| Technical and organisational conditions and measures | |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA Workers 3.0<br>ART 1.5 |
| • Occupational Health and Safety Management System: Basic | TRA Workers 3.0 |
| • General ventilation: No restrictions on general ventilation | ART 1.5 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| Other conditions affecting workers exposure | |
| • Place of use: Indoor | ART 1.5 |
| • Operating temperature: <= 40.0 °C | ART 1.5 |
| • Spreading of liquids - Scale of application: Surface/ work piece > 3 m2/hour | ART 1.5 |
| • Housekeeping: No | ART 1.5 |
| • Distance to the source: < 1 m (Near Field) | ART 1.5 |
| • Volume of working room: Any size workroom | ART 1.5 |
| Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply | |
| • Use of eye protection: Yes | |

## 9.4.3.2. Exposure and risks for workers

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

**Table 9.39. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 4.4 mg/m³ (ART 1.5) | RCR = 0.178 |
| Dermal, systemic, long term | 1.097 mg/kg bw/day (TRA Workers) | RCR = 0.157 |
| Combined routes, systemic, long-term | | RCR = 0.335 |

**Remarks on exposure data from external estimation tools:**

ART 1.5
Explanation: 90th percentile for the task has been taken as reference value for exposure estimation
Type of activity in ART: Spreading of liquid products

**Risk characterisation**

Qualitative risk characterisation:

Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## 9.4.4. Worker CS 4: Spraying (PROC 11)

### 9.4.4.1. Conditions of use

| | **Method** |
|---|---|
| Product (Article) characteristics | |
| • Percentage (w/w) of substance in mixture/article: <= 2.0 % | Stoffenmanager 4.5<br>TRA Workers 3.0 |
| • Physical form of the used product: Liquid | Stoffenmanager 4.5<br>TRA Workers 3.0 |
| • Product designed for reducing emissions: No | Stoffenmanager 4.5 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Duration of activity: <= 8.0 h/day | Stoffenmanager 4.5<br>TRA Workers 3.0 |
| Technical and organisational conditions and measures | |
| • Occupational Health and Safety Management System: Basic | TRA Workers 3.0 |
| • Engineering controls or containment: No [Effectiveness Inhalation: 0%] | Stoffenmanager 4.5 |
| • General ventilation: No [Effectiveness Inhalation: 0%] | Stoffenmanager 4.5 |
| • Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%] | TRA Workers 3.0 |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| • Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory protective equipment: Half/Full face powered air respirator TMP2 or 3 (gas cartridge) [Effectiveness Inhalation: 90%] | Stoffenmanager 4.5 |
| Other conditions affecting workers exposure | |
| • Operating temperature: <= 40.0 °C | Stoffenmanager 4.5 |
| • Place of use: Indoor | Stoffenmanager 4.5 |
| • Volume of working room: < 100 m3 | Stoffenmanager 4.5 |
| • Distance to the source: < 1 m (Near Field) | Stoffenmanager 4.5 |
| Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply | |
| • Chemical Protective Clothing (CPC) (overall and boots recommended to prevent skin contact) | |
| • Use of eye protection: Yes | |

### 9.4.4.2. Exposure and risks for workers

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

**Table 9.40. Exposure concentrations and risks for workers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk quantification** |
|---|---|---|
| Inhalation, systemic, long term | 9.46 mg/m³ (Stoffenmanager 4.5) | RCR = 0.383 |
| Dermal, systemic, long term | 4.286 mg/kg bw/day (TRA Workers) | RCR = 0.612 |
| Combined routes, systemic, long-term | | RCR = 0.995 |

**Remarks on exposure data from external estimation tools:**

Stoffenmanager 4.5
Explanation: 90th percentile for the task has been taken as reference value for exposure estimation
Type of activity in Stoffenmanager: “Handling of liquids at high pressure resulting in substantial generation of mist or spray/haze”

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.

## Notes and Comments

**Re: RCR very close to 1**

For uses where the RCR is very close to 1, like in the example above, some caution is needed when checking that all assumptions made are sufficiently conservative. For example:

- The estimations made by Stoffenmanager can be considered sufficiently conservative, as the tool specifically covers exposure to aerosol. The selected activity type in Stoffenmanager “high pressure handling of liquids” (worst case) is another element of conservatism.

- In contrast to this, there is more uncertainty around the dermal exposure estimate by ECETOC TRA. As the dermal route significantly contributes to the overall exposure, the outcome of the ongoing projects for comparison between TRA estimates for the dermal route and measured data for a number of PROCs should be closely followed.

# 9.5. Exposure scenario 5: Consumer use - Consumer painting

**Market sector:** Coatings and Inks

| | | |
|---|---|---|
| **Environment contributing scenario(s):** | | |
| CS 1 | Use leading to inclusion into/onto matrix | ERC 8f |
| **Consumer contributing scenario(s):** | | |
| CS 2 | Waterborne paint; Roller application or brushing | PC 9a |
| CS 3 | Solvent rich paint; Roller application or brushing | PC 9a |

**Further description of the use:**

This scenario covers general exposures of consumers arising from the use of ECHA Substance in household products sold as paints/decorative coatings (PC 9a). Activities covered in this scenario are roller application and brushing. The paints may be water-borne or solvent-borne.

**Explanation on the approach taken for the ES**

The concentration in consumer products of ECHA substance is set to a maximum level of 1%, corresponding to typical concentration of consumer paints.
Environmental releases are estimated according to ERC 8f (outdoor widespread use leading to inclusion into matrix) release factor. This covers also the indoor use of coatings (ERC 8c)
Inhalation and dermal consumer exposure were assessed using ConsExpo Web.
Two contributing scenarios are assessed:

- Water-based wall paint (RIVM report 320104008/2007, paragraph 2.6)
- Solvent rich paint (RIVM report 320104008/2007, paragraph 2.3)

The factsheet is in: http://www.rivm.nl/bibliotheek/rapporten/320104008.pdf

## Notes and Comments

**Re: Identification of RIVM factsheets covering consumer uses**
The most suitable factsheets/product type proposed by RIVM covering the consumer activities (roller and brushing application) have been selected for assessment purposes. Moreover, ECHA Substance is not present in product for spraying application.
**Re: Model input parameters: condition of use or model assumptions**
Parameters that can be regarded as conditions of use (amounts, concentration, consumer habits) are reported in the ES while the model assumptions are reported in the exposure tables.

**Re: Exposure concentration and long-term systemic DNEL inhalation**
According to the R.15 guidance, the exposure estimation to be compared to the long-term DNEL for inhalation is the "event" concentration. The guidance gives the registrant the possibility, under certain conditions, to "average" the event exposure concentration over the day of exposure using appropriate modifying factors depending on the duration of the exposure. This procedure has been implemented and exemplified in the Contributing Scenarios below.
**Re: Risk characterisation: infrequent uses**
Additionally, in case the use of the product containing the substance is infrequent (i.e. less than 15 days/year), the registrant has the possibility to set a new DNEL for infrequent uses to be used for the risk characterisation. Provisions on how to derive such DNELs are given in the R.15 guidance. In this example, this feature has not been exemplified (i.e. exposure/doses during the day of exposure is compared to the long-term systemic DNELs and no DNELs for infrequent uses have been set in the example); this because the long-term systemic DNELs were sufficient to ensure the safe use of the

substance.

## 9.5.1. Env CS 1: Use leading to inclusion into/onto matrix (ERC 8f)

Covers also ERC 8c (indoor application)

### 9.5.1.1. Conditions of use

| Amount used, frequency and duration of use (or from service life) |
|---|
| • Daily local widespread use amount: <= 0.000028 tonnes/day |
| Conditions and measures related to external treatment of waste (including article waste) |
| • Particular considerations on the waste treatment operations: No (low risk)<br>*ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.* |
| Other conditions affecting environmental exposure |
| • Biological STP: Standard [Effectiveness Water: 22.16%] |

### 9.5.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

**Table 9.41. Local releases to the environment**

| Release | Release estimation method | Explanations |
|---|---|---|
| Water | ERC | **Release factor before on site RMM:** 5%<br>**Release factor after on site RMM:** 5%<br>**Local release rate:** 1.37E-3 kg/day |
| Air | ERC | **Release factor before on site RMM:** 15%<br>**Release factor after on site RMM:** 15% |
| Non agricultural soil | ERC | **Release factor after on site RMM:** 0.5% |

### 9.5.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

**Table 9.42. Exposure concentrations and risks for the environment and man via the environment**

| Protection target | Exposure concentration | Risk quantification |
|---|---|---|
| Fresh water | **Local PEC:** 6.5E-5 mg/L | RCR < 0.01 |
| Sediment (freshwater) | **Local PEC:** 5.28E-3 mg/kg dw | RCR < 0.01 |
| Marine water | **Local PEC:** 6.42E-6 mg/L | RCR < 0.01 |
| Sediment (marine water) | **Local PEC:** 5.22E-4 mg/kg dw | RCR < 0.01 |
| Sewage Treatment Plant | **Local PEC:** 5.35E-4 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 2.12E-4 mg/kg dw | RCR < 0.01 |
| Man via environment – Inhalation | **Concentration in air:** 7.13E-7 mg/m³ | RCR < 0.01 |
| Man via environment - Oral | **Exposure via food consumption:** 4.51E-4 mg/kg bw/day | RCR < 0.01 |

| Protection target | Exposure concentration | Risk quantification |
|---|---|---|
| Man via environment - combined routes | | RCR < 0.01 |

# 9.5.2. Cons CS 2: Waterborne paint; Roller application or brushing (PC 9a)

## 9.5.2.1. Conditions of use

| | Method |
|---|---|
| Product (article) characteristics | |
| • Physical form of the used product: Liquid | |
| • Percentage (w/w) of substance in mixture/article: <= 1.0 % | ConsExpo web 1.2 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Frequency of use over a year: Infrequent | ConsExpo web 1.2 |
| • Frequency of use over a day: = 1.0 events per day | ConsExpo web 1.2 |
| • Amount of product used per application: <= 3750 g/event | ConsExpo web 1.2 |
| • Dermal contact rate: <= 30.0 mg/min | ConsExpo web 1.2 |
| • Dermal exposure duration: <= 120.0 min | ConsExpo web 1.2 |
| • Emission/Application duration: <= 120.0 min | ConsExpo web 1.2 |
| • Inhalation exposure duration per event: <= 132.0 min | ConsExpo web 1.2 |
| Information and behavioral advice for consumers | |
| • Adult/child assumed: Adult | ConsExpo web 1.2 |
| Other conditions affecting consumers exposure | |
| • Room volume: >= 20.0 m3 | ConsExpo web 1.2 |
| • Ventilation rate: >= 0.6 ach (air changes per hour) | ConsExpo web 1.2 |
| • Release area: <= 15.0 m2 | ConsExpo web 1.2 |

## 9.5.2.2. Exposure and risks for consumers

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

**Table 9.43. Exposure concentrations and risks for consumers**

| Route of exposure and type of effects | Exposure concentration | Risk quantification |
|---|---|---|
| Inhalation, systemic, long term | 1.9 mg/m³ (ConsExpo web 1.2) | RCR = 0.312 |
| Dermal, systemic, long term | 0.6 mg/kg bw/day (ConsExpo web 1.2) | RCR = 0.171 |
| Oral, systemic, long term | 0 mg/kg bw/day (ConsExpo web 1.2) | RCR < 0.01 |
| Combined routes, systemic, long-term | | RCR = 0.484 |

**Remarks on exposure data from external estimation tools:**

ConsExpo web 1.2
Explanation:
Product name: water born wall paints
Description of the scenario: Based on factsheet (RIVM report 320104008/2007, paragraph 2.6)
Model used for dermal exposure estimation: Direct product contact – Constant rate
Model used for inhalation exposure estimation: Exposure to vapour – Evaporation
Body weight assumed = 60 kg
Frequency of use over the year: 2 days/year

The area of release increases over time
Weight fraction substance for dermal route = 0.01 (fraction)
Weight fraction substance for inhalation route = 0.01 (fraction)
Mass transfer coefficient = 129000 m/hr
Molecular weight matrix = 120 g/mol
Event concentration from ConsExpo has been reduced by a factor of 2 to calculate the daily concentration used in the risk assessment, according to ECHA R.15 Guidance on consumer exposure, paragraph 5.2.3

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.
Additional remarks on risk characterisation:
No DNEL for infrequent uses is available. Therefore RCR is based on long term systemic DNELs.

# 9.5.3. Cons CS 3: Solvent rich paint; Roller application or brushing (PC 9a)

## 9.5.3.1. Conditions of use

| | **Method** |
|---|---|
| Product (article) characteristics | |
| • Physical form of the used product: Liquid | |
| • Percentage (w/w) of substance in mixture/article: <= 1.0 % | ConsExpo web 1.2 |
| Amount used (or contained in articles), frequency and duration of use/exposure | |
| • Frequency of use over a year: Infrequent | ConsExpo web 1.2 |
| • Frequency of use over a day: = 1.0 events per day | ConsExpo web 1.2 |
| • Amount of product used per application: <= 1000 g/event | ConsExpo web 1.2 |
| • Dermal contact rate: <= 30.0 mg/min | ConsExpo web 1.2 |
| • Dermal exposure duration: <= 120.0 min | ConsExpo web 1.2 |
| • Emission/Application duration: <= 120.0 min | ConsExpo web 1.2 |
| • Inhalation exposure duration per event: <= 132.0 min | ConsExpo web 1.2 |
| Information and behavioral advice for consumers | |
| • Adult/child assumed: Adult | ConsExpo web 1.2 |
| Other conditions affecting consumers exposure | |
| • Room volume: >= 20.0 m3 | ConsExpo web 1.2 |
| • Ventilation rate: >= 0.6 ach (air changes per hour) | ConsExpo web 1.2 |
| • Release area: <= 10.0 m2 | ConsExpo web 1.2 |

## 9.5.3.2. Exposure and risks for consumers

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

**Table 9.44. Exposure concentrations and risks for consumers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk quantification** |
|---|---|---|
| Inhalation, systemic, long term | 4.35 mg/m³ (ConsExpo web 1.2) | RCR = 0.716 |
| Dermal, systemic, long term | 0.6 mg/kg bw/day (ConsExpo web 1.2) | RCR = 0.171 |
| Oral, systemic, long term | 0 mg/kg bw/day (ConsExpo web 1.2) | RCR < 0.01 |
| Combined routes, systemic, long-term | | RCR = 0.887 |

**Remarks on exposure data from external estimation tools:**

ConsExpo web 1.2
Explanation:
Product name: solvent rich paints
Description of the scenario: Based on factsheet (RIVM report 320104008/2007, paragraph 2.3)
Model used for dermal exposure estimation: Direct product contact – Constant rate
Model used for inhalation exposure estimation: Exposure to vapour – Evaporation
Body weight assumed = 60 kg
Frequency of use over the year: 1 day/year
The area of release increases over time
Weight fraction substance for dermal route = 0.01 (fraction)
Weight fraction substance for inhalation route = 0.01 (fraction)
Molecular weight = 300 g/mol
Mass transfer coefficient = 129000 m/hr
Event concentration from ConsExpo has been reduced by a factor of 2 to calculate the daily concentration used in the risk assessment, according to ECHA R.15 Guidance on consumer exposure, paragraph 5.2.3

**Risk characterisation**

Qualitative risk characterisation:
Irritation effects on skin, eyes and the respiratory tract are controlled by substance concentration below the classification threshold for mixtures for irritation (< 10 %), and thus no local effects are expected.
Additional remarks on risk characterisation:
No DNEL for infrequent uses is available. Therefore RCR is based on long term systemic DNELs.

# 10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

## 10.1. Human health

**Notes and Comments**

**Re: Combined Risk to Human Health**

When relevant, select the combinations of exposure scenarios which could result in simultaneous exposure of humans and report the outcome of the assessment here. This may occur for example, when it is foreseeable that a worker may undertake a combination of tasks in a shift, or that a person could be exposed both from work and via the environment. Combined exposure could also occur for consumers via different products containing the same substance.

### 10.1.1. Workers

### 10.1.2. Consumer

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

### 10.2.1. All uses (regional scale)

#### 10.2.1.1. Total releases

The total releases to the environment from all the exposure scenarios covered are presented in the table below. This is the sum of the releases to the environments from all exposure scenarios addressed.
Where there is more than one contributing scenario for the environment for a given exposure scenario, the highest release per route across all the contributing scenarios within the use has been taken into account as the release for the use (both for the regional and the exposure due to all the widespread uses). This may lead to overestimation of the PEC.

**Table 10.1. Total releases to the environment per year from all life cycle stages**

| Release route | Total releases per year |
|---|---|
| Water | 7.06E3 kg/year |
| Air | 1.86E4 kg/year |
| Soil | 500 kg/year |

### 10.2.2. Regional assessment

The regional predicted environmental concentration (PEC regional) and the related risk characterisation ratios when a PNEC is available are presented in the table below. The exposure to man via the environment from regional exposure and the related risk characterisation ratios are also provided. The exposure concentration for human via inhalation is equal to the PEC air.
The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

**Table 10.2. Predicted regional exposure concentrations (Regional PEC) and risks for the environment**

| Protection target | Regional PEC | Risk characterisation |
|---|---|---|
| Fresh water | **Regional PEC:** 1.16E-5 mg/L | RCR < 0.01 |
| Sediment (freshwater) | **Regional PEC:** 1.11E-3 mg/kg dw | RCR < 0.01 |
| Marine water | **Regional PEC:** 1.08E-6 mg/L | RCR < 0.01 |
| Sediment (marine water) | **Regional PEC:** 8.46E-5 mg/kg dw | RCR < 0.01 |
| Agricultural soil | **Regional PEC:** 1.15E-6 mg/kg dw | RCR < 0.01 |
| Man via environment - Inhalation | **Concentration in air:** 6.61E-7 mg/m³ | RCR < 0.01 |
| Man via environment - Oral | **Exposure via food consumption:** 7.94E-5 mg/kg bw/day | RCR < 0.01 |
| Man via environment - combined routes | | RCR < 0.01 |

## 10.2.3. Local exposure due to all widespread uses

The predicted local environmental concentrations (PEC local) and the exposure to man via the environment based on the releases from all widespread uses are reported in the table below, when relevant, together with the risk characterisation ratio when a PNEC is available. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

**Table 10.3. Predicted exposure concentrations and risks for the environment and man via the environment due to all wide spread uses**

| Protection target | PEC local due to all widespread uses | Risk characterisation |
|---|---|---|
| Fresh water | **PEC:** 1.18E-4 mg/L | RCR = 0.012 |
| Sediment (freshwater) | **PEC:** 9.62E-3 mg/kg dw | RCR = 0.012 |
| Marine water | **PEC:** 1.18E-5 mg/L | RCR = 0.011 |
| Sediment (marine water) | **PEC:** 9.56E-4 mg/kg dw | RCR = 0.011 |
| Sewage Treatment Plant | **PEC:** 1.07E-3 mg/L | RCR < 0.01 |
| Agricultural soil | **PEC:** 4.22E-4 mg/kg dw | RCR < 0.01 |
| Man via environment - Inhalation | **PEC:** 7.66E-7 mg/m³ | RCR < 0.01 |
| Man via environment - Oral | **PEC:** 8.23E-4 mg/kg bw/day | RCR < 0.01 |
| Man via environment - combined routes | | RCR < 0.01 |

## 10.2.4. Local exposure due to combined uses at a site

**Notes and Comments**

**Re: Environmental Risk for combined uses at site**

When relevant, select the combinations of exposure scenarios which could result in simultaneous environmental exposure at a site and report the outcome of the assessment here. This may occur for example, when manufacturing and formulation takes place at the same site.

# Annexes

# 1. Annex: References

Ref 4.1.1.1 2007: Hydrolysis (study report), Report date:

Ref 4.1.2.1.1.a 2006: Biodegradation in water, OECD 301B (study report), Report date:

Ref 4.1.2.1.1.b 2009: Biodegradation in water, OECD 301A (study report), Report date:

Ref 4.1.2.1.2 1993: Biodegradation in water and sediments, simulation test (study report), Report date:

Ref 4.1.2.2 1988: Biodegradation in soil (study report), Report date:

Ref 4.2.1 2007: Adsorption/desorption (study report), Report date:

Ref 4.3.1 1991: Bioaccumulation in aquatic system (study report), Report date:

Ref 5.2.1.1 2005: Acute oral toxicity (study report), Report date:

Ref 5.2.1.2 2004: Acute inhalation toxicity (study report), Report date:

Ref 5.2.1.3 2005: Acute dermal toxicity (study report), Report date:

Ref 5.3.1.1 2000: Skin irritation (study report), Report date:

Ref 5.3.2.1 1995: Eye irritation (study report), Report date:

Ref 5.5.1.1 1996: Skin sensitisation (study report), Report date:

Ref 5.6.1.1a 2005: Oral 28-day study (study report), Report date:

Ref 5.6.1.1b 2005: Oral 90-day study (study report), Report date:

Ref 5.7.1.1a 2008: Gene mutation study in mammalian cells (study report), Report date:

Ref 5.7.1.1b 2007: Ames test (study report), Report date:

Ref 5.7.1.1c 2007: Chromosome aberration study (study report), Report date:

Ref 5.9.1.1 2007: Screening study for reproductive toxicity (study report), Report date:

Ref 6.2 2012: Flash point (study report), Report date:

Ref 7.1.1.1 2007: Short term toxicity to fish (study report), Report date:

Ref 7.1.2.1 2006: Short term toxicity to aquatic invertebrates (study report), Report date:

Ref 7.1.3 2007: Toxicity to aquatic algae and cyanobacteria (study report), Report date:

Ref 7.1.4 2007: Toxicity to microorganism (study report), Report date:

# 2. Annex: Information on Test Material

Test material: **ECHA Substance / 11111-11-1**
Form: **liquid**

| | | |
|---|---|---|
| Composition type:<br>Constituent | Reference substance: ECHA Substance<br>EC no.:<br>CAS no: 11111-11-1<br>IUPAC name: ECHA Substance | **Concentration range:**<br>Additional information: |

Composition / purity:
Details on test material:

# 3. Annex: Report on measured dataset

Not developed in the context of this example.

*(Note also, an Annex such as this one, is not generated automatically from the CSR report generator; it has to be generated manually.)*

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