
# SAFETY DATA SHEET
# MENTHOL CRYSTALS

Commission Regulation (EU) No 2015/830 of 28 May 2015.

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

| | |
|---|---|
| Product name | MENTHOL CRYSTALS |
| Chemical name | MENTHOL |
| Product number | MENCRY, 1D |
| REACH registration number | 01-2119458866-21-XXXX |
| REACH registration notes | REACH registration only covers products which FLUID SCIENCE LTD have imported into Europe or sourced within Europe. If the product is sold directly outside Europe this is not covered under the registration. It is the responsibility of the subsequent importer into Europe to ensure their volume of product is covered under the REACH regulations. |
| CAS number | 2216-51-5 |
| EC number | 218-690-9 |

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

| | |
|---|---|
| Identified uses | see exposure scenario |

### 1.3. Details of the supplier of the safety data sheet

| | |
|---|---|
| Supplier | Fluid Science Ltd<br>Unit 5, Pride Point,<br>Ashcroft Road,<br>Knowsley Ind. Est.,<br>Liverpool<br>L33 7TW |

### 1.4. Emergency telephone number

| | |
|---|---|
| Emergency Telephone | 01244 506 860 (Office Hours Only) |

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture Classification (EC 1272/2008)

| | |
|---|---|
| Physical hazards | Not Classified |
| Health hazards | Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 |
| Environmental hazards | Not Classified |

### 2.2. Label elements

| | |
|---|---|
| EC number | 218-690-9 |

Hazard pictograms

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| | |
|---|---|
| Signal word | Warning |
| Hazard statements | H315 Causes skin irritation.<br>H319 Causes serious eye irritation. |
| Precautionary statements | P264 Wash contaminated skin thoroughly after handling.<br>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.<br>P302+P352 IF ON SKIN: Wash with plenty of water.<br>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321 Specific treatment (see medical advice on this label). |
| Supplementary precautionary statements | P332+P313 If skin irritation occurs: Get medical advice/ attention.<br>P337+P313 If eye irritation persists: Get medical advice/ attention.<br>P362+P364 Take off contaminated clothing and wash it before reuse. |

2.3. Other hazards

## SECTION 3: Composition/information on ingredients

3.1. Substances

| | |
|---|---|
| L-MENTHOL | >99% |
| CAS number: 2216-51-5 EC number: 218-690-9 | |
| Classification<br>Skin Irrit. 2 - H315<br>Eye Irrit. 2 - H319 | |

The full text for all hazard statements is displayed in Section 16.

| | |
|---|---|
| Product name | MENTHOL CRYSTALS |
| Chemical name | MENTHOL |
| REACH registration number | 01-2119458866-21-XXXX |
| REACH registration notes | REACH registration only covers products which FLUID SCIENCE LTD have imported into Europe or sourced within Europe. If the product is sold directly outside Europe this is not covered under the registration. It is the responsibility of the subsequent importer into Europe to ensure their volume of product is covered under the REACH regulations. |
| CAS number | 2216-51-5 |
| EC number | 218-690-9 |

## SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---|---|
| General information | No information available. |
| Inhalation | Move affected person to fresh air at once. Seek medical advice if symptoms persist. |
| Ingestion | Immediately rinse mouth and drink plenty of water (200-300 ml). Do not induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention immediately. |
| Skin contact | Wash skin thoroughly with soap and water. Continue to rinse for at least 15 minutes. Get medical attention if irritation persists after washing. |
| Eye contact | Rinse immediately with plenty of water. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes. Get medical attention if irritation persists after washing. Show this Safety Data Sheet to the medical personnel. |
| Protection of first aiders | No information available. |

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4.2. Most important symptoms and effects, both acute and delayed

| | |
|---|---|
| General information | No information available. |
| Inhalation | No information available. |
| Ingestion | No information available. |
| Skin contact | No information available. |
| Eye contact | No information available. |

4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor No information available. Specific treatments No information available.

## SECTION 5: Firefighting measures

5.1. Extinguishing media

| | |
|---|---|
| Suitable extinguishing media | Water spray. Alcohol-resistant foam. Dry chemicals, sand, dolomite etc. Carbon dioxide (CO2). |
| Unsuitable extinguishing media | Do not use water jet as an extinguisher, as this will spread the fire. |

5.2. Special hazards arising from the substance or mixture

| | |
|---|---|
| Specific hazards | No information available. |
| Hazardous combustion products | No information available. |

5.3. Advice for firefighters

| | |
|---|---|
| Protective actions during firefighting | Cool containers exposed to heat with water spray and remove them from the fire area if it can be done without risk. |
| Special protective equipment protective for firefighters | Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate clothing. |

## SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear protective clothing as described in Section 8 of this safety data sheet.

For non-emergency personnel No information available. For emergency responders No information available.

6.2. Environmental precautions

Environmental precautions Do not discharge into drains or watercourses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Collect mechanically. Place waste in labelled, sealed containers. Dam up. Avoid open flames and other sources of ignition. Local authorities should be advised if significant spillages cannot be contained.

6.4. Reference to other sections

Reference to other sections For personal protection, see Section 8. For waste disposal, see Section 13. See Section 11 for additional information on health hazards. See Section 12 for additional information on ecological hazards.

## SECTION 7: Handling and storage

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7.1. Precautions for safe handling

| | |
|---|---|
| Usage precautions | Good personal hygiene procedures should be implemented. Do not eat, drink or smoke when using the product. Provide adequate ventilation. |

Advice on general occupational hygiene No information available.

7.2. Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| Storage precautions | Store in tightly-closed, original container in a dry, cool and well-ventilated place. Protect from light. Keep away from heat. |
| Storage class | No information available. |

7.3. Specific end use(s)

Specific end use(s) No information available. Usage description No information available.

## SECTION 8: Exposure controls/Personal protection

8.1. Control parameters

Occupational exposure limits

No information available.

| | |
|---|---|
| Ingredient comments | No exposure limits known for ingredient(s). |
| Biological limit values | No information available. |
| DNEL | No information available. |
| DMEL | No information available. |
| PNEC | - Fresh water; 15.6 µg/L<br>- marine water; 1.56 µg/L<br>- Intermittent release; 156 µg/L<br>- Sediment (Freshwater); 289 µg/kg<br>- Sediment (Marinewater); 28.9 µg/kg<br>- Soil; 48.4 µg/kg |

8.2. Exposure controls

Protective equipment

| | |
|---|---|
| Appropriate engineering controls | Provide adequate general and local exhaust ventilation. |
| Personal protection | No information available. |
| Eye/face protection | The following protection should be worn: Chemical splash goggles. |
| Hand protection | Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. Wear chemicals-resistant gloves, e.g. safety gloves of chloroprene Level 2 or of butyl rubber Level 6. |
| Other skin and body protection | Provide eyewash station and safety shower. Wear lightweight protective clothing Wash contaminated clothing before reuse. |
| Hygiene measures | Wash hands after handling. Do not eat, drink or smoke when using this product. |
| Respiratory protection | No specific requirements are anticipated under normal conditions of use. Protection against nuisance dust must be used when the airborne concentration exceeds 10 mg/m3. |
| Thermal hazards | No information available. |

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| | |
|---|---|
| Environmental exposure controls | No information available. |

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

| | |
|---|---|
| Appearance | Crystalline solid |
| Colour | whitish to white solid |
| Odour | Characteristic. Fresh. Peppermint. |
| Odour threshold | No specific test data are available. |
| pH | No specific test data are available. |
| Melting point | 41.2 - 41.7°C @ 1013 hPa |
| Initial boiling point and range | 212°C @ |
| Flash point | 94°C Closed cup. |
| Evaporation rate | No specific test data are available. |
| Evaporation factor | No specific test data are available. |
| Flammability (solid, gas) | No specific test data are available. |
| Upper/lower flammability or explosive limits | No specific test data are available. |
| Other flammability | No specific test data are available. |
| Vapour pressure | 19 Pa @ 25°C |
| Vapour density | No specific test data are available. |
| Relative density | No specific test data are available. |
| Bulk density | 0.49 g/cm3 |
| Solubility(ies) | soluble in organic solvents 100 - 1000 mg/l water @ 20°C |
| Partition coefficient | log Pow: 3.15 |
| Auto-ignition temperature | No specific test data are available. |
| Decomposition Temperature | No specific test data are available. |
| Viscosity | No specific test data are available. |
| Explosive properties | No specific test data are available. |
| Explosive under the influence of a flame | No information available. |
| Oxidising properties | Not available. |
| Comments | No information available. |

### 9.2. Other information

| | |
|---|---|
| Other information | Not available. |
| Refractive index | No information available. |
| Particle size | No information available. |
| Molecular weight | No information available. |
| Volatility | No information available. |
| Saturation concentration | No information available. |

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| | |
|---|---|
| Critical temperature | No information available. |
| Volatile organic compound | No information available. |

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

| | |
|---|---|
| Reactivity | No information available. |

### 10.2. Chemical stability

| | |
|---|---|
| Stability | Stable at normal ambient temperatures. |

### 10.3. Possibility of hazardous reactions

| | |
|---|---|
| Possibility of hazardous reactions | None under normal processing. |

### 10.4. Conditions to avoid

| | |
|---|---|
| Conditions to avoid | No information available. |

### 10.5. Incompatible materials

| | |
|---|---|
| Materials to avoid | Strong acids. Strong alkalis. Strong oxidising agents. |

### 10.6. Hazardous decomposition products

Hazardous decomposition products: Carbon monoxide (CO). Unidentified organic compounds may be formed during combustion.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

| | |
|---|---|
| Toxicological effects | To the best of our knowledge, the chemical/physical/toxicological properties have not been thoroughly investigated. |
| Other health effects | No information available. |

Acute toxicity - oral

| | |
|---|---|
| Acute toxicity oral ($LD_{50}$ mg/kg) | 3,180.0 |
| Notes (oral $LD_{50}$) | $LD_{50}$ 2.615 g/kg, Oral, Rat |

Acute toxicity - dermal

| | |
|---|---|
| Acute toxicity dermal ($LD_{50}$ mg/kg) | 5,000.0 |
| Species | Rabbit |

Acute toxicity - inhalation

| | |
|---|---|
| Notes (inhalation $LC_{50}$) | $LD_{50}$ 5289 mg/m³, Inhalation, Rat |

Skin corrosion/irritation

| | |
|---|---|
| Animal data | Irritating. |
| Human skin model test | No information available. |
| Extreme pH | No information available. |

Serious eye damage/irritation

| | |
|---|---|
| Serious eye damage/irritation | Moderate to intense reactions of rabbit eye cornea and conjunctiva, which is complete reversible within 7 days. |

Respiratory sensitisation

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| | |
|---|---|
| Respiratory sensitisation | Not sensitising. |

Skin sensitisation

| | |
|---|---|
| Skin sensitisation | No information available. |

Germ cell mutagenicity

| | |
|---|---|
| Genotoxicity - in vitro | Bacterial reverse mutation test: Negative. |
| Genotoxicity - in vivo | micronucleus test: Negative. |

Carcinogenicity

| | |
|---|---|
| Carcinogenicity | No evidence of carcinogenicity in animal studies. |
| Target organ for carcinogenicity | No information available. |
| IARC carcinogenicity | No information available. |
| NTP carcinogenicity | No information available. |

Reproductive toxicity

| | |
|---|---|
| Reproductive toxicity - fertility | Fertility - NOAEL 667 mg/kg, Oral, Mouse |
| Reproductive toxicity development | Not embryo- or fetotoxic and had no teratogenic properties in rat at non-maternally toxic doses (218 mg/kg bw/day). |

Specific target organ toxicity - single exposure

STOT - single exposure No information available. Target

organs No information available.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure No information available. Target

organs No information available.

Aspiration hazard

| | |
|---|---|
| Aspiration hazard | No information available. |

| | |
|---|---|
| Toxicokinetics | No information available. |
| General information | No information available. |
| Inhalation | Irritating to respiratory system. |
| Ingestion | May be harmful if swallowed. |
| Skin contact | Irritating to skin. |
| Eye contact | Irritating to eyes. |
| Acute and chronic health hazards | No information available. |
| Route of exposure | No information available. |
| Target organs | No information available. |
| Medical symptoms | No information available. |
| Medical considerations | No information available. |

## SECTION 12: Ecological information

| | |
|---|---|
| Ecotoxicity | No data on possible environmental effects have been found. |

12.1. Toxicity

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| | |
|---|---|
| Toxicity | No information available. |

Acute aquatic toxicity

| | |
|---|---|
| Acute toxicity - fish | $LC_0$, 96 hours: 13.2 mg/l, Brachydanio rerio (Zebra Fish)<br>$LC_{50}$, 96 hours: 15.6 mg/l, Brachydanio rerio (Zebra Fish)<br>$LC_{100}$, 96 hours: 18.4 mg/l, Brachydanio rerio (Zebra Fish) |
| Acute toxicity - aquatic invertebrates | $EC_0$, 24 hours: 25 mg/l, Daphnia magna<br>$EC_{50}$, 24 hours: 37.7 mg/l, Daphnia magna<br>$EC_{100}$, 24 hours: 100 mg/l, Daphnia magna<br>$EC_0$, 48 hours: 11.35 mg/l, Daphnia magna<br>$EC_{50}$, 48 hours: 26.6 mg/l, Daphnia magna<br>$EC_{100}$, 48 hours: 92.35 mg/l, Daphnia magna |
| Acute toxicity - aquatic plants | $EC_{50}$, 72 hours: 21.4 mg/l, Desmodesmus subspicatus<br>NOEC, 72 hours: 9.65 mg/l, Desmodesmus subspicatus<br>LOEC, 72 hours: 18.75 mg/l, Desmodesmus subspicatus |
| Acute toxicity microorganisms | EC10, 3 hours: 51 mg/l, Activated sludge<br>$EC_{50}$, 3 hours: 237 mg/l, Activated sludge |
| Acute toxicity - terrestrial | No information available. |

Chronic aquatic toxicity

| | |
|---|---|
| Chronic toxicity - fish early life stage | No information available. |
| Short term toxicity - embryo and sac fry stages | No information available. |
| Chronic toxicity - aquatic invertebrates | No information available. |
| Toxicity to soil | No information available. |
| Toxicity to terrestrial plants | No information available. |

12.2. Persistence and degradability

| | |
|---|---|
| Persistence and degradability | No information available. |
| Phototransformation | - Half-life : 16 hours |
| Stability (hydrolysis) | No information available. |
| Biodegradation | Readily biodegradable |

Biological oxygen demand No information available. Chemical

oxygen demand No information available.

12.3. Bioaccumulative potential

| | |
|---|---|
| Bioaccumulative potential | The product does not contain any substances expected to be bioaccumulating. |
| Partition coefficient | log Pow: 3.15 |

12.4. Mobility in soil

| | |
|---|---|
| Mobility | No information available. |
| Adsorption/desorption coefficient | - koc: 88.15 - 149 L/kg @ °C |
| Henry's law constant | 4.8 Pa m³/mol @ 12°C |
| Surface tension | No information available. |

12.5. Results of PBT and vPvB assessment

| | |
|---|---|
| Results of PBT and vPvB assessment | This substance is not classified as PBT or vPvB according to current EU criteria. |

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12.6. Other adverse effects

| | |
|---|---|
| Other adverse effects | No information available. |

## SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|---|---|
| General information | No information available. |
| Disposal methods | Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority. Reuse or recycle products wherever possible. Disposal should be in accordance with applicable regional, national and local laws and regulations. Contaminated packaging material should be treated at the product. |
| Waste class | No information available. |

## SECTION 14: Transport information

| | |
|---|---|
| General | The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID). |

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant
No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

| | |
|---|---|
| Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | Not applicable. |

## SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

| | |
|---|---|
| National regulations | No information available. |
| EU legislation | Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended).<br>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended). |
| Guidance | No information available. |
| Health and environmental listings | No information available. |

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| | |
|---|---|
| Authorisations (Annex XIV Regulation 1907/2006) | No information available. |
| Restrictions (Annex XVII Regulation 1907/2006) | No information available. |

15.2. Chemical safety assessment

No information available.

Inventories

EU - EINECS/ELINCS
No information available.

Canada - DSL/NDSL
No information available.

US - TSCA
No information available.

US - TSCA 12(b) Export Notification No information available.

Australia - AICS
No information available.

Japan - ENCS
No information available.
Korea - KECI
No information available.

China - IECSC
No information available.

Philippines – PICCS No information available.

New Zealand - NZIOC
No information available.

South Korea

## SECTION 16: Other information

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| | |
|---|---|
| Abbreviations and acronyms used in the safety data sheet | ECHA: European Chemicals Agency<br>ATE: Acute Toxicity Estimate<br>ADR:European Agreement concerning the International Carriage of Dangerous Goods by Road<br>CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008<br>CAS# / CAS NO. CAS-numero (eräs kemikaalien tunnistenumero)<br>DNEL: Derived No Effect Level<br>C&L: Classification and Labelling<br>EC NO.: EINECS and ELINCS Number (see also EINECS and ELINCS)<br>EINECS: European Inventory of Existing Commercial Substances<br>IATA: International Air Transport Association<br>kow: octanol-water partition coefficient<br>LC50: Lethal Concentration to 50 % of a test population<br>LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)<br>SDS: Safety Data Sheet<br>OECD: Organization for Economic Co-operation and Development<br>PBT: Persistent, Bioaccumulative and Toxic substance<br>PEC: Predicted Effect Concentration<br>PNEC: Predicted No Effect Concentration(s)<br>PPE: Personal Protection Equipment<br>QSAR: Qualitative Structure Activity Relationship<br>REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006<br>SIEF: Substance Information Exchange Forum<br>STOT: Specific Target Organ Toxicity<br>STOT (RE): Repeated Exposure<br>STOT (SE): Single Exposure<br>vPvB: Very Persistent and Very Bioaccumulative |
| General information | No information available. |
| Key literature references and sources for data | Source: European Chemicals Agency, http://echa.europa.eu/ Material Safety Data Sheet, Misc. manufacturers. |
| Classification procedures according to Regulation (EC) 1272/2008 | No information available. |
| Training advice | No information available. |
| Revision comments | Revision due to amendment of contents in section: 1, 16. |
| Revision date | 24/07/2020 |
| Revision | 004 |
| Supersedes date | 15/09/2016 |
| SDS number | 11000 |
| Hazard statements in full | H315 Causes skin irritation.<br>H319 Causes serious eye irritation. |

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.

# 9. EXPOSURE ASSESSMENT (and related risk characterisation)

## 9.0. Introduction

### 9.0.1. Overview of uses and Exposure Scenarios

**Tonnage information:**

Assessed tonnage: 999.0 tonnes/year based on:

- 999.0 tonnes/year imported

The following table list all the exposure scenarios (ES) assessed in this CSR.

**Table 44. Overview of exposure scenarios and contributing scenarios**

| Identifiers | Market Sector | Titles of exposure scenarios and the related contributing scenarios | Tonnage (tonnes per year) |
|---|---|---|---|
| ES1 - F1 | | Formulation - Formulation of compounds at small sites<br>- Formulation of preparations (ERC 2)<br>- Use in closed process, no likelihood of exposure (PROC 1) - Use in closed, continuous process with occasional controlled exposure (PROC 2)<br>- Use in closed batch process (synthesis or formulation) (PROC 3)<br>- Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)<br>- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)<br>- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)<br>- Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)<br>- Use as laboratory reagent (PROC 15) | 100.0 |

| | | | |
|---|---|---|---|
| ES2 - F2 | | Formulation - Formulation of end-products at small sites<br>- Formulation of preparations (ERC 2)<br>- Use in closed process, no likelihood of exposure (PROC 1) - Use in closed, continuous process with occasional controlled exposure (PROC 2)<br>- Use in closed batch process (synthesis or formulation) (PROC 3)<br>- Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)<br>- industrial spraying (PROC 7)<br>- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)<br>- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)<br>- Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)<br>- Production of preparations or articles by tabletting, compression, extrusion, pelletisation (PROC 14) - Use as laboratory reagent (PROC 15) | 112.5 |
| ES3 - IW1 | | Use at industrial site - Use of L-Menthol as intermediate | 135.0 |

| **Identifiers** | **Market Sector** | **Titles of exposure scenarios and the related contributing scenarios** | **Tonnage (tonnes per year)** |
|---|---|---|---|
| | | - Industrial use resulting in manufacture of another substance (use of intermediates) (ERC 6a)<br>- Use in closed, continuous process with occasional controlled exposure (PROC 2)<br>- Use in closed batch process (synthesis or formulation) (PROC 3) - Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)<br>- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)<br>- Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)<br>- Use as laboratory reagent (PROC 15) | |
| ES4 - IW2 | | Use at industrial site - Industrial end-use of washing and cleaning products<br>- Industrial use of processing aids in processes and products, not becoming part of articles (ERC 4)<br>- Use in closed process, no likelihood of exposure (PROC 1) - Use in closed, continuous process with occasional controlled exposure (PROC 2)<br>- Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)<br>- industrial spraying (PROC 7)<br>- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)<br>- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)<br>- Roller application or brushing (PROC 10) | 0.0 |

| | | | |
|---|---|---|---|
| | | - Treatment of articles by dipping and pouring (PROC 13) | |
| ES5 - PW1 | | Use by professional worker - Professional end-use of washing and cleaning products<br>- Wide dispersive outdoor use of processing aids in open systems<br>(ERC 8d)<br>- Use in closed process, no likelihood of exposure (PROC 1) - Use in closed, continuous process with occasional controlled exposure (PROC 2)<br>- Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)<br>- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)<br>- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)<br>- Roller application or brushing (PROC 10)<br>- Non industrial spraying (PROC 11)<br>- Treatment of articles by dipping and pouring (PROC 13) | 500.0 |
| ES6 - PW2 | | Use by professional worker - Professional end-use of polishes and wax blends<br>- Wide dispersive indoor use of processing aids in open systems (ERC 8a)<br>- Use in closed, continuous process with occasional controlled exposure (PROC 2)<br>- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC | 500.0 |
| **Identifiers** | **Market Sector** | **Titles of exposure scenarios and the related contributing scenarios** | **Tonnage (tonnes per year)** |
| | | 8a)<br>- Roller application or brushing (PROC 10)<br>- Non industrial spraying (PROC 11) | |

| | | | |
|---|---|---|---|
| ES7 - C1 | | Consumer Use - Consumer end-use of washing and cleaning products<br>- Wide dispersive outdoor use of processing aids in open systems<br>(ERC 8d)<br>- Laundry and dish washing products (PC 35)<br>- Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners ) (PC 35) - Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners) (PC 35) | 500.0 |
| ES8 - C2 | | Consumer Use - Consumer Use - Consumer end-use of air care products<br>- Wide dispersive indoor use of processing aids in open systems (ERC 8a)<br>- Aircare, instant action (aerosol sprays) (PC 3)<br>- Aircare, continuous action (solid and liquid) (PC 3) | 500.0 |
| ES9 - C3 | | Consumer Use - Consumer Use - Consumer end-use of biocides (covers ERCs 8d "outdoor" and 8a "indoor")<br>- Wide dispersive outdoor use of processing aids in open systems<br>(ERC 8d)<br>- Biocide, instant action (aerosol sprays) (PC 8)<br>- Biocides, continuous action (solid and liquid - evaporation through heating using electrical evaporator) (PC 8) | 500.0 |
| ES10 - C4 | | Consumer Use - Consumer Use - Consumer end-use of polishes and wax blends<br>- Wide dispersive indoor use of processing aids in open systems (ERC 8a)<br>- Polishes, wax / cream (floor, furniture, shoes) (PC 31)<br>- Polishes, spray (furniture, shoes) (PC 31) | 500.0 |
| ES11 - C5 | | Consumer Use - Consumer Use - Consumer and Professional end-use of cosmetics & pharmaceuticals<br>- Wide dispersive indoor use of processing aids in open systems (ERC 8a)<br>- Cosmetics, personal care products (PC 39)<br>- Perfumes, Fragrances (PC 28) | 500.0 |
| **Manufacture: M-#, Formulation: F-#, Industrial end use at site: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial site): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.)** | | | |

## 9.0.2. Introduction to the assessment

### 9.0.2.1. Environment

**Scope and type of assessment**

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 45. Type of risk characterisation required for the environment**

| **Protection target** | **Type of risk characterisation** | **Hazard conclusion (see section 7)** |
|---|---|---|
| Freshwater | Quantitative | PNEC aqua (freshwater) = 15.6 µg/L |
| Sediment (freshwater) | Quantitative | PNEC sediment (freshwater) = 289 |
| **Protection target** | **Type of risk characterisation** | **Hazard conclusion (see section 7)** |
| | | µg/kg sediment dw |

| | | |
|---|---|---|
| Marine water | Quantitative | PNEC aqua (marine water) = 1.56 µg/L |
| Sediment (marine water) | Quantitative | PNEC sediment (marine water) = 28.9 µg/kg sediment dw |
| Sewage treatment plant | Quantitative | PNEC STP = 2.37 mg/L |
| Air | Not needed | No hazard identified |
| Agricultural soil | Quantitative | PNEC soil = 48.4 µg/kg soil dw |
| Predator | Quantitative | PNEC oral = 83.3 mg/kg food |

**Comments on assessment approach:**

The regional concentrations are reported in section 10.2.1.2 (see Table 124, “Predicted regional exposure concentrations (Regional PEC)”). 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).

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

- Half-life in air (16 h)

**9.0.2.2. Man via environment**

**Scope and type of assessment**

The exposure assessment for man via environment is not needed.

According to REACH “Guidance on information requirements and chemical safety assessment: R16 environmental exposure estimation”, the criteria of whether the exposure route is relevant or not as follows: Assessment of indirect exposure is generally only conducted if: 1) The tonnage >1,000 t/y or 2) The tonnage >100 t/Y and the substance is classified as “Toxic” with a risk phrase “R48”; or as a carcinogen or mutagen (of any category); or as toxic to reproduction (category 1 or 2). Indirect exposure of human via environment is not relevant as L-menthol does not fit with any of the above criteria.

**9.0.2.3. Workers**

**Scope and type of assessment**

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 46. Type of risk characterisation required for workers**

| Route | Type of effect | Type of risk characterisation | Hazard conclusion (see section 5.11) |
|---|---|---|---|
| **Inhalation** | Systemic, long-term | Quantitative | DNEL (Derived No Effect Level) = 132 mg/m³ |
| | Systemic, acute | Not needed | No hazard identified |
| | Local, long-term | Quantitative | DNEL (Derived No Effect Level) = 10 mg/m³ |
| | Local, acute | Quantitative | DNEL (Derived No Effect Level) = 10 mg/m³ |
| **Dermal** | Systemic, long-term | Quantitative | DNEL (Derived No Effect Level) = 19 mg/kg bw/day |
| | Systemic, acute | Not needed | No hazard identified |

| | | | |
|---|---|---|---|
| | Local, long-term | Qualitative | Medium hazard (no threshold derived) |
| **Route** | **Type of effect** | **Type of risk characterisation** | **Hazard conclusion (see section 5.11)** |
| | Local, acute | Qualitative | Medium hazard (no threshold derived) |
| **Eye** | Local | Qualitative | Medium hazard (no threshold derived) |

**9.0.2.4. Consumers**

**Scope and type of assessment**

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

**Table 47. Type of risk characterisation required for consumers**

| Route | Type of effect | Type of risk characterisation | Hazard conclusion (see section 5.11) |
|---|---|---|---|
| **Inhalation** | Systemic, long-term | Quantitative | DNEL (Derived No Effect Level) = 33 mg/m³ |
| | Systemic, acute | Not needed | No hazard identified |
| | Local, long-term | Not needed | No hazard identified |
| | Local, acute | Not needed | No hazard identified |
| **Dermal** | Systemic, long-term | Quantitative | DNEL (Derived No Effect Level) = 9.4 mg/kg bw/day |
| | Systemic, acute | Not needed | No hazard identified |
| | Local, long-term | Qualitative | Low hazard (no threshold derived) |
| | Local, acute | Qualitative | Low hazard (no threshold derived) |
| **Eye** | Local | Qualitative | Medium hazard (no threshold derived) |
| **Oral** | Systemic, long-term | Quantitative | DNEL (Derived No Effect Level) = 9.4 mg/kg bw/day |

# 9.1. Exposure scenario 1: Formulation - Formulation of compounds at small sites

| | |
|---|---|
| **Environment contributing scenario(s):** | |
| Formulation of preparations | ERC 2 |
| **Worker contributing scenario(s):** | |
| Use in closed process, no likelihood of exposure | PROC 1 |
| Use in closed, continuous process with occasional controlled exposure | PROC 2 |
| Use in closed batch process (synthesis or formulation) | PROC 3 |
| Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) | PROC 5 |
| Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities | PROC 8a |
| Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities | PROC 8b |
| Transfer of substance or preparation into small containers (dedicated filling line, including weighing) | PROC 9 |

| | |
|---|---|
| 218-690-9 | 2216-51-5 |
| Use as laboratory reagent | PROC 15 |

Description of the technical process covered by the SpERC: IFRA 2.1

Mixing of individual fragrance substances with other fragrance substances, stabilizers and solvents to create a mixture (named fragrance compound), including reception of goods, packing and re-packing of the substance and its mixtures in batch or continuous operations, including storage, materials transfers, filling process equipment, mixing of ingredients, filling of containers, large and small scale packing, sampling, cleaning, maintenance and associated laboratory activities

## 9.1.1. Environmental contributing scenario 1: Formulation of preparations

**9.1.1.1. Conditions of use** small sites: Quantity of fragrance compound produced per year on one site less than 1,000 tonnes.

| **Amount used, frequency and duration of use (or from service life)** |
|---|
| • Daily use at site: <= 0.4 tonnes/day |
| • Annual use at a site: <= 100 tonnes/year |
| • Percentage of EU tonnage used at regional scale: = 100 % |
| **Conditions and measures related to sewage treatment plant** |
| • Municipal STP: Yes [Effectiveness Water: 88.07%] |
| • Discharge rate of STP: >= 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |
| **Conditions and measures related to treatment of waste (including article waste)** |
| • Particular considerations on the waste treatment operations: No (low risk) (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** |
| • Receiving surface water flow rate: >= 1.8E4 m3/d |

**9.1.1.2. Releases**

The local releases to the environment are reported in the following table.

**Table 48. Local releases to the environment**

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|
| **Water** | SpERC based<br><br>IFRA 2.1 - IFRA 2.1b.v1<br><br>IFRA-Formulation of fragrance compound - IFRA - Formulation of fragrance compounds at small sites | **Initial release factor:** 0.5%<br>**Final release factor:** 0.5%<br>**Local release rate:** 2 kg/day<br>**Explanation / Justification:** A survey was conducted in 2008 to obtain information on the emission to water during the compounding process13. Responses to the questionnaire were received from 7 compounding sites with varying size and varying degree of emission control. Most responses showed that the COD in wastewater was caused mainly by the presence of fragrances in the water. Based on indications of the COD and the production volumes, and assuming that the COD of most of the fragrance ingredients in wastewater = 3 mg O/mg substance it was possible to estimate the release of products to wastewater. This fraction, prior to any treatment, ranges from 0.2 to < 0.43 % for the small compounders whereas for the large compounders the estimates range from 0.01 to 0.15%. |

| | | |
|---|---|---|
| **Air** | SpERC based<br>same as above | **Initial release factor:** 2.5%<br>**Final release factor:** 2.5%<br>**Local release rate:** 10 kg/day<br>**Explanation / Justification:** Default conservative value from ERC2 |
| **Soil** | SpERC based<br>same as above | **Final release factor:** 0%<br>**Explanation / Justification:** All solid waste is collected. Used packaging which has been in contact with chemicals are recycled, collected by waste companies or incinerated. The delivery area as well as the mixing halls is in contained area, so all water is collected in dedicated sewers. This implies that there is no direct emission to the soil. Spills are cleaned with specific sorbing materials or cleaned with water that is collected in dedicated sewers along with the process water. Spilled fragrances may be collected and recycled in the process. |

**Releases to waste**

**Release factor to waste from the process:** 0%

Waste is treated under national regulations. Spills are absorbed and collected as chemical waste. The same is true for samples, packaging materials and sludge residues from water treatment. It is disposed of to an outside contractor and may be treated, incinerated on put in a landfill, according to local regulations.
The wastewater is consistently discharged to a biological treatment plant (activated sludge) which is either on the site or a municipal sewage treatment plant.

#### 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.

**Table 49. Exposure concentrations and risks for the environment**

| Protection target | Exposure concentration | Risk characterisation |
|---|---|---|
| Freshwater | **Local PEC:** 0.012 mg/L | RCR = 0.8 |
| Sediment (freshwater) | **Local PEC:** 0.231 mg/kg dw | RCR = 0.799 |
| Marine water | **Local PEC:** 0.001 mg/L | RCR = 0.795 |
| Sediment (marine water) | **Local PEC:** 0.023 mg/kg dw | RCR = 0.794 |
| Predator (freshwater) | **Local PEC:** 0.069 mg/kg ww | RCR < 0.01 |
| Predator (marine water) | **Local PEC:** 0.007 mg/kg ww | RCR < 0.01 |
| Top predator (marine water) | **Local PEC:** 0.002 mg/kg ww | RCR < 0.01 |
| **Protection target** | **Exposure concentration** | **Risk characterisation** |
| Sewage treatment plant | **Local PEC:** 0.119 mg/L | RCR = 0.05 |
| Agricultural soil | **Local PEC:** 0.04 mg/kg dw | RCR = 0.825 |
| Predator (terrestrial) | **Local PEC:** 0.032 mg/kg ww | RCR < 0.01 |

## 9.1.2. Worker contributing scenario 1: Use in closed process, no likelihood of exposure (PROC 1)

#### 9.1.2.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |

| | |
|---|---|
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed system (minimal contact during routine operations) | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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 Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: One hand face only (240 cm2) | 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 50. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, acute | **0.04 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, systemic, long-term | **0.034 mg/kg bw/day** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.01 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR < 0.01 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye

exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.1.3. Worker contributing scenario 2: Use in closed, continuous process with occasional controlled exposure (PROC 2)

### 9.1.3.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed continuous process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | 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 51. Exposure concentrations and risks for workers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, acute | **0.04 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, systemic, long-term | **0.274 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.014 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.04 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
| Eye, local | | Qualitative (see below) |

| | | |
|---|---|---|
| Combined routes, systemic, long-term | | RCR = 0.014 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.1.4. Worker contributing scenario 3: Use in closed batch process (synthesis or formulation) (PROC 3)

### 9.1.4.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed batch process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: One hand face only (240 cm2) | TRA Workers 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 52. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **0.138 mg/kg bw/day** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.04 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR < 0.01 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.1.5. Worker contributing scenario 4: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)

### 9.1.5.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| | **Method** |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

**9.1.5.2. Exposure and risks for workers**

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

**Table 53. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.4 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.148 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.1.6. Worker contributing scenario 5: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

### 9.1.6.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| | **Method** |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | TRA Workers 3.0 |

### 9.1.6.2. Exposure and risks for workers

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

**Table 54. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.148 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.1.7. Worker contributing scenario 6: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

### 9.1.7.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Semi-closed process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | TRA Workers 3.0 |

### 9.1.7.2. Exposure and risks for workers

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

**Table 55. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.145 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.1.8. Worker contributing scenario 7: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

### 9.1.8.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Semi-closed process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

#### 9.1.8.2. Exposure and risks for workers

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

**Table 56. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **1.372 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.072 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.073 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.1.9. Worker contributing scenario 8: Use as laboratory reagent (PROC 15)

#### 9.1.9.1. Conditions of use

| | Method |
|---|---|

| | |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: One hand face only (240 cm2) | TRA Workers 3.0 |

**9.1.9.2. Exposure and risks for workers**

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

**Table 57. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **0.068 mg/kg bw/day** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.02 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR < 0.01 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.

In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

# 9.2. Exposure scenario 2: Formulation - Formulation of end-products at small sites

| | |
|---|---|
| **Environment contributing scenario(s):** | |
| Formulation of preparations | ERC 2 |
| **Worker contributing scenario(s):** | |
| Use in closed process, no likelihood of exposure | PROC 1 |
| Use in closed, continuous process with occasional controlled exposure | PROC 2 Use in closed batch |
| process (synthesis or formulation) | PROC 3 |
| Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) | PROC 5 |
| industrial spraying | PROC 7 |
| Transfer of substance or preparation (charging/discharging) from/to vessels/large at non-dedicated facilities | PROC 8a containers |
| Transfer of substance or preparation (charging/discharging) from/to vessels/large at dedicated facilities | PROC 8b containers |
| Transfer of substance or preparation into small containers (dedicated filling line, weighing) | PROC 9 including |
| Production of preparations or articles by tabletting, compression, extrusion, pelletisation | PROC 14 |
| Use as laboratory reagent | PROC 15 |

Description of the technical process covered by the SpERC: Cosmetics Europe 2.1g.v2

For economic reasons, formulation of mixtures requires minimized losses of raw materials during the mixing and packaging of products. Losses of raw materials via volatilization are negligible. Significant losses to the environment can be the result of cleaning of mixing vessels, tubing, production/packaging lines. High viscosity products adhere more strongly to the walls of mixing vessels, tubing, production/packaging lines. They are less efficiently transferred into the packaging. Hence, emissions caused by equipment cleaning are higher and lower for high and low viscosity products, respectively. These losses occur irrespective of the physical-chemical properties of the substance employed in a cosmetic product. For that reason, this SPERC pertains to all substances.

Technical comments
- Before treatment means: emissions as entering an on-site biological WWTP, or if absent, as leaving the site towards a municipal WWTP.
- It is assumed for simplicity that 1 kg cosmetic product (excl. water) represents ~ 1 kg COD. Actual average value for the chemical ingredients may range from 1-2.
- Emissions to soil or solid waste are not discussed here, as justified in IFRA (2009), these are considered negligible.

## 9.2.1. Environmental contributing scenario 1: Formulation of preparations

**9.2.1.1. Conditions of use** small sites: Quantity of fragrance compound produced per year on one site less than 1,000 tonnes.

| |
|---|
| **Amount used, frequency and duration of use (or from service life)** |
| • Daily use at site: <= 0.45 tonnes/day<br>*The default daily use amount is a maximum daily site tonnage (MSpERC represents an indicative worst case value for the substance use rate per site. The MSPERC values have been estimated in dependence of the size of the operation, the number of days emitting, and the concentration of the substance in a finished product (i.e. mixture)). - Emission days (days/year): 250* |
| • Annual use at a site: <= 112.5 tonnes/year |
| • Percentage of EU tonnage used at regional scale: = 100 % |
| **Technical and organisational conditions and measures** |
| • Type of Process: Substance applied in aqueous process solution with negligible volatilization |
| • Equipment cleaning: Equipment cleaned with water, washing disposed of with wastewater. |
| • Indoor/outdoor use: Indoor use (Indoor) |
| • Process efficiency: Process with efficient use of raw materials. (Typically implemented measures for reducing emissions to waste water may include: - Closed batch systems ) |
| **Conditions and measures related to sewage treatment plant** |
| • Municipal STP: Yes [Effectiveness Water: 88.07%] |
| • Discharge rate of STP: >= 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |
| • on-site WW treatment: yes [Effectiveness Water: 80%] |
| **Conditions and measures related to treatment of waste (including article waste)** |
| • Particular considerations on the waste treatment operations: No (low risk) (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** |
| • Receiving surface water flow rate: >= 1.8E4 m3/d |

**9.2.1.2. Releases**

The local releases to the environment are reported in the following table.

**Table 58. Local releases to the environment**

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|

| | | |
|---|---|---|
| **Water** | SpERC based<br><br>Cosmetics Europe 2.1g.v2 - Cosmetics Europe 2.1g.v2<br><br>Industrial use in formulation of liquid water-borne cosmetic products - high viscosity body care products (small scale) - Formulation of high viscosity body care products (small scale) | **Initial release factor:** 2%<br>**Final release factor:** 0.4%<br>**Local release rate:** 1.8 kg/day<br>**Explanation / Justification:** Releases to the wastewater can be the result of cleaning of mixing vessels, tubing, production/packaging lines with water. The spent cleaning water is discharged to the wastewater. The numbers that are presented in this SPERC originate from the study by Royal Haskoning (2009). The spERCs for Cosmetics Europe 2.1.f.v2 and Cosmetics Europe 2.1.g.v2 (high viscosity body care) reflect emission values between the product type of liquid conditioner, shampoos and shower gels (low viscosity) and non-liquid creams. Hence, these emission factors were interpolated between these values. Reference: Royal Haskoning 2009 Review and evaluation of environmental emission scenarios for fragrance materials during compounding of perfume oils and formulation of consumer products (Research Institute for Fragrance Materials Ref.:9S3975.01/R0007/Nijm, 2009). |
| **Air** | SpERC based<br>same as above | **Initial release factor:** 0%<br>**Final release factor:** 0%<br>**Local release rate:** 0 kg/day<br>**Explanation / Justification:** Releases of raw materials via volatilization are quantitatively very low. For that reason, the study by Royal Haskoning (2009) does not consider to establish release factors for the use of fragrance materials in the manufacturing of detergent products. It is assumed that these findings also apply for the manufacturing of personal care and cosmetics products. For that reason, the release factor is set to zero. |
| **Release** | **Release factor estimation method** | **Explanation / Justification** |
| **Soil** | SpERC based same<br>as above | **Final release factor:** 0%<br>**Explanation / Justification:** Direct releases to soil must be avoided. |

**Releases to waste**

**Release factor to waste from the process:** 0%

Not relevant – no obligatory RMM which divert substances to waste.

**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.

**Table 59. Exposure concentrations and risks for the environment**

| Protection target | Exposure concentration | Risk characterisation |
|---|---|---|
| Freshwater | **Local PEC:** 0.011 mg/L | RCR = 0.723 |
| Sediment (freshwater) | **Local PEC:** 0.209 mg/kg dw | RCR = 0.722 |
| Marine water | **Local PEC:** 0.001 mg/L | RCR = 0.719 |
| Sediment (marine water) | **Local PEC:** 0.021 mg/kg dw | RCR = 0.718 |
| Predator (freshwater) | **Local PEC:** 0.063 mg/kg ww | RCR < 0.01 |
| Predator (marine water) | **Local PEC:** 0.006 mg/kg ww | RCR < 0.01 |

| | | |
|---|---|---|
| Top predator (marine water) | **Local PEC:** 0.002 mg/kg ww | RCR < 0.01 |
| Sewage treatment plant | **Local PEC:** 0.107 mg/L | RCR = 0.045 |
| Agricultural soil | **Local PEC:** 0.036 mg/kg dw | RCR = 0.736 |
| Predator (terrestrial) | **Local PEC:** 0.028 mg/kg ww | RCR < 0.01 |

## 9.2.2. Worker contributing scenario 1: Use in closed process, no likelihood of exposure (PROC 1)

### 9.2.2.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed system (minimal contact during routine operations) | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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 Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |

| | Method |
|---|---|
| • Skin surface potentially exposed: One hand face only (240 cm2) | 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 60. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, acute | **0.04 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, systemic, long-term | **0.034 mg/kg bw/day** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.01 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR < 0.01 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.2.3. Worker contributing scenario 2: Use in closed, continuous process with occasional controlled exposure (PROC 2)

**9.2.3.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |

| | |
|---|---|
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed continuous process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| | **Method** |
| • 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | 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 61. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, acute | **0.04 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, systemic, long-term | **0.274 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.014 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.04 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.014 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than

25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.2.4. Worker contributing scenario 3: Use in closed batch process (synthesis or formulation) (PROC 3)

### 9.2.4.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| | **Method** |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed batch process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: One hand face only (240 cm2) | 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 62. Exposure concentrations and risks for workers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **0.138 mg/kg bw/day** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.04 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |

| | | |
|---|---|---|
| Combined routes, systemic, long-term | | RCR < 0.01 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.2.5. Worker contributing scenario 4: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)

### 9.2.5.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | 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 63. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.4 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.148 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.2.6. Worker contributing scenario 5: industrial spraying (PROC 7)

### 9.2.6.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands and upper wrists (1500 cm2) | 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 64. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **1 mg/m³** (TRA Workers 3.0) | RCR = 0.1 |
| Inhalation, local, acute | **4 mg/m³** (TRA Workers 3.0) | RCR = 0.4 |
| Dermal, systemic, long-term | **8.572 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.451 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.4 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.459 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.2.7. Worker contributing scenario 6: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

**9.2.7.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | 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 65. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.148 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational

measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.2.8. Worker contributing scenario 7: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

### 9.2.8.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Semi-closed process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| | **Method** |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | TRA Workers 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 66. Exposure concentrations and risks for workers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |

| | | |
|---|---|---|
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.145 |

**Conclusion on risk characterisation**

In accordance with 'Guidance on information requirements and Chemical safety assessment' Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.2.9. Worker contributing scenario 8: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

### 9.2.9.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| | **Method** |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Semi-closed process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |

| Other conditions affecting workers exposure | |
|---|---|
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

**9.2.9.2. Exposure and risks for workers**

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

**Table 67. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **1.372 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.072 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.073 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.2.10. Worker contributing scenario 9: Production of preparations or articles by tabletting, compression, extrusion, pelletisation (PROC 14)

**9.2.10.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |

| | |
|---|---|
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

**9.2.10.2. Exposure and risks for workers**

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

**Table 68. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **0.686 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.036 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.1 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.037 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than

25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.2.11. Worker contributing scenario 10: Use as laboratory reagent (PROC 15)

### 9.2.11.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: One hand face only (240 cm2) | TRA Workers 3.0 |

### 9.2.11.2. Exposure and risks for workers

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

**Table 69. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **0.068 mg/kg bw/day** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.02 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR < 0.01 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

# 9.3. Exposure scenario 3: Use at industrial site - Use of L-Menthol as intermediate

**Sector of use:**
SU 9, Manufacture of fine chemicals

| **Environment contributing scenario(s):** | |
|---|---|
| Industrial use resulting in manufacture of another substance (use of intermediates) | ERC 6a |
| **Worker contributing scenario(s):** | |
| Use in closed, continuous process with occasional controlled exposure | PROC 2 |
| Use in closed batch process (synthesis or formulation) | PROC 3 |
| Use in batch and other process (synthesis) where opportunity for exposure arises | PROC 4 |
| Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities | PROC 8a |
| Transfer of substance or preparation into small containers (dedicated filling line, including weighing) | PROC 9 |
| Use as laboratory reagent | PROC 15 |

## 9.3.1. Environmental contributing scenario 1: Industrial use resulting in manufacture of another substance (use of intermediates)

### 9.3.1.1. Conditions of use

| **Amount used, frequency and duration of use (or from service life)** |
|---|
| • Daily use at site: <= 0.45 tonnes/day |
| • Annual use at a site: <= 135 tonnes/year |
| • Percentage of EU tonnage used at regional scale: = 100 % |
| **Conditions and measures related to sewage treatment plant** |
| • Municipal STP: Yes [Effectiveness Water: 88.07%] |
| • Discharge rate of STP: >= 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |
| • on-site WW treatment: yes [Effectiveness Water: 80%] |
| **Conditions and measures related to treatment of waste (including article waste)** |
| • Particular considerations on the waste treatment operations: No (low risk) (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** |
| • Receiving surface water flow rate: >= 1.8E4 m3/d |

### 9.3.1.2. Releases

The local releases to the environment are reported in the following table.

**Table 70. Local releases to the environment**

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|

| | | |
|---|---|---|
| **Water** | ERC based | **Initial release factor:** 2%<br>**Final release factor:** 0.4%<br>**Local release rate:** 1.8 kg/day |
| **Air** | ERC based | **Initial release factor:** 5%<br>**Final release factor:** 5%<br>**Local release rate:** 22.5 kg/day |

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|
| **Soil** | ERC based | **Final release factor:** 0.1% |

**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.

**Table 71. Exposure concentrations and risks for the environment**

| Protection target | Exposure concentration | Risk characterisation |
|---|---|---|
| Freshwater | **Local PEC:** 0.011 mg/L | RCR = 0.723 |
| Sediment (freshwater) | **Local PEC:** 0.209 mg/kg dw | RCR = 0.722 |
| Marine water | **Local PEC:** 0.001 mg/L | RCR = 0.719 |
| Sediment (marine water) | **Local PEC:** 0.021 mg/kg dw | RCR = 0.718 |
| Predator (freshwater) | **Local PEC:** 0.074 mg/kg ww | RCR < 0.01 |
| Predator (marine water) | **Local PEC:** 0.007 mg/kg ww | RCR < 0.01 |
| Top predator (marine water) | **Local PEC:** 0.002 mg/kg ww | RCR < 0.01 |
| Sewage treatment plant | **Local PEC:** 0.107 mg/L | RCR = 0.045 |
| Agricultural soil | **Local PEC:** 0.037 mg/kg dw | RCR = 0.755 |
| Predator (terrestrial) | **Local PEC:** 0.03 mg/kg ww | RCR < 0.01 |

## 9.3.2. Worker contributing scenario 1: Use in closed, continuous process with occasional controlled exposure (PROC 2)

**9.3.2.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed continuous process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |

| | |
|---|---|
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

**9.3.2.2. Exposure and risks for workers**

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

**Table 72. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, acute | **0.04 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, systemic, long-term | **0.274 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.014 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.04 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.014 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.3.3. Worker contributing scenario 2: Use in closed batch process (synthesis or formulation) (PROC 3)

**9.3.3.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |

| | |
|---|---|
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed batch process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| | **Method** |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: One hand face only (240 cm2) | TRA Workers 3.0 |

**9.3.3.2. Exposure and risks for workers**

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

**Table 73. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **0.138 mg/kg bw/day** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.04 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR < 0.01 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.3.4. Worker contributing scenario 3: Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)

### 9.3.4.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| | **Method** |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Semi-closed process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | 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 74. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **1.372 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.072 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.076 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.3.5. Worker contributing scenario 4: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

### 9.3.5.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | 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 75. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.148 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.3.6. Worker contributing scenario 5: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

### 9.3.6.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Semi-closed process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | 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 76. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **1.372 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.072 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.073 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.3.7. Worker contributing scenario 6: Use as laboratory reagent (PROC 15)

#### 9.3.7.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |

| | |
|---|---|
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: One hand face only (240 cm2) | TRA Workers 3.0 |

**9.3.7.2. Exposure and risks for workers**

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

**Table 77. Exposure concentrations and risks for workers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **0.068 mg/kg bw/day** (TRA Workers 3.0) | RCR < 0.01 |
| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.02 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR < 0.01 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.

In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

# 9.4. Exposure scenario 4: Use at industrial site - Industrial end-use of washing and cleaning products

| **Environment contributing scenario(s):** | |
|---|---|
| Industrial use of processing aids in processes and products, not becoming part of articles | ERC 4 |
| **Worker contributing scenario(s):** | |
| Use in closed process, no likelihood of exposure | PROC 1 |
| Use in closed, continuous process with occasional controlled exposure | PROC 2 Use in batch and |
| other process (synthesis) where opportunity for exposure arises | PROC 4 industrial spraying |
| | PROC 7 |
| Transfer of substance or preparation (charging/discharging) from/to vessels/large at non-dedicated facilities | PROC 8a containers |
| Transfer of substance or preparation (charging/discharging) from/to vessels/large at dedicated facilities | PROC 8b containers |
| Roller application or brushing | PROC 10 |
| Treatment of articles by dipping and pouring | PROC 13 |

## 9.4.1. Environmental contributing scenario 1: Industrial use of processing aids in processes and products, not becoming part of articles

### 9.4.1.1. Conditions of use

| **Amount used, frequency and duration of use (or from service life)** |
|---|
| • Daily use at site: <= 1.65E-5 tonnes/day<br>*As washing and cleaning products are widely used throughout all industrial sectors, many industrial sites do consume such products and a wide dispersive use is assumed resulting in 10% use at regional scale. Based on 30 t/a of L-Menthol going into such applications, this results in a daily wide dispersive use of 1.65E-5 t/day.* |
| • Annual use at a site: <= 0.006 tonnes/year<br>*As L-Menthol is widely used in washing and cleaning products, many industrial sites do consume such products and a wide dispersive use is assumed resulting in 10% use at regional scale. Based on 30 t/a of L-Menthol going into such applications, this results in a daily wide dispersive use of 1.65E-5 t/day. As washing and cleaning products are used in industrial, professional and consumer settings, the tonnage dedicated to the three different uses is not specific to one of the uses. In total 230 t/a are assessed for end-use in washing and cleaning products.* |
| • Percentage of EU tonnage used at regional scale: = 10 % |
| **Conditions and measures related to sewage treatment plant** |
| • Municipal STP: Yes [Effectiveness Water: 88.07%] |
| • Discharge rate of STP: >= 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |
| **Conditions and measures related to treatment of waste (including article waste)** |
| • Particular considerations on the waste treatment operations: No (low risk) (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** |
| • Receiving surface water flow rate: >= 1.8E4 m3/d |

### 9.4.1.2. Releases

The local releases to the environment are reported in the following table.

**Table 78. Local releases to the environment**

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|
| **Water** | Release factor<br><br>(ERC 8d) | **Initial release factor:** 100%<br>**Final release factor:** 100%<br>**Local release rate:** 0.016 kg/day |
| **Air** | Release factor<br><br>(ERC 8d) | **Initial release factor:** 100%<br>**Final release factor:** 100%<br>**Local release rate:** 0.016 kg/day |
| **Soil** | Release factor<br><br>(ERC 8d) | **Final release factor:** 20% |

**Releases to waste**

**Release factor to waste from the process:** 0%

Laundry detergents, and cleaners are applied as additives to water. After cleaning of substrate the washing / cleaning solutions is disposed of with the waste water such that 100% of the product ingredients enter the waste water system. Product residues remaining on the substrate are likely to be washed off in the next cleaning event.

#### 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.

**Table 79. Exposure concentrations and risks for the environment**

| Protection target | Exposure concentration | Risk characterisation |
|---|---|---|
| Freshwater | **Local PEC:** 6.429E-4 mg/L | RCR = 0.041 |
| Sediment (freshwater) | **Local PEC:** 0.012 mg/kg dw | RCR = 0.041 |
| Marine water | **Local PEC:** 5.73E-5 mg/L | RCR = 0.037 |
| Sediment (marine water) | **Local PEC:** 0.001 mg/kg dw | RCR = 0.037 |
| Predator (freshwater) | **Local PEC:** 0.009 mg/kg ww | RCR < 0.01 |
| Predator (marine water) | **Local PEC:** 7.853E-4 mg/kg ww | RCR < 0.01 |
| Top predator (marine water) | **Local PEC:** 7.265E-4 mg/kg ww | RCR < 0.01 |
| Sewage treatment plant | **Local PEC:** 9.845E-4 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 3.425E-4 mg/kg dw | RCR < 0.01 |
| Predator (terrestrial) | **Local PEC:** 4.462E-4 mg/kg ww | RCR < 0.01 |

**Conclusion on risk characterisation**

As washing and cleaning products are widely used throughout all industrial sectors, a wide dispersive use is assumed resulting in 10% use at regional scale.
The default ERCs for the wide dispersive end-use of washing and cleaning products are ERC8a and ERC8d which were used for the assessment.
The use was proved safe under the described conditions.

## 9.4.2. Worker contributing scenario 1: Use in closed process, no likelihood of exposure (PROC 1)

#### 9.4.2.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |

| | |
|---|---|
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| | **Method** |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed system (minimal contact during routine operations) | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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 Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: One hand face only (240 cm2) | 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 80. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, acute | **0.04 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, systemic, long-term | **0.034 mg/kg bw/day** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.01 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR < 0.01 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.

In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.4.3. Worker contributing scenario 2: Use in closed, continuous process with occasional controlled exposure (PROC 2)

### 9.4.3.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed continuous process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

### 9.4.3.2. Exposure and risks for workers

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

**Table 81. Exposure concentrations and risks for workers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, acute | **0.04 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, systemic, long-term | **0.274 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.014 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.04 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |

| | | |
|---|---|---|
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.014 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.4.4. Worker contributing scenario 3: Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)

### 9.4.4.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Semi-closed process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

### 9.4.4.2. Exposure and risks for workers

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

**Table 82. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **1.372 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.072 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.076 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.4.5. Worker contributing scenario 4: industrial spraying (PROC 7)

### 9.4.5.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands and upper wrists (1500 cm2) | TRA Workers 3.0 |

**9.4.5.2. Exposure and risks for workers**

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

**Table 83. Exposure concentrations and risks for workers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **1 mg/m³** (TRA Workers 3.0) | RCR = 0.1 |
| Inhalation, local, acute | **4 mg/m³** (TRA Workers 3.0) | RCR = 0.4 |
| Dermal, systemic, long-term | **8.572 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.451 |
| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.4 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.459 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.4.6. Worker contributing scenario 5: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

**9.4.6.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | TRA Workers 3.0 |

**9.4.6.2. Exposure and risks for workers**

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

**Table 84. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.148 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational

measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.4.7. Worker contributing scenario 6: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

### 9.4.7.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Semi-closed process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| • Occupational Health and Safety Management System: Advanced | TRA Workers 3.0 |
| | **Method** |
| **Conditions and measures related to personal protection, hygiene and health evaluation** | |
| • Dermal Protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | TRA Workers 3.0 |

### 9.4.7.2. Exposure and risks for workers

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

**Table 85. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |

| | | |
|---|---|---|
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.145 |

**Conclusion on risk characterisation**

In accordance with 'Guidance on information requirements and Chemical safety assessment' Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.4.8. Worker contributing scenario 7: Roller application or brushing (PROC 10)

### 9.4.8.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| | **Method** |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |

| | |
|---|---|
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | TRA Workers 3.0 |

**9.4.8.2. Exposure and risks for workers**

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

**Table 86. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **5.486 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.289 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.4 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.293 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.4.9. Worker contributing scenario 8: Treatment of articles by dipping and pouring (PROC 13)

**9.4.9.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |

| | |
|---|---|
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

**9.4.9.2. Exposure and risks for workers**

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

**Table 87. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.4 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.145 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

# 9.5. Exposure scenario 5: Use by professional worker - Professional end-use of washing and cleaning products

| | |
|---|---|
| **Environment contributing scenario(s):** | |
| Wide dispersive outdoor use of processing aids in open systems | ERC 8d, ERC 8a |
| **Worker contributing scenario(s):** | |
| Use in closed process, no likelihood of exposure | PROC 1 |
| Use in closed, continuous process with occasional controlled exposure | PROC 2 |
| Use in batch and other process (synthesis) where opportunity for exposure arises | PROC 4 |
| Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities | PROC 8a |
| Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities | PROC 8b |
| Roller application or brushing | PROC 10 |
| Non industrial spraying | PROC 11 |
| Treatment of articles by dipping and pouring | PROC 13 |

## 9.5.1. Environmental contributing scenario 1: Wide dispersive outdoor use of processing aids in open systems

### 9.5.1.1. Conditions of use

| |
|---|
| **Amount used, frequency and duration of use (or from service life)** |
| • Daily wide dispersive use: <= 2.75E-4 tonnes/day |
| • Percentage of EU tonnage used at regional scale: = 10 % |
| **Conditions and measures related to sewage treatment plant** |
| • Municipal STP: Yes [Effectiveness Water: 88.07%] |
| • Discharge rate of STP: >= 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |
| **Conditions and measures related to treatment of waste (including article waste)** |
| • Particular considerations on the waste treatment operations: No (low risk) (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** |
| • Receiving surface water flow rate: >= 1.8E4 m3/d |

### 9.5.1.2. Releases

The local releases to the environment are reported in the following table.

**Table 88. Local releases to the environment**

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|
| **Water** | ERC based | **Initial release factor:** 100%<br>**Final release factor:** 100%<br>**Local release rate:** 0.275 kg/day |

| | | |
|---|---|---|
| **Air** | ERC based | **Initial release factor:** 100% **Final release factor:** 100% |
| **Soil** | ERC based | **Final release factor:** 20% |

**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.

**Table 89. Exposure concentrations and risks for the environment**

| Protection target | Exposure concentration | Risk characterisation |
|---|---|---|
| Freshwater | **Local PEC:** 0.002 mg/L | RCR = 0.14 |
| Sediment (freshwater) | **Local PEC:** 0.04 mg/kg dw | RCR = 0.14 |
| Marine water | **Local PEC:** 2.115E-4 mg/L | RCR = 0.136 |
| Sediment (marine water) | **Local PEC:** 0.004 mg/kg dw | RCR = 0.135 |
| Predator (freshwater) | **Local PEC:** 0.02 mg/kg ww | RCR < 0.01 |
| Predator (marine water) | **Local PEC:** 0.002 mg/kg ww | RCR < 0.01 |
| Top predator (marine water) | **Local PEC:** 9.579E-4 mg/kg ww | RCR < 0.01 |
| Sewage treatment plant | **Local PEC:** 0.016 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 0.005 mg/kg dw | RCR = 0.113 |
| Predator (terrestrial) | **Local PEC:** 0.004 mg/kg ww | RCR < 0.01 |

## 9.5.2. Worker contributing scenario 1: Use in closed process, no likelihood of exposure (PROC 1)

**9.5.2.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed system (minimal contact during routine operations) | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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 Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: One hand face only (240 cm2) | TRA Workers 3.0 |

**9.5.2.2. Exposure and risks for workers**

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

**Table 90. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, acute | **0.04 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, systemic, long-term | **0.034 mg/kg bw/day** (TRA Workers 3.0) | RCR < 0.01 |
| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.01 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR < 0.01 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.5.3. Worker contributing scenario 2: Use in closed, continuous process with occasional controlled exposure (PROC 2)

### 9.5.3.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed continuous process with occasional controlled exposure | TRA Workers 3.0 |

| | |
|---|---|
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

**9.5.3.2. Exposure and risks for workers**

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

**Table 91. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, acute | **0.04 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, systemic, long-term | **0.274 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.014 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.04 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.014 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.5.4. Worker contributing scenario 3: Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)

**9.5.4.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Semi-closed process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| | **Method** |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

**9.5.4.2. Exposure and risks for workers**

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

**Table 92. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **1.372 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.072 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.076 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal

protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.5.5. Worker contributing scenario 4: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

### 9.5.5.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| | **Method** |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | TRA Workers 3.0 |

### 9.5.5.2. Exposure and risks for workers

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

**Table 93. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |

| | | |
|---|---|---|
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.148 |

**Conclusion on risk characterisation**

In accordance with 'Guidance on information requirements and Chemical safety assessment' Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.5.6. Worker contributing scenario 5: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

### 9.5.6.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Semi-closed process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |

| Other conditions affecting workers exposure | |
|---|---|
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | TRA Workers 3.0 |

**9.5.6.2. Exposure and risks for workers**

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

**Table 94. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.145 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.5.7. Worker contributing scenario 6: Roller application or brushing (PROC 10)

**9.5.7.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |

| | |
|---|---|
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | TRA Workers 3.0 |

**9.5.7.2. Exposure and risks for workers**

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

**Table 95. Exposure concentrations and risks for workers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **5.486 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.289 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.4 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
| Combined routes, systemic, long-term | | RCR = 0.293 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than

25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.5.8. Worker contributing scenario 7: Non industrial spraying (PROC 11)

### 9.5.8.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands and upper wrists (1500 cm2) | TRA Workers 3.0 |

### 9.5.8.2. Exposure and risks for workers

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

**Table 96. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **1 mg/m³** (TRA Workers 3.0) | RCR = 0.1 |
| Inhalation, local, acute | **4 mg/m³** (TRA Workers 3.0) | RCR = 0.4 |
| Dermal, systemic, long-term | **10.71 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.564 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.5 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.572 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.5.9. Worker contributing scenario 8: Treatment of articles by dipping and pouring (PROC 13)

### 9.5.9.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| | **Method** |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

### 9.5.9.2. Exposure and risks for workers

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

**Table 97. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.1 mg/m³** (TRA Workers 3.0) | RCR = 0.01 |
| Inhalation, local, acute | **0.4 mg/m³** (TRA Workers 3.0) | RCR = 0.04 |
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.4 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.145 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

# 9.6. Exposure scenario 6: Use by professional worker - Professional end-use of polishes and wax blends

| | |
|---|---|
| **Environment contributing scenario(s):** | |
| Wide dispersive indoor use of processing aids in open systems | ERC 8a |
| **Worker contributing scenario(s):** | |
| Use in closed, continuous process with occasional controlled exposure | PROC 2 |
| Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities | PROC 8a |
| Roller application or brushing | PROC 10 |
| Non industrial spraying | PROC 11 |

## 9.6.1. Environmental contributing scenario 1: Wide dispersive indoor use of processing aids in open systems

### 9.6.1.1. Conditions of use

| Amount used, frequency and duration of use (or from service life) |
|---|
| • Daily wide dispersive use: <= 2.75E-4 tonnes/day |

| |
|---|
| • Percentage of EU tonnage used at regional scale: = 10 % |
| **Conditions and measures related to sewage treatment plant** |
| • Municipal STP: Yes [Effectiveness Water: 88.07%] |
| • Discharge rate of STP: >= 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |
| **Conditions and measures related to treatment of waste (including article waste)** |
| • Particular considerations on the waste treatment operations: No (low risk) (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** |
| • Receiving surface water flow rate: >= 1.8E4 m3/d |

#### 9.6.1.2. Releases

The local releases to the environment are reported in the following table.

**Table 98. Local releases to the environment**

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|
| **Water** | ERC based | **Initial release factor:** 100%<br>**Final release factor:** 100%<br>**Local release rate:** 0.275 kg/day |
| **Air** | ERC based | **Initial release factor:** 100% **Final release factor:** 100% |
| **Soil** | ERC based | **Final release factor:** 0% |

#### 9.6.1.3. 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.

**Table 99. Exposure concentrations and risks for the environment**

| Protection target | Exposure concentration | Risk characterisation |
|---|---|---|
| Freshwater | **Local PEC:** 0.002 mg/L | RCR = 0.14 |
| **Protection target** | **Exposure concentration** | **Risk characterisation** |
| Sediment (freshwater) | **Local PEC:** 0.04 mg/kg dw | RCR = 0.14 |
| Marine water | **Local PEC:** 2.115E-4 mg/L | RCR = 0.136 |
| Sediment (marine water) | **Local PEC:** 0.004 mg/kg dw | RCR = 0.135 |
| Predator (freshwater) | **Local PEC:** 0.02 mg/kg ww | RCR < 0.01 |
| Predator (marine water) | **Local PEC:** 0.002 mg/kg ww | RCR < 0.01 |
| Top predator (marine water) | **Local PEC:** 9.579E-4 mg/kg ww | RCR < 0.01 |
| Sewage treatment plant | **Local PEC:** 0.016 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 0.005 mg/kg dw | RCR = 0.113 |
| Predator (terrestrial) | **Local PEC:** 0.004 mg/kg ww | RCR < 0.01 |

### 9.6.2. Worker contributing scenario 1: Use in closed, continuous process with occasional controlled exposure (PROC 2)

#### 9.6.2.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: Closed continuous process with occasional controlled exposure | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands face (480 cm2) | TRA Workers 3.0 |

**9.6.2.2. Exposure and risks for workers**

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

**Table 100. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.01 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, acute | **0.04 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Dermal, systemic, long-term | **0.274 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.014 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.04 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.014 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk

characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.6.3. Worker contributing scenario 2: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

### 9.6.3.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | TRA Workers 3.0 |

### 9.6.3.2. Exposure and risks for workers

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

**Table 101. Exposure concentrations and risks for workers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |

| | | |
|---|---|---|
| Dermal, systemic, long-term | **2.742 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.144 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.2 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.148 |

**Conclusion on risk characterisation**

In accordance with 'Guidance on information requirements and Chemical safety assessment' Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.6.4. Worker contributing scenario 3: Roller application or brushing (PROC 10)

### 9.6.4.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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) [Effectiveness Dermal: 80%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| | **Method** |
| **Other conditions affecting workers exposure** | |

| | |
|---|---|
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands (960 cm2) | TRA Workers 3.0 |

**9.6.4.2. Exposure and risks for workers**

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

**Table 102. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **0.5 mg/m³** (TRA Workers 3.0) | RCR = 0.05 |
| Inhalation, local, acute | **2 mg/m³** (TRA Workers 3.0) | RCR = 0.2 |
| Dermal, systemic, long-term | **5.486 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.289 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.4 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.293 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

## 9.6.5. Worker contributing scenario 4: Non industrial spraying (PROC 11)

**9.6.5.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Dustiness of material: Low | TRA Workers 3.0 |
| • Concentration of substance in mixture: Substance as such | TRA Workers 3.0 |
| **Amount used (or contained in articles), frequency and duration of use/exposure** | |
| • Duration of activity: < 8 hours | TRA Workers 3.0 |
| **Technical and organisational conditions and measures** | |

| | Method |
|---|---|
| • General ventilation: Basic general ventilation (1-3 air changes per hour) | TRA Workers 3.0 |
| • Containment: No | TRA Workers 3.0 |
| • Local exhaust ventilation: no [Effectiveness Inhal: 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: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] | TRA Workers 3.0 |
| • Respiratory Protection: No [Effectiveness Inhal: 0%] | TRA Workers 3.0 |
| **Other conditions affecting workers exposure** | |
| • Place of use: Indoor | TRA Workers 3.0 |
| • Process temperature (for solid): Ambient | TRA Workers 3.0 |
| • Skin surface potentially exposed: Two hands and upper wrists (1500 cm2) | TRA Workers 3.0 |

**9.6.5.2. Exposure and risks for workers**

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

**Table 103. Exposure concentrations and risks for workers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **1 mg/m³** (TRA Workers 3.0) | RCR < 0.01 |
| Inhalation, local, long-term | **1 mg/m³** (TRA Workers 3.0) | RCR = 0.1 |
| Inhalation, local, acute | **4 mg/m³** (TRA Workers 3.0) | RCR = 0.4 |
| Dermal, systemic, long-term | **10.71 mg/kg bw/day** (TRA Workers 3.0) | RCR = 0.564 |
| Dermal, local, long-term | **Additional data not used for RCR:** 0.5 mg/cm² (TRA Workers 3.0) | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Combined routes, systemic, long-term | | RCR = 0.572 |

**Conclusion on risk characterisation**

In accordance with ‘Guidance on information requirements and Chemical safety assessment’ Party E: Risk characterization Table E.3-1, the substance is categorized as having a low hazard profile due to skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, when the substance is used as such or at concentration above 25%, acute and long-term dermal exposure assessment and risk characterization for local effects should be minimised by appropriate risk management measures. Personal protective equipments such as suitable gloves and protective clothing are recommended. Further organisational measures apply, training for workers on good practise, good standard of personal hygiene, special procedures for cleaning and maintenance etc.
In accordance with 'Guidance on information requirements and chemical safety assessment' Part E: Risk characterisation Table E.3-1, the substance is categorised as having a low hazard profile due to Eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, when the substance is used as such or at concentration above 25%, chemical goggles should be implemented to protect human from eye exposure for use of the substance itself. For the use of substance present in mixture at concentration of less than 25%, no chemical goggles are needed if the mixture is not classified as Eye Irritation according to CLP regulation.

# 9.7. Exposure scenario 7: Consumer Use - Consumer end-use of washing and cleaning products

| | |
|---|---|
| **Environment contributing scenario(s):** | |
| Wide dispersive outdoor use of processing aids in open systems | ERC 8d, ERC 8a |
| **Consumer contributing scenario(s):** | |
| Laundry and dish washing products | PC 35 |
| Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners ) | PC 35 |
| Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners) | PC 35 |

## 9.7.1. Environmental contributing scenario 1: Wide dispersive outdoor use of processing aids in open systems

### 9.7.1.1. Conditions of use

| **Amount used, frequency and duration of use (or from service life)** |
|---|
| • Daily wide dispersive use: <= 2.75E-4 tonnes/day |
| • Percentage of EU tonnage used at regional scale: = 10 % |
| **Conditions and measures related to treatment of waste (including article waste)** |
| • Particular considerations on the waste treatment operations: No (low risk) (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** |
| • Municipal STP: Yes [Effectiveness Water: 88.07%] |
| • Discharge rate of STP: >= 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |
| • Receiving surface water flow rate: >= 1.8E4 m3/d |

### 9.7.1.2. Releases

The local releases to the environment are reported in the following table.

**Table 104. Local releases to the environment**

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|
| **Water** | ERC based | **Initial release factor:** 100%<br>**Final release factor:** 100%<br>**Local release rate:** 0.275 kg/day |
| **Air** | ERC based | **Initial release factor:** 100% **Final release factor:** 100% |
| **Soil** | ERC based | **Final release factor:** 20% |

### 9.7.1.3. 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.

**Table 105. Exposure concentrations and risks for the environment**

| Protection target | Exposure concentration | Risk characterisation |
|---|---|---|
| Freshwater | **Local PEC:** 0.002 mg/L | RCR = 0.14 |

| | | |
|---|---|---|
| Sediment (freshwater) | **Local PEC:** 0.04 mg/kg dw | RCR = 0.14 |
| Marine water | **Local PEC:** 2.115E-4 mg/L | RCR = 0.136 |
| **Protection target** | **Exposure concentration** | **Risk characterisation** |
| Sediment (marine water) | **Local PEC:** 0.004 mg/kg dw | RCR = 0.135 |
| Predator (freshwater) | **Local PEC:** 0.02 mg/kg ww | RCR < 0.01 |
| Predator (marine water) | **Local PEC:** 0.002 mg/kg ww | RCR < 0.01 |
| Top predator (marine water) | **Local PEC:** 9.579E-4 mg/kg ww | RCR < 0.01 |
| Sewage treatment plant | **Local PEC:** 0.016 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 0.005 mg/kg dw | RCR = 0.113 |
| Predator (terrestrial) | **Local PEC:** 0.004 mg/kg ww | RCR < 0.01 |

## 9.7.2. Consumer contributing scenario 1: Laundry and dish washing products (PC 35)

### 9.7.2.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Product/Article subcategory: Laundry and dish washing products | TRA Consumers 3.0 |
| • Spray: No | TRA Consumers 3.0 |
| • Concentration of substance in mixture: = 0.01 g/g | TRA Consumers 3.0 |
| • Oral contact foreseen: No | TRA Consumers 3.0 |
| **Amount used, frequency and duration of use/exposure** | |
| • Amount of product used per application: = 50 g/event | TRA Consumers 3.0 |
| • Exposure time: = 1 hr | TRA Consumers 3.0 |
| • Frequency of use over a day: = 1 events/day | TRA Consumers 3.0 |
| **Other conditions affecting consumers exposure** | |
| • Body parts potentially exposed: Hands | TRA Consumers 3.0 |
| • Dermal transfer factor: = 1 | TRA Consumers 3.0 |

### 9.7.2.2. Exposure and risks for consumers

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

**Table 106. Exposure concentrations and risks for consumers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **15.62 mg/m³** (TRA Consumers 3.0) | RCR = 0.474 |
| Dermal, systemic, long-term | **1.429 mg/kg bw/day** (TRA Consumers 3.0) | RCR = 0.152 |
| Dermal, local, long-term | | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Oral, systemic, long-term | **0 mg/kg bw/day** (TRA Consumers 3.0) | RCR < 0.01 |

| | | |
|---|---|---|
| Combined routes, systemic, long-term | | RCR = 0.626 |

**Conclusion on risk characterisation**

The substance is classified as skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, consumer products containing this substance less than 25% is not classified as skin irritation. There is no need to conduct acute and long-term dermal exposure assessment and risk characterization for local effects for consumer products containing this substance less than 25%.
The substance is classified as eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, consumer products containing this substance less than 25% is not classified as eye irritation. There is no need to conduct exposure assessment and risk characterization for eye local effects for consumer products containing this substance less than 25%.

## 9.7.3. Consumer contributing scenario 2: Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners ) (PC 35)

### 9.7.3.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Product/Article subcategory: Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners ) | TRA Consumers 3.0 |
| • Concentration of substance in mixture: = 0.002 g/g | TRA Consumers 3.0 |
| • Oral contact foreseen: No | TRA Consumers 3.0 |
| **Amount used, frequency and duration of use/exposure** | |
| • Amount of product used per application: = 250 g/event | TRA Consumers 3.0 |
| • Exposure time: = 0.33 hr | TRA Consumers 3.0 |
| • Frequency of use over a day: = 1 events/day | TRA Consumers 3.0 |
| **Other conditions affecting consumers exposure** | |
| • Body parts potentially exposed: Hands | TRA Consumers 3.0 |
| • Dermal transfer factor: = 1 | TRA Consumers 3.0 |

### 9.7.3.2. Exposure and risks for consumers

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

**Table 107. Exposure concentrations and risks for consumers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **20.87 mg/m³** (TRA Consumers 3.0) | RCR = 0.632 |
| Dermal, systemic, long-term | **0.286 mg/kg bw/day** (TRA Consumers 3.0) | RCR = 0.03 |
| Dermal, local, long-term | | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Oral, systemic, long-term | **0 mg/kg bw/day** (TRA Consumers 3.0) | RCR < 0.01 |

| | | |
|---|---|---|
| Combined routes, systemic, long-term | | RCR = 0.663 |

**Conclusion on risk characterisation**

The substance is classified as skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, consumer products containing this substance less than 25% is not classified as skin irritation. There is no need to conduct acute and long-term dermal exposure assessment and risk characterization for local effects for consumer products containing this substance less than 25%.
The substance is classified as eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, consumer products containing this substance less than 25% is not classified as eye irritation. There is no need to conduct exposure assessment and risk characterization for eye local effects for consumer products containing this substance less than 25%.

## 9.7.4. Consumer contributing scenario 3: Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners) (PC 35)

### 9.7.4.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Product/Article subcategory: Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners) | TRA Consumers 3.0 |
| • Spray: Yes | TRA Consumers 3.0 |
| • Concentration of substance in mixture: = 0.02 g/g | TRA Consumers 3.0 |
| • Oral contact foreseen: No | TRA Consumers 3.0 |
| **Amount used, frequency and duration of use/exposure** | |
| • Amount of product used per application: = 35 g/event | TRA Consumers 3.0 |
| • Exposure time: = 4 hr | TRA Consumers 3.0 |
| • Frequency of use over a day: = 1 events/day | TRA Consumers 3.0 |
| **Other conditions affecting consumers exposure** | |
| • Body parts potentially exposed: Hands | TRA Consumers 3.0 |
| • Dermal transfer factor: = 1 | TRA Consumers 3.0 |

### 9.7.4.2. Exposure and risks for consumers

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

**Table 108. Exposure concentrations and risks for consumers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **10.29 mg/m³** (TRA Consumers 3.0) | RCR = 0.312 |
| Dermal, systemic, long-term | **2.858 mg/kg bw/day** (TRA Consumers 3.0) | RCR = 0.304 |
| Dermal, local, long-term | | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Oral, systemic, long-term | **0 mg/kg bw/day** (TRA Consumers 3.0) | RCR < 0.01 |

| | | |
|---|---|---|
| Combined routes, systemic, long-term | | RCR = 0.616 |

**Conclusion on risk characterisation**

The substance is classified as skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, consumer products containing this substance less than 25% is not classified as skin irritation. There is no need to conduct acute and long-term dermal exposure assessment and risk characterization for local effects for consumer products containing this substance less than 25%.
The substance is classified as eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, consumer products containing this substance less than 25% is not classified as eye irritation. There is no need to conduct exposure assessment and risk characterization for eye local effects for consumer products containing this substance less than 25%.

# 9.8. Exposure scenario 8: Consumer Use - Consumer Use - Consumer end-use of air care products

| | |
|---|---|
| **Environment contributing scenario(s):** | |
| Wide dispersive indoor use of processing aids in open systems | ERC 8a |
| **Consumer contributing scenario(s):** | |
| Aircare, instant action (aerosol sprays) | PC 3 |
| Aircare, continuous action (solid and liquid) | PC 3 |

## 9.8.1. Environmental contributing scenario 1: Wide dispersive indoor use of processing aids in open systems

### 9.8.1.1. Conditions of use

| **Amount used, frequency and duration of use (or from service life)** |
|---|
| • Daily wide dispersive use: <= 2.75E-4 tonnes/day |
| • Percentage of EU tonnage used at regional scale: = 10 % |
| **Conditions and measures related to treatment of waste (including article waste)** |
| • Particular considerations on the waste treatment operations: No (low risk) (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** |
| • Municipal STP: Yes [Effectiveness Water: 88.07%] |
| • Discharge rate of STP: >= 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |
| • Receiving surface water flow rate: >= 1.8E4 m3/d |

### 9.8.1.2. Releases

The local releases to the environment are reported in the following table.

**Table 109. Local releases to the environment**

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|
| **Water** | ERC based | **Initial release factor:** 100%<br>**Final release factor:** 100%<br>**Local release rate:** 0.275 kg/day |

| | | |
|---|---|---|
| **Air** | ERC based | **Initial release factor:** 100% **Final release factor:** 100% |
| **Soil** | ERC based | **Final release factor:** 0% |

**9.8.1.3. 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.

**Table 110. Exposure concentrations and risks for the environment**

| Protection target | Exposure concentration | Risk characterisation |
|---|---|---|
| Freshwater | **Local PEC:** 0.002 mg/L | RCR = 0.14 |
| Sediment (freshwater) | **Local PEC:** 0.04 mg/kg dw | RCR = 0.14 |
| Marine water | **Local PEC:** 2.115E-4 mg/L | RCR = 0.136 |
| Sediment (marine water) | **Local PEC:** 0.004 mg/kg dw | RCR = 0.135 |
| Predator (freshwater) | **Local PEC:** 0.02 mg/kg ww | RCR < 0.01 |
| **Protection target** | **Exposure concentration** | **Risk characterisation** |
| Predator (marine water) | **Local PEC:** 0.002 mg/kg ww | RCR < 0.01 |
| Top predator (marine water) | **Local PEC:** 9.579E-4 mg/kg ww | RCR < 0.01 |
| Sewage treatment plant | **Local PEC:** 0.016 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 0.005 mg/kg dw | RCR = 0.113 |
| Predator (terrestrial) | **Local PEC:** 0.004 mg/kg ww | RCR < 0.01 |

## 9.8.2. Consumer contributing scenario 1: Aircare, instant action (aerosol sprays) (PC 3)

**9.8.2.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Product/Article subcategory: Aircare, instant action (aerosol sprays) | TRA Consumers 3.0 |
| • Spray: Yes | TRA Consumers 3.0 |
| • Concentration of substance in mixture: = 0.01 g/g | TRA Consumers 3.0 |
| • Dermal exposure negligible compared to inhalation: Yes | TRA Consumers 3.0 |
| • Oral contact foreseen: No | TRA Consumers 3.0 |
| **Amount used, frequency and duration of use/exposure** | |
| • Amount of product used per application: = 10 g/event | TRA Consumers 3.0 |
| • Exposure time: = 0.25 hr | TRA Consumers 3.0 |
| • Frequency of use over a day: = 4 events/day | TRA Consumers 3.0 |

**9.8.2.2. Exposure and risks for consumers**

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

**Table 111. Exposure concentrations and risks for consumers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **17.39 mg/m³** (TRA Consumers 3.0) | RCR = 0.527 |
| Dermal, systemic, long-term | **0 mg/kg bw/day** (TRA Consumers 3.0) | RCR < 0.01 |

| | | |
|---|---|---|
| Dermal, local, long-term | | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Oral, systemic, long-term | **0 mg/kg bw/day** (TRA Consumers 3.0) | RCR < 0.01 |
| Combined routes, systemic, long-term | | RCR = 0.527 |

**Conclusion on risk characterisation**

The substance is classified as skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, consumer products containing this substance less than 25% is not classified as skin irritation. There is no need to conduct acute and long-term dermal exposure assessment and risk characterization for local effects for consumer products containing this substance less than 25%.
The substance is classified as eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, consumer products containing this substance less than 25% is not classified as eye irritation. There is no need to conduct exposure assessment and risk characterization for eye local effects for consumer products containing this substance less than 25%.

## 9.8.3. Consumer contributing scenario 2: Aircare, continuous action (solid and liquid) (PC 3)

### 9.8.3.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Product/Article subcategory: Aircare, continuous action (solid and liquid) | TRA Consumers 3.0 |
| • Concentration of substance in mixture: = 0.01 g/g | TRA Consumers 3.0 |
| • Oral contact foreseen: No | TRA Consumers 3.0 |
| **Amount used, frequency and duration of use/exposure** | |
| • Amount of product used per application: = 50 g/event | TRA Consumers 3.0 |
| • Exposure time: = 8 hr | TRA Consumers 3.0 |
| • Frequency of use over a day: = 1 events/day | TRA Consumers 3.0 |
| **Other conditions affecting consumers exposure** | |
| • Body parts potentially exposed: Fingertips | TRA Consumers 3.0 |
| • Dermal transfer factor: = 1 | TRA Consumers 3.0 |

### 9.8.3.2. Exposure and risks for consumers

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

**Table 112. Exposure concentrations and risks for consumers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **4.31 mg/m³** (TRA Consumers 3.0) | RCR = 0.131 |
| Dermal, systemic, long-term | **0.006 mg/kg bw/day** (TRA Consumers 3.0) | RCR < 0.01 |
| Dermal, local, long-term | | Qualitative (see below) |

| | | |
|---|---|---|
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Oral, systemic, long-term | **0 mg/kg bw/day** (TRA Consumers 3.0) | RCR < 0.01 |
| Combined routes, systemic, long-term | | RCR = 0.131 |

**Conclusion on risk characterisation**

The substance is classified as skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, consumer products containing this substance less than 25% is not classified as skin irritation. There is no need to conduct acute and long-term dermal exposure assessment and risk characterization for local effects for consumer products containing this substance less than 25%.
The substance is classified as eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, consumer products containing this substance less than 25% is not classified as eye irritation. There is no need to conduct exposure assessment and risk characterization for eye local effects for consumer products containing this substance less than 25%.

# 9.9. Exposure scenario 9: Consumer Use - Consumer Use - Consumer end-use of biocides (covers ERCs 8d "outdoor" and 8a "indoor")

| | |
|---|---|
| **Environment contributing scenario(s):** | |
| Wide dispersive outdoor use of processing aids in open systems | ERC 8d, ERC 8a |
| **Consumer contributing scenario(s):** | |
| Biocide, instant action (aerosol sprays) | PC 8 |
| Biocides, continuous action (solid and liquid - evaporation through heating using electrical evaporator) | PC 8 |

## 9.9.1. Environmental contributing scenario 1: Wide dispersive outdoor use of processing aids in open systems

### 9.9.1.1. Conditions of use

| |
|---|
| **Amount used, frequency and duration of use (or from service life)** |
| • Daily wide dispersive use: <= 2.75E-4 tonnes/day |
| • Percentage of EU tonnage used at regional scale: = 10 % |
| **Conditions and measures related to treatment of waste (including article waste)** |
| • Particular considerations on the waste treatment operations: No (low risk) (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** |
| • Municipal STP: Yes [Effectiveness Water: 88.07%] |
| • Discharge rate of STP: >= 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |
| • Receiving surface water flow rate: >= 1.8E4 m3/d |

### 9.9.1.2. Releases

The local releases to the environment are reported in the following table.

**Table 113. Local releases to the environment**

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|
| **Water** | ERC based | **Initial release factor:** 100%<br>**Final release factor:** 100%<br>**Local release rate:** 0.275 kg/day |
| **Air** | ERC based | **Initial release factor:** 100% **Final release factor:** 100% |
| **Soil** | ERC based | **Final release factor:** 20% |

#### 9.9.1.3. 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.

**Table 114. Exposure concentrations and risks for the environment**

| Protection target | Exposure concentration | Risk characterisation |
|---|---|---|
| Freshwater | **Local PEC:** 0.002 mg/L | RCR = 0.14 |
| Sediment (freshwater) | **Local PEC:** 0.04 mg/kg dw | RCR = 0.14 |
| Marine water | **Local PEC:** 2.115E-4 mg/L | RCR = 0.136 |
| Sediment (marine water) | **Local PEC:** 0.004 mg/kg dw | RCR = 0.135 |
| **Protection target** | **Exposure concentration** | **Risk characterisation** |
| Predator (freshwater) | **Local PEC:** 0.02 mg/kg ww | RCR < 0.01 |
| Predator (marine water) | **Local PEC:** 0.002 mg/kg ww | RCR < 0.01 |
| Top predator (marine water) | **Local PEC:** 9.579E-4 mg/kg ww | RCR < 0.01 |
| Sewage treatment plant | **Local PEC:** 0.016 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 0.005 mg/kg dw | RCR = 0.113 |
| Predator (terrestrial) | **Local PEC:** 0.004 mg/kg ww | RCR < 0.01 |

### 9.9.2. Consumer contributing scenario 1: Biocide, instant action (aerosol sprays) (PC 8)

#### 9.9.2.1. Conditions of use

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Product/Article subcategory: Aircare, instant action (aerosol sprays) | External Tool (TRA consumer 3.0) |
| • Spray: Yes | External Tool (TRA consumer 3.0) |
| • Concentration of substance in mixture: = 0.01 g/g | External Tool (TRA consumer 3.0) |
| • Dermal exposure negligible compared to inhalation: Yes | External Tool (TRA consumer 3.0) |
| • Oral contact foreseen: No | External Tool (TRA consumer 3.0) |
| **Amount used, frequency and duration of use/exposure** | |
| • Frequency of use over a day: = 4 events/day | External Tool (TRA consumer 3.0) |

| | |
|---|---|
| • Amount of product used per application: = 10 g/event | External Tool (TRA consumer 3.0) |
| • Exposure time: = 0.25 hr | External Tool (TRA consumer 3.0) |
| **Other conditions affecting consumers exposure** | |
| • room volume in m3: >= 20 m3 | External Tool (TRA consumer 3.0) |

**9.9.2.2. Exposure and risks for consumers**

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

**Table 115. Exposure concentrations and risks for consumers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **17.39 mg/m³** (External Tool (TRA consumer 3.0)) | RCR = 0.527 |
| Dermal, systemic, long-term | **0 mg/kg bw/day** (External Tool (TRA consumer 3.0)) | RCR < 0.01 |
| Dermal, local, long-term | | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Oral, systemic, long-term | **0 mg/kg bw/day** (External Tool (TRA consumer 3.0)) | RCR < 0.01 |
| Combined routes, systemic, | | RCR = 0.527 |
| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
| long-term | | |

**Conclusion on risk characterisation**

The substance is classified as skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, consumer products containing this substance less than 25% is not classified as skin irritation. There is no need to conduct acute and long-term dermal exposure assessment and risk characterization for local effects for consumer products containing this substance less than 25%.
The substance is classified as eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, consumer products containing this substance less than 25% is not classified as eye irritation. There is no need to conduct exposure assessment and risk characterization for eye local effects for consumer products containing this substance less than 25%.

## 9.9.3. Consumer contributing scenario 2: Biocides, continuous action (solid and liquid - evaporation through heating using electrical evaporator) (PC 8)

**9.9.3.1. Conditions of use**

| | Method |
|---|---|
| **Product (article) characteristics** | |
| • Product/Article subcategory: Aircare, continuous action (solid and liquid) | External Tool (ECETOC TRA v3 Consumer tool) |

| | |
|---|---|
| • Concentration of substance in mixture: = 0.01 g/g | External Tool (ECETOC TRA v3 Consumer tool) |
| • Oral contact foreseen: No | External Tool (ECETOC TRA v3 Consumer tool) |
| **Amount used, frequency and duration of use/exposure** | |
| • Amount of product used per application: = 50 g/event | External Tool (ECETOC TRA v3 Consumer tool) |
| • Exposure time: = 8 hr | External Tool (ECETOC TRA v3 Consumer tool) |
| • Frequency of use over a day: = 1 events/day | External Tool (ECETOC TRA v3 Consumer tool) |
| **Other conditions affecting consumers exposure** | |
| • Body parts potentially exposed: Fingertips | External Tool (ECETOC TRA v3 Consumer tool) |
| • Dermal transfer factor: = 1 | External Tool (ECETOC TRA v3 Consumer tool) |

**9.9.3.2. Exposure and risks for consumers**

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

**Table 116. Exposure concentrations and risks for consumers**

| Route of exposure and type of effects | Exposure concentration | Risk characterisation |
|---|---|---|
| Inhalation, systemic, long-term | **4.31 mg/m³** (External Tool (ECETOC TRA v3 Consumer tool)) | RCR = 0.131 |
| Dermal, systemic, long-term | **0.006 mg/kg bw/day** (External Tool (ECETOC TRA v3 Consumer tool)) | RCR < 0.01 |
| Dermal, local, long-term | | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
| Eye, local | | Qualitative (see below) |
| Oral, systemic, long-term | **0 mg/kg bw/day** (External Tool (ECETOC TRA v3 Consumer tool)) | RCR < 0.01 |
| Combined routes, systemic, long-term | | RCR = 0.131 |

**Conclusion on risk characterisation**

The substance is classified as skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, consumer products containing this substance less than 25% is not classified as skin irritation. There is no need to conduct acute and long-term dermal exposure assessment and risk characterization for local effects for consumer products containing this substance less than 25%.
The substance is classified as eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, consumer products containing this substance less than 25% is not classified as eye irritation. There is no need to conduct exposure assessment and risk characterization for eye local effects for consumer products containing this substance less than 25%.

# 9.10. Exposure scenario 10: Consumer Use - Consumer Use - Consumer end-use of polishes and wax blends

| | |
|---|---|
| **Environment contributing scenario(s):** | |
| Wide dispersive indoor use of processing aids in open systems | ERC 8a |
| **Consumer contributing scenario(s):** | |
| Polishes, wax / cream (floor, furniture, shoes) | PC 31 |
| Polishes, spray (furniture, shoes) | PC 31 |

## 9.10.1. Environmental contributing scenario 1: Wide dispersive indoor use of processing aids in open systems

### 9.10.1.1. Conditions of use

| **Amount used, frequency and duration of use (or from service life)** |
|---|
| • Daily wide dispersive use: <= 2.75E-4 tonnes/day |
| • Percentage of EU tonnage used at regional scale: = 10 % |
| **Conditions and measures related to treatment of waste (including article waste)** |
| • Particular considerations on the waste treatment operations: No (low risk) (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** |
| • Municipal STP: Yes [Effectiveness Water: 88.07%] |
| • Discharge rate of STP: >= 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |
| • Receiving surface water flow rate: >= 1.8E4 m3/d |

### 9.10.1.2. Releases

The local releases to the environment are reported in the following table.

**Table 117. Local releases to the environment**

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|
| **Water** | ERC based | **Initial release factor:** 100%<br>**Final release factor:** 100%<br>**Local release rate:** 0.275 kg/day |
| **Air** | ERC based | **Initial release factor:** 100% **Final release factor:** 100% |
| **Soil** | ERC based | **Final release factor:** 0% |

### 9.10.1.3. 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.

**Table 118. Exposure concentrations and risks for the environment**

| Protection target | Exposure concentration | Risk characterisation |
|---|---|---|
| Freshwater | **Local PEC:** 0.002 mg/L | RCR = 0.14 |
| Sediment (freshwater) | **Local PEC:** 0.04 mg/kg dw | RCR = 0.14 |

| | | |
|---|---|---|
| Marine water | **Local PEC:** 2.115E-4 mg/L | RCR = 0.136 |
| Sediment (marine water) | **Local PEC:** 0.004 mg/kg dw | RCR = 0.135 |
| Predator (freshwater) | **Local PEC:** 0.02 mg/kg ww | RCR < 0.01 |
| **Protection target** | **Exposure concentration** | **Risk characterisation** |
| Predator (marine water) | **Local PEC:** 0.002 mg/kg ww | RCR < 0.01 |
| Top predator (marine water) | **Local PEC:** 9.579E-4 mg/kg ww | RCR < 0.01 |
| Sewage treatment plant | **Local PEC:** 0.016 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 0.005 mg/kg dw | RCR = 0.113 |
| Predator (terrestrial) | **Local PEC:** 0.004 mg/kg ww | RCR < 0.01 |

## 9.10.2. Consumer contributing scenario 1: Polishes, wax / cream (floor, furniture, shoes) (PC 31)

### 9.10.2.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Product/Article subcategory: Polishes, wax / cream (floor, furniture, shoes) | TRA Consumers 3.0 |
| • Concentration of substance in mixture: = 0.001 g/g | TRA Consumers 3.0 |
| • Oral contact foreseen: No | TRA Consumers 3.0 |
| **Amount used, frequency and duration of use/exposure** | |
| • Amount of product used per application: = 550 g/event | TRA Consumers 3.0 |
| • Exposure time: = 4 hr | TRA Consumers 3.0 |
| • Frequency of use over a day: = 1 events/day | TRA Consumers 3.0 |
| **Other conditions affecting consumers exposure** | |
| • Body parts potentially exposed: Hands | TRA Consumers 3.0 |
| • Dermal transfer factor: = 1 | TRA Consumers 3.0 |

### 9.10.2.2. Exposure and risks for consumers

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

**Table 119. Exposure concentrations and risks for consumers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **8.088 mg/m³** (TRA Consumers 3.0) | RCR = 0.245 |
| Dermal, systemic, long-term | **0.143 mg/kg bw/day** (TRA Consumers 3.0) | RCR = 0.015 |
| Dermal, local, long-term | | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Oral, systemic, long-term | **0 mg/kg bw/day** (TRA Consumers 3.0) | RCR < 0.01 |
| Combined routes, systemic, long-term | | RCR = 0.26 |

**Conclusion on risk characterisation**

The substance is classified as skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, consumer products containing this substance less than 25% is not classified as skin irritation. There is no need to conduct acute and long-term dermal exposure assessment and risk characterization for local effects for consumer products containing this substance less than 25%.
The substance is classified as eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, consumer products containing this substance less than 25% is not classified as eye irritation. There is no need to conduct exposure assessment and risk characterization for eye local effects for consumer products containing this substance less than 25%.

## 9.10.3. Consumer contributing scenario 2: Polishes, spray (furniture, shoes) (PC 31)

### 9.10.3.1. Conditions of use

| | **Method** |
|---|---|
| **Product (article) characteristics** | |
| • Product/Article subcategory: Polishes, spray (furniture, shoes) | TRA Consumers 3.0 |
| • Spray: Yes | TRA Consumers 3.0 |
| • Concentration of substance in mixture: = 0.01 g/g | TRA Consumers 3.0 |
| • Oral contact foreseen: No | TRA Consumers 3.0 |
| **Amount used, frequency and duration of use/exposure** | |
| • Amount of product used per application: = 135 g/event | TRA Consumers 3.0 |
| • Exposure time: = 4 hr | TRA Consumers 3.0 |
| • Frequency of use over a day: = 1 events/day | TRA Consumers 3.0 |
| **Other conditions affecting consumers exposure** | |
| • Body parts potentially exposed: Hands | TRA Consumers 3.0 |
| • Dermal transfer factor: = 1 | TRA Consumers 3.0 |

### 9.10.3.2. Exposure and risks for consumers

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

**Table 120. Exposure concentrations and risks for consumers**

| **Route of exposure and type of effects** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Inhalation, systemic, long-term | **19.85 mg/m³** (TRA Consumers 3.0) | RCR = 0.602 |
| Dermal, systemic, long-term | **1.429 mg/kg bw/day** (TRA Consumers 3.0) | RCR = 0.152 |
| Dermal, local, long-term | | Qualitative (see below) |
| Dermal, local, acute | | Qualitative (see below) |
| Eye, local | | Qualitative (see below) |
| Oral, systemic, long-term | **0 mg/kg bw/day** (TRA Consumers 3.0) | RCR < 0.01 |
| Combined routes, systemic, long-term | | RCR = 0.754 |

**Conclusion on risk characterisation**

The substance is classified as skin irritation Category 2. Considering specific concentration limits of skin irritation Category 2, consumer products containing this substance less than 25% is not classified as skin irritation. There is no need to conduct acute and long-term dermal exposure assessment and risk characterization for local effects for consumer products containing this substance less than 25%.
The substance is classified as eye irritation Category 2. Considering specific concentration limits of eye irritation Category 2, consumer products containing this substance less than 25% is not classified as eye irritation. There is no need to conduct exposure assessment and risk characterization for eye local effects for consumer products containing this substance less than 25%.

# 9.11. Exposure scenario 11: Consumer Use - Consumer Use - Consumer and Professional end-use of cosmetics & pharmaceuticals

| | |
|---|---|
| **Environment contributing scenario(s):** | |
| Wide dispersive indoor use of processing aids in open systems | ERC 8a |
| **Consumer contributing scenario(s):** | |
| Cosmetics, personal care products | PC 39 |
| Perfumes, Fragrances | PC 28 |

## 9.11.1. Environmental contributing scenario 1: Wide dispersive indoor use of processing aids in open systems

### 9.11.1.1. Conditions of use

| |
|---|
| **Amount used, frequency and duration of use (or from service life)** |
| • Daily wide dispersive use: <= 2.75E-4 tonnes/day |
| • Percentage of EU tonnage used at regional scale: = 10 % |
| **Conditions and measures related to treatment of waste (including article waste)** |
| • Particular considerations on the waste treatment operations: No (low risk) (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** |
| • Municipal STP: Yes [Effectiveness Water: 88.07%] |
| • Discharge rate of STP: >= 2E3 m3/d |
| • Application of the STP sludge on agricultural soil: Yes |
| • Receiving surface water flow rate: >= 1.8E4 m3/d |

### 9.11.1.2. Releases

The local releases to the environment are reported in the following table.

**Table 121. Local releases to the environment**

| Release | Release factor estimation method | Explanation / Justification |
|---|---|---|
| **Water** | ERC based | **Initial release factor:** 100%<br>**Final release factor:** 100%<br>**Local release rate:** 0.275 kg/day |
| **Air** | ERC based | **Initial release factor:** 100% **Final release factor:** 100% |

| | | |
|---|---|---|
| **Soil** | ERC based | **Final release factor:** 0% |

**9.11.1.3. 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.

**Table 122. Exposure concentrations and risks for the environment**

| **Protection target** | **Exposure concentration** | **Risk characterisation** |
|---|---|---|
| Freshwater | **Local PEC:** 0.002 mg/L | RCR = 0.14 |
| Sediment (freshwater) | **Local PEC:** 0.04 mg/kg dw | RCR = 0.14 |
| Marine water | **Local PEC:** 2.115E-4 mg/L | RCR = 0.136 |
| Sediment (marine water) | **Local PEC:** 0.004 mg/kg dw | RCR = 0.135 |
| Predator (freshwater) | **Local PEC:** 0.02 mg/kg ww | RCR < 0.01 |
| **Protection target** | **Exposure concentration** | **Risk characterisation** |
| Predator (marine water) | **Local PEC:** 0.002 mg/kg ww | RCR < 0.01 |
| Top predator (marine water) | **Local PEC:** 9.579E-4 mg/kg ww | RCR < 0.01 |
| Sewage treatment plant | **Local PEC:** 0.016 mg/L | RCR < 0.01 |
| Agricultural soil | **Local PEC:** 0.005 mg/kg dw | RCR = 0.113 |
| Predator (terrestrial) | **Local PEC:** 0.004 mg/kg ww | RCR < 0.01 |

## 9.11.2. Consumer contributing scenario 1: Cosmetics, personal care products (PC 39)

REACH regulation Article 14(5) text: The chemical safety report need not include consideration of the risks to human health from the following end uses:
(a) in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food; (b) in cosmetic products within the scope of Directive 76/768/EEC.
According to REACH regulations article 14, the chemical safety report of L-menthol need not include consideration of the risks to human health in cosmetic products within the scope of Directive 76/768/EEC.

## 9.11.3. Consumer contributing scenario 2: Perfumes, Fragrances (PC 28)

REACH regulation Article 14(5) text: The chemical safety report need not include consideration of the risks to human health from the following end uses:
(a) in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food; (b) in cosmetic products within the scope of Directive 76/768/EEC.
According to REACH regulations article 14, the chemical safety report of L-menthol need not include consideration of the risks to human health in cosmetic products within the scope of Directive 76/768/EEC.