Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)



Revision date: 2022-01-26 Supercedes date: 2022-01-19

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

1.1. Product identifier:

Product trade name: Kalama* Cinnamic Alcohol, FCC

Company product number: CNALCFCC

REACH registration number: 01-2119934496-29-0003
Substance name: Cinnamyl alcohol

Substance identification number: EC 203-212-3

Other means of identification: Cinnamyl alcohol, 3-Phenyl-2-propen-1-ol, Styryl carbinol

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

Uses: Intermediate. Flavor and fragrance ingredient/additive. See Annex for covered

uses.

Uses advised against: None identified

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

Manufacturer/Supplier: Emerald Kalama Chemical, LLC

1296 NW Third Street

Kalama, WA 98625 United States Telephone: +1-360-673-2550

1499 SE Tech Center Place, Suite 300 Vancouver, WA 98683 United States Telephone: +1-360-954-7100

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Avenue des Arts 10 B-1210 Brussels

Belgium

Telephone: +32 (0) 2 403 7239

email: pcbvba09@penmanconsulting.com

For further information about this SDS: Email: product.compliance@emeraldmaterials.com

1.4. Emergency telephone number:

ChemTel (24 hours): 1-800-255-3924 (USA); +1-813-248-0585 (outside USA).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:

Product classification according to Regulation (EC) 1272/2008 (CLP) as amended:

Skin Irritation, category 2, H315 Skin Sensitizer, category 1, H317

See Section 2.2 for full text of H (Hazard) statements (EC 1272/2008).

2.2. Label elements:

Product labeling according to Regulation (EC) 1272/2008 (CLP) as amended:

Hazard pictogram(s):



Signal word:

Warning

Hazard statements:

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before reuse.

Supplemental information: No Additional Information

Precautionary statements are listed according to the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) - Annex III and ECHA Guidance on Labelling and Packaging. Regulations in individual countries/regions may determine which statements are required on the product label. See product label for specifics.

2.3. Other hazards:

PBT/vPvB criteria: This product does not meet the PBT and vPvB classification criteria.

Endocrine disrupting properties: No specific information available.

Other hazards: No Additional Information

See Section 11 for toxicological information.

SECTION 3: Composition/information on ingredients

3.1. Substance:

CAS-No.	Chemical Name	Weight%	<u>Classification</u>	H Statements
000104-54-1	Cinnamyl alcohol	99-100	Skin Irrit. 2- Skin Sens. 1	H315-317
000104-55-2	Cinnamaldehyde	0.1-<0.3	Acute Tox. 4 Dermal- Eye Irrit. 2- Skin Irrit. 2- Skin Sens. 1	H312-315-317-319
CAS-No.	Chemical Name	REACH Reg	istration No.	EC/List Number
000104-54-1	Cinnamyl alcohol	01-21199344	196-29-0003	203-212-3
000104-55-2	Cinnamaldehyde	Impurity		203-213-9
CAS-No.	Chemical Name	M-factor	<u>SCLs</u>	<u>ATE</u>
000104-54-1	Cinnamyl alcohol	N/A	N/E	Not Available
000104-55-2	Cinnamaldehyde	N/A	N/E	Dermal ATE 1160 mg/kg

See Section 16 for full text of H (Hazard) statements (EC 1272/2008).

Amounts specified are typical and do not represent a specification. Remaining components are proprietary, non-hazardous, and/or present at amounts below reportable limits.

SECTION 4: First aid measures

4.1. Description of first aid measures:

General: If irritation or other symptoms occur or persist from any route of exposure, remove the affected individual from the area: see a physician/get medical attention.

Following eye contact: Any material that contacts the eye should be washed out immediately with water. Get medical attention if symptoms occur.

Following skin contact: Immediately remove contaminated clothing and shoes. Wash the affected area with plenty of soap and water until no evidence of the chemical remains (at least 15-20 minutes). Launder clothing before reuse. If skin irritation occurs: Get medical advice/attention.

Following inhalation: If affected, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Call a POISON CENTER or doctor/physician if you feel unwell.

Following ingestion: Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse out the mouth with water. Get medical attention immediately.

Protection of first aid responders: Wear proper personal protective clothing and equipment.

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

Irritation. Pre-existing skin problems may be aggravated by prolonged or repeated contact. See section 11 for additional information.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media:

Suitable: Carbon dioxide, dry chemical, foam, water fog.

Unsuitable: None known.

5.2. Special hazards arising from the substance or mixture:

Unusual fire/explosion hazards: Product is not considered a fire hazard, but will burn if ignited.

Hazardous combustion products: Irritating or toxic substances may be emitted upon burning, combustion or decomposition. See section 10 (10.6 Hazardous decomposition products) for additional information.

5.3. Advice for firefighters:

Wear self-contained breathing apparatus (SCBA) equipped with a full facepiece and operated in a pressure-demand mode (or other positive pressure mode) and approved protective clothing. Personnel without suitable respiratory protection must leave the area to prevent significant exposure to hazardous gases from combustion, burning or decomposition. In an enclosed or poorly ventilated area, wear SCBA during cleanup immediately after a fire as well as during the attack phase of firefighting operations.

See section 9 for additional information.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

See Section 8 for recommendations on the use of personal protective equipment. If spilled in an enclosed area, ventilate. Personal Protective Equipment must be worn.

6.2. Environmental precautions:

Do not flush product into public sewer, water systems or surface waters.

6.3. Methods and material for containment and cleaning up:

Contain spill. Wear proper personal protective clothing and equipment. Sweep up carefully and place into container for reuse or disposal. Avoid causing dust. Place into labeled, closed container; store in safe location to await disposal. Change contaminated clothing and launder before reuse.

6.4. References to other sections:

See Section 8 for recommendations on the use of personal protection and Section 13 for waste disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling:

As with any chemical product, use good laboratory/workplace procedures. Wash thoroughly after handling this product. Always wash up before eating, smoking or using the facilities. Use under well-ventilated conditions. Avoid eye and skin contact. Avoid breathing dust. Avoid drinking, tasting, swallowing or ingesting this product. Wash contaminated clothing before reuse. Provide eyewash fountains and safety showers in the work area.

7.2. Conditions for safe storage, including any incompatibilities:

Store cool and dry, under well-ventilated conditions. Store this material away from incompatible substances (see section 10). Do not store in open, unlabeled or mislabeled containers. Keep container closed when not in use. Product can easily oxidize. It is recommended that opened containers be padded with nitrogen.

7.3. Specific end use(s):

Further information concerning special risk management measures: see annex of this safety data sheet (exposure scenarios).

SECTION 8: Exposure controls / personal protection

8.1. Control parameters:

Occupational exposure limits (OEL):

EU IOELV Chemical Name EU OELV ACGIH - TWA/Ceiling **ACGIH - STEL** Cinnamyl alcohol N/E N/E N/E Cinnamaldehyde N/F N/F N/F N/F **UK WEL Chemical Name** Ireland OEL

 Ginnami alcohol
 N/E
 N/E

 Cinnamaldehyde
 N/E
 N/E

N/E=Not established (no exposure limits established for the listed substances for listed country/region/organization).

Derived No Effect Levels (DNELs):

Cinnamyl alcohol

 Population
 Route
 Acute (local)
 Acute (systemic)
 Long Term (local)
 Long Term (systemic)

 Workers
 Inhalation
 N/E
 N/E
 N/E
 8.8 mg/m3

Long Term (systemic) **Population** Acute (local) Route Acute (systemic) Long Term (local) Workers Dermal N/F 2,5 mg/kg bw/day General population Inhalation N/E N/E N/E 1,32 mg/m3 0,892 mg/kg bw/day General population Dermal N/E N/E N/E General population N/E N/E N/E 0,892 mg/kg bw/day Oral Human via the environment N/E N/E N/E 1,32 mg/m3 Inhalation Human via the environment N/F N/F 0,892 mg/kg bw/day Oral

Predicted No Effect Concentration (PNECs):

Cinnamyl alcohol

 Compartment
 PNEC

 Freshwater
 7,7 μg/L

 Freshwater sediment
 0,118 mg/kg dw

 Marine water
 0,77 μg/L

 Marine water sediment
 11,8 μg/kg dw

 Intermittent releases
 77 μg/L

 Soil
 19 μg/kg dw

Oral No potential for bioaccumulation

N/E=Not established; N/A=Not applicable (not required); bw=body weight; dw=dry weight; ww=wet weight.

8.2. Exposure controls:

Appropriate engineering controls: Always provide effective general and, when necessary, local exhaust ventilation to draw dust away from workers to prevent routine inhalation. Ventilation must be adequate to maintain the ambient workplace atmosphere below the exposure limit(s) outlined in the SDS.

Individual protection measures, such as personal protective equipment:

Eye/face protection: Wear eye protection.

Hand protection: Avoid skin contact when mixing or handling the material by wearing impervious and chemical resistant gloves. In case of prolonged immersion or frequently repeated contact, gloves with breakthrough times greater than 480 minutes (protection class 6) are recommended. For brief contact or splash applications, gloves with breakthrough times of 30 minutes or greater are recommended (protection class 2 or greater). Suggested materials for protective gloves: Butyl rubber, Viton. The protective gloves to be used must comply with the specifications of the Regulation (EU) 2016/425 and the resultant standard EN 374. Suitability and durability of a glove is dependent on usage (e.g. frequency and duration of contact, other chemicals which may be handled, chemical resistance of glove material and dexterity). Always seek advice of the glove supplier as to the most suitable glove material.

Skin and body protection: Use good laboratory/workplace procedures including personal protective clothing: labcoat, safety glasses and protective gloves.

Respiratory protection: In case of insufficient ventilation, wear suitable respiratory equipment. Wear an approved respirator (e.g., an organic vapor respirator, a full face air purifying respirator for organic vapors, or a self-contained breathing apparatus) whenever exposure to aerosol, mist, spray, fume or vapor exceed the applicable exposure limit(s) of any chemical substance listed in this SDS.

Further information: Eyewash fountains and safety showers are recommended in the work area.

Environmental exposure controls: See Sections 6 and 12.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Physical state: Crystalline mass (solid)
Colour: White to slight yellow

Odour: Floral
Odour threshold: Not Available

Melting point/Freezing point: 31 °C (88 °F) (solidification point)

Boiling point °C: 234 °C
Boiling point °F: 453 °F

Flammability: Not flammable
Lower and upper explosion limit: LEL: Not Available
UEL: Not Available

Flash point: >93.3 °C (>200 °F) Pensky-Marten Closed Cup

Auto-ignition temperature:Not AvailableDecomposition temperature:Not AvailablepH:4.7 (1% solution)

Kinematic viscosity: 27.449 mm2/s @ 40°C; 14.482 mPa.s @ 40°C

Solubility in water: 2542 mg/L @ 25° C Partition coefficient n-octanol/water (log 1.452 (OECD 117)

value):

Vapour pressure:0.358 Pa @ 25 °CDensity and/or relative density:1.044 (25°C)Relative vapour density:4.6 (Air=1)Particle characteristics:Not Available% Volatile by weight:100%

VOC: 100%

Surface tension: 42.6 mN/m @ 20°C (calculated)

Amounts specified are typical and do not represent a specification.

9.2. Other information:

Information with regard to physical hazard classes:

Explosive properties: Not explosive Oxidising properties: Not oxidizing

Other safety characteristics: Evaporation rate: <1

SECTION 10: Stability and reactivity

10.1. Reactivity:

Oxidizes when exposed to air.

10.2. Chemical stability:

This product is stable.

10.3. Possibility of hazardous reactions:

Hazardous polymerization will not occur.

10.4. Conditions to avoid:

Avoid exposure to air, moisture, ignition sources and elevated temperatures.

10.5. Incompatible materials:

Avoid contact with strong oxidizing agents.

10.6. Hazardous decomposition products:

Carbon dioxide and carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity: Not classified (based on available data, the classification criteria are not met).

Oral LD50 **Chemical Name** Inhalation LC50 **Species Species Dermal LD50 Species** Cinnamyl alcohol 2675 mg/kg >5000 mg/kg Rabbit/ adult Mouse Cinnamaldehyde 757 mg/L (4 hours, Rat/ adult 2220 mg/kg 1160 mg/kg Guinea Pig/ Rat/ adult vapor, estimated)

Skin corrosion/irritation: Causes skin irritation - Category 2.

 Chemical Name
 Skin irritation
 Species

 Cinnamyl alcohol
 Irritant
 Guinea pig/ adult

 Cinnamaldehyde
 Moderate irritant
 Rabbit/ adult

Serious eye damage/irritation: Not classified (based on available data, the classification criteria are not met).

<u>Chemical Name</u> <u>Eye irritation</u> <u>Species</u>

Cinnamyl alcohol Non-irritant Rabbit & Guinea Pig
Cinnamaldehyde Moderate irritant Rabbit/ adult

Respiratory or skin sensitization: Skin sensitization - Category 1.

<u>Chemical Name</u> <u>Skin sensitisation</u> <u>Species</u>

Cinnamyl alcohol Sensitizer Guinea pig and Human Cinnamaldehyde Sensitizer Guinea Pig/ adult

Carcinogenicity: Not classified (no relevant information found).

Germ cell mutagenicity: Not classified (based on available data, the classification criteria are not met). CINNAMYL ALCOHOL: Negative results were observed in Ames tests with and without activation (in-vitro). Ames testing showed no mutagenic activity and mixed results both positive (at doses approaching cytotoxic levels) and negative were observed from other in-vitro genotoxicity assays. The weight of the evidence indicates this material is not mutagenic or clastogenic.

Reproductive toxicity: Not classified (based on available data, the classification criteria are not met). CINNAMYL ALCOHOL: Reproductive toxicity, oral study in rats: NOAEL (no-observed adverse-effect-level) = 535 mg/kg bw/day. Developmental toxicity oral study, rats: NOAEL, developmental toxicity=53.5 mg/kg bw/day.

Specific target organ toxicity (STOT) - single exposure: Not classified (based on available data, the classification criteria are not met).

Specific target organ toxicity (STOT) - repeated exposure: Not classified (based on available data, the classification criteria are not met). CINNAMYL ALCOHOL: Repeated dose study, oral, 4 months, rat: NOAEL (no-observed-adverse-effect-level) = 53.5 mg/kg bw/day (no adverse effects observed). Additional animal study data: Repeated dose study, oral, 17 weeks, rat: LOAEL (Lowest-Observed-Adverse-Effect-Level) = 6366 mg/kg bw/day (blood (changes in serum composition) and biochemical (enzyme) effects were observed); READ-ACROSS (trans-cinnamaldehyde): Repeated dose study, oral, 14 weeks: NOAEL (rat) = 275-300 mg/kg bw/day, NOAEL (mouse) = 625-650 mg/kg bw/day.

Aspiration hazard: Not classified (based on available data, the classification criteria are not met).

Other toxicity information: No additional information available.

Information on likely routes of exposure:

General: Caution must be exercised through the prudent use of protective equipment and handling procedures to minimize exposure.

Eyes: Solid particles on the eye (powder/dust) may cause pain and be accompanied by irritation.

Skin: May cause allergic skin reaction. Causes skin irritation.

Inhalation: Dust inhalation may cause respiratory irritation. Chronic exposure may cause headache, dizziness, tiredness, nausea and vomiting.

Ingestion: May be harmful if swallowed. Ingestion may cause irritation.

11.2. Information on other hazards

Endocrine disrupting properties: No specific information available.

Other information: No additional information available.

SECTION 12: Ecological information

12.1. Toxicity:

Chemical Name	<u>Species</u>	<u>Acute</u>	<u>Acute</u>	Chronic
Cinnamyl alcohol	Fish	LC50 9 mg/L (96 hours)	LC50 4.15 mg/L(96 hours)	N/E
Cinnamyl alcohol	Invertebrates	EC50 7.7 mg/L (48 hours)	N/E	N/E
Cinnamyl alcohol	Algae	EC50 19.7 mg/L (72 hours)	N/E	N/E
Cinnamyl alcohol	Micro-organisms	IC50 161.27 mg/L (48 hours) (population growth rate)		
Cinnamaldehyde	Fish	LC50 >3.5 mg/L (96 hours)	LC100 2.35-3.93 mg/L(24 hours)	N/E
Cinnamaldehyde	Invertebrates	EC50 1.20-7.05 mg/L (48 hours)	EC50 3.1 mg/L(24 hours)	N/E
Cinnamaldehyde	Algae	EC50 6.87 mg/L (72 hours)	EC50 7.55 mg/L(96 hours)	N/E
Cinnamaldehvde	Micro-organisms	EC50 71 mg/L (3 hours)	3 (/	

12.2. Persistence and degradability:

Chemical Name Biodegradation

Cinnamyl alcohol Readily biodegradable (OECD 301C)
Cinnamaldehyde Readily biodegradable (weight of evidence)

12.3. Bioaccumulative potential:

 Chemical Name
 Bioconcentration Factor (BCF)
 Log Kow

 Cinnamyl alcohol
 4.989 L/kg (calculated)
 1.452 (OECD 117)

 Cinnamaldehyde
 8.3 (estimated)
 1.83 @ 27°C

12.4. Mobility in soil:

Chemical NameMobility in soil (Koc/Kow)Cinnamyl alcohol116.9 (log KOC=2.068)Cinnamaldehyde29.456 L/kg @ 20°C (estimated)

12.5. Results of PBT and vPvB assessment:

This product does not meet the PBT and vPvB classification criteria.

12.6. Endocrine disrupting properties:

No specific information available.

12.7. Other adverse effects:

No additional information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods:

Dispose of unused contents (incineration or landfill) in accordance with national and local regulations. Dispose of container in accordance with national and local regulations. Ensure the use of properly authorized waste management companies, where appropriate.

See Section 8 for recommendations on the use of personal protective equipment.

SECTION 14: Transport information

The information below is provided to assist in documentation. It may supplement the information on the package. The package in your possession may carry a different version of the label depending on the date of manufacture. Depending on inner packaging quantities and packaging instructions, it may be subject to specific regulatory exceptions.

14.1. UN number or ID number: N/A

14.2. UN proper shipping name:

Not regulated - See Bill of Lading for Details

14.3. Transport hazard class(es):

U.S. DOT hazard class: N/A Canada TDG hazard class: N/A

Europe ADR/RID/ADN hazard class: N/A IMDG Code (ocean) hazard class: N/A ICAO/IATA (air) hazard class: N/A

A "N/A" listing for the hazard class indicates the product is not regulated for transport by that regulation.

14.4. Packing group: N/A

14.5. Environmental hazards:

Marine pollutant: Not Applicable

Hazardous substance (USA): Not Applicable

14.6. Special precautions for user:

Not Applicable

14.7. Maritime transport in bulk according to IMO instruments

Not Applicable

SECTION 15: Regulatory information

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

Europe REACH (EC) 1907/2006: Applicable components are registered, exempt or otherwise compliant. EU REACH is only relevant to substances either manufactured or imported into the EU. Emerald Kalama Chemical has met its obligations under the EU REACH regulation. EU REACH information regarding this product is provided for informational purposes only. Each Legal Entity may have differing EU REACH obligations, depending on their place in the supply chain. Emerald's compliance with EU REACH does not imply automatic coverage for Downstream Users located in the EU. For material manufactured outside of the EU, the importer of record must understand and meet their specific obligations under the regulation.

EU Authorizations and/or restrictions on use: Not Applicable

Other EU information: No Additional Information National regulations: No Additional Information

Chemical inventories:

<u>Regulation</u>	<u>Status</u>
Australian Inventory of Industrial Chemicals (AIIC):	Υ
Canadian Domestic Substances List (DSL):	Υ
Canadian Non-Domestic Substances List (NDSL):	N
China Inventory of Existing Chemical Substances (IECSC):	Υ
European EC Inventory (EINECS, ELINCS, NLP):	Υ
Japan Existing and New Chemical Substances (ENCS):	Υ
Japan Industrial Safety and Health Law (ISHL):	Υ
Korean Existing and Evaluated Chemical Substances (KECL):	Υ
New Zealand Inventory of Chemicals (NZIoC):	Υ

 Regulation
 Status

 Philippines Inventory of Chemicals and Chemical Substances (PICCS):
 Y

 Taiwan Inventory of Existing Chemicals:
 Y

U.S. Toxic Substances Control Act (TSCA) (Active):

A "Y" listing indicates all intentionally added components are either listed or are otherwise compliant with the regulation. A "N" listing indicates that for one or more components: 1) there is no listing on the public inventory (or is not on the ACTIVE inventory for U.S. TSCA); 2) no information is available; or 3) the component has not been reviewed. A "Y" for New Zealand may mean that a qualified group standard may exist for the components in this product.

UK REACH: As the UK has formally left the European Union, EU REACH [(EC) 1907/2006] is no longer directly applicable within the UK. Please see UK REACH formatted SDS for information related to UK REACH compliance.

15.2. Chemical safety assessment:

A chemical safety assessment has been carried out for the substance or mixture.

SECTION 16: Other information

Hazard (H) Statements in the Composition section (Section 3):

H312 Harmful in contact with skin.
H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Reason for revision: Changes in Section(s): 1, 9, Safety data sheet format (Regulation (EU) 2020/878)

Evaulation method for classification of mixtures: Not Applicable (substance)

Legend:

*: Trademark owned by Emerald Kalama Chemical, LLC.

ACGIH: American Conference of Governmental Industrial Hygienists

ATE: Acute toxicity estimate

EU OELV: European Union Occupational Exposure Limit Value

EU IOELV: European Union Indicative Occupational Exposure Limit Value

N/A: Not Applicable N/E: None Established

SCL: Specific concentration limit STEL: Short Term Exposure Limit

TWA: Time Weighted Average (exposure for 8-hour workday)

Users Responsibility/Disclaimer of Liability:

The information set forth herein is based on our current knowledge, and is intended to describe the product solely with respect to health, safety and the environment. As such, it must not be interpreted as a guarantee of any specific property of the product. As a result, the customer shall be solely responsible for deciding whether said information is suitable and beneficial.

Safety Data Sheet Preparer:
Product Compliance Department
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United States

Annex

Exposure Scenarios

Substance information:

Name of substance: Cinnamyl alcohol. EC# 203-212-3 / CAS# 104-54-1.

REACH Registration number: 01-2119934496-29-0003

List of exposure scenarios:

ES1: Use at industrial sites - Industrial end-use of washing and cleaning products

ES2: Use at industrial sites - Use in pharma application

ES3: Use at industrial sites - Use as a laboratory chemical

ES4: Use at industrial sites - Use as an intermediate

ES5: Formulation - Formulation of fragrance compounds ES6: Formulation - Formulation of fragrance products

ES7: Formulation - Formulation of fragranced end-products

ES8: Use by professional workers - Professional use of polishes and wax blends

ES9: Use by professional workers - Professional end-use of washing and cleaning products

ES10: Consumer use - Consumer end-use of biocides.

ES11: Consumer use - Consumer end-use of cosmetics

ES12: Consumer use - Consumer end-use of washing and cleaning products

ES13: Consumer use - Consumer end-use of fragrances

ES14: Consumer use - Consumer end-use of air care products

ES15: Consumer use - Consumer end-use of polishes and wax blends

General remarks:

The environmental exposure assessments have been performed using EUSES 2.1.2 which is part of Chemical Safety Assessment and Reporting tool (CHESAR v3.2).

The worker exposure assessments have been performed using TRA Worker v3 which is part of Chemical Safety Assessment and Reporting tool (CHESAR v3.2).

The Consumer TRA v3 (R15) tool has been used to estimate consumer exposures.

Exposure scenario (1): Use at industrial sites - Industrial end-use of washing and cleaning products

1. Exposure scenario (1)

Short title of the exposure scenario:

Use at industrial sites - Industrial end-use of washing and cleaning products

List of use descriptors:

Product category (PC): PC35
Process category (PROC): PROC2, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC10, PROC13.

Environmental release category (ERC): ERC4

List of names of contributing worker scenarios and corresponding PROCs:

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions.

PROC4 Chemical production where opportunity for exposure arises.

PROC5 Mixing or blending in batch processes. Covers mixing or blending of solid or liquid materials in the context of manufacturing or formulating sectors, as well as upon end use.

PROC7 Industrial spraying. Air dispersive techniques i.e. dispersion into air (= atomization) by e.g. pressurized air, hydraulic pressure or centrifugation, applicable for liquids and powders.

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities. Transfer includes loading, filling, dumping, bagging and weighing.

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging. PROC10 Roller application or brushing. This includes application of paints, coatings, removers, adhesives or cleaning agents to surfaces with potential exposure arising from splashes.

PROC13 Treatment of articles by dipping and pouring

Name of contributing environmental scenario and corresponding ERCs:

ERC4 Use of non-reactive processing aid at industrial site (no inclusion into or onto article)

Further explanations:

PC35 Washing and cleaning products.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://quidance.echa.europa.eu/docs/quidance_document/ information_requirements_r12_en.pdf)

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately

Product characteristics:

Concentration of substance: Up to 100%.

Physical state: liquid.

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration: <=8 hours/day

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Domain: Industrial use.

Process temperature: <= 40 °C

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation:

- PROC2, PROC4, PROC5, PROC8a, PROC8b, PROC10, PROC13: Basic general ventilation (1-3 air changes per hour): 0%.
- PROC7: Good general ventilation (3-5 air changes per hour): 30%.

Local exhaust ventilation:

- PROC2, PROC4, PROC5, PROC8a, PROC8b, PROC10, PROC13: Not required.
- PROC7: Yes (95% effectiveness).

Occupational Health and Safety Management System: Advanced

Conditions and measures related to personal protection, hygiene and health evaluation:

Respiratory protection:

- PROC2, PROC4, PROC5, PROC8b: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).
- PROC7, PROC8a, PROC10, PROC13: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%).

Dermal protection:

- PROC2: No (Effectiveness Dermal: 0%).
- PROC4: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%)
- PROC5, PROC8a, PROC8b, PROC13: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness

Dermal: 90%).

- PROC7, PROC10: Yes (chemically resistant gloves conforming to EN374 with specific activity training) (Effectiveness Dermal: 95%).

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice.

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Maximum daily use at a site: 0,02 ton/day. Maximum annual use at a site: 5 tons/year.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.

Industrial use.

Release fraction to air from process (initial release): 0,01; (final release): 0,01. Local release rate: 0,2 kg/day.

Release fraction to wastewater from process (initial release): 0,01; (final release): 0,01. Local release rate: 0,2 kg/day.

Release fraction to soil from process: 0,05.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: CHESAR v3.2-Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

· round			
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	2,143 mg/kg bw/day	0,857	PROC7
Worker, long-term, systemic, Inhalation	2,795 mg/m3	0,318	PROC4, PROC5, PROC8a, PROC8b, PROC10, PROC13
Worker, long-term, systemic, Combined routes	N/A	0,968	PROC7
Environment			
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Freshwater	0,00129 mg/L	0,168	
Freshwater sediment	0,02 mg/kg dw	0,167	
Marine water	0,000129 mg/L	0,167	
Marine water sediment	0,00197 mg/kg dw	0,167	
Soil	0,00428 mg/kg dw	0,225	
Human via environment, Inhalation	0,0000383 mg/m3	<0,01	
Human via environment, Oral	0,000262 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, PROC7: LEV used. Duration: <=8 hours/day. Respiratory protection: PROC2, PROC4, PROC5, PROC8b: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%). PROC7, PROC8a, PROC10, PROC13: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%). Dermal protection: PROC2: No (Effectiveness Dermal: 0%). PROC4: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%). PROC5, PROC8a, PROC13: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). PROC7, PROC10: Yes (chemically resistant gloves conforming to EN374 with specific activity training) (Effectiveness Dermal: 95%). Concentration of substance: Up to 100%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (2): Use at industrial sites - Use in pharma application

1. Exposure scenario (2)

Short title of the exposure scenario:

Use at industrial sites - Use in pharma application

List of use descriptors:

Sector of use category (SU): SU4, SU9, SU24

Product category (PC): PC29

Process category (PROC): PROC1, PROC2, PROC3, PROC5, PROC8a, PROC8b, PROC9

Environmental release category (ERC): ERC4

List of names of contributing worker scenarios and corresponding PROCs:

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions. PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent

containment conditions.

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition.

PROC5 Mixing or blending in batch processes. Covers mixing or blending of solid or liquid materials in the context of manufacturing or formulating sectors, as well as upon end use.

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities. Transfer includes loading, filling, dumping, bagging and weighing.

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging. PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing). Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage.

Name of contributing environmental scenario and corresponding ERCs:

ERC4 Use of non-reactive processing aid at industrial site (no inclusion into or onto article).

Further explanations:

PC29 Pharmaceuticals.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance: Up to 100%.

Physical state: liquid.

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration: <=8 hours/day

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Domain: Industrial use.

Process temperature: <= 40 °C.

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation: Basic general ventilation (1-3 air changes per hour): 0%.

Local exhaust ventilation: Not required.

Occupational Health and Safety Management System: Advanced.

Conditions and measures related to personal protection, hygiene and health evaluation:

Respiratory protection:

- PROC1: Not required.
- PROC2, PROC3, PROC5, PROC8b, PROC9: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).
- PROC8a: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%).

Dermal protection:

- PROC1, PROC2, PROC3: No (Effectiveness Dermal: 0%).
- PROC9: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%).
- PROC5, PROC8a, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice.

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Maximum daily use at a site: 0,02 ton/day. Maximum annual use at a site: 5 tons/year.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.

Industrial use.

Release fraction to air from process (initial release): 0,01; (final release): 0,01. Local release rate: 0,2 kg/day.

Release fraction to wastewater from process (initial release): 0,01; (final release): 0,01. Local release rate: 0,2 kg/day.

Release fraction to soil from process: 0,05.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town)

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: CHESAR v3.2-Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	1,372 mg/kg bw/day	0,549	PROC9
Worker, long-term, systemic, Inhalation	2,795 mg/m3	0,318	PROC5, PROC8a, PROC8b, PROC9
Worker, long-term, systemic, Combined routes	N/A	0,867	PROC9
Environment			
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	Notes
Freshwater	0,00129 mg/L	0,168	
Freshwater sediment	0,02 mg/kg dw	0,167	
Marine water	0,000129 mg/L	0,167	
Marine water sediment	0,00197 mg/kg dw	0,167	
Soil	0,00428 mg/kg dw	0,225	
Human via environment, Inhalation	0,0000383 mg/m3	<0,01	
Human via environment, Oral	0,000262 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, without LEV. Duration: <=8 hours/day. Respiratory protection: PROC1: Not required. PROC2, PROC3, PROC5, PROC8b, PROC9: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%). PROC8a: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%). Dermal protection: PROC1, PROC2, PROC3: No (Effectiveness Dermal: 0%). PROC9: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%). PROC5, PROC8a, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). Concentration of substance: Up to 100%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (3): Use at industrial sites - Use as a laboratory chemical

1. Exposure scenario (3)

Short title of the exposure scenario:

Use at industrial sites - Use as a laboratory chemical

List of use descriptors:

Sector of use category (SU): SU9 Product category (PC): PC21

Process category (PROC): PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC15

Environmental release category (ERC): ERC6b

List of names of contributing worker scenarios and corresponding PROCs:

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions.

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition.

PROC4 Chemical production where opportunity for exposure arises.

PROC5 Mixing or blending in batch processes. Covers mixing or blending of solid or liquid materials in the context of manufacturing or formulating sectors, as well as upon end use.

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities. Transfer includes loading, filling, dumping, bagging and weighing.

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging. PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing). Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage.

PROC15 Use as laboratory reagent. Use of substances at small scale in laboratories (less than or equal to 1 l or 1 kg present at workplace).

Name of contributing environmental scenario and corresponding ERCs:

ERC6b Use of reactive processing aid at industrial site (no inclusion into or onto article).

Further explanations:

PC21 Laboratory chemicals.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance: Up to 100%.

Physical state: liquid.

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration: <=8 hours/day.

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Domain: Industrial use.

Process temperature: <= 40 °C.

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation: Basic general ventilation (1-3 air changes per hour): 0%.

Local exhaust ventilation: Not required.

Occupational Health and Safety Management System: Advanced.

Conditions and measures related to personal protection, hygiene and health evaluation:

Respiratory protection:

- PROC1: Not required
- PROC2, PROC3, PROC4, PROC5, PROC8b, PROC9, PROC15: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).
- PROC8a: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%).

Dermal protection:

- PROC1, PROC2, PROC3, PROC15: No (Effectiveness Dermal: 0%).
- PROC4, PROC9: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%).
- PROC5, PROC8a, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice.

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Maximum daily use at a site: 0,015 ton/day.

Maximum annual use at a site: 5 tons/year.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.

Industrial use.

Release fraction to air from process (initial release): 0,001; (final release): 0,001. Local release rate: 0,015 kg/day.

Release fraction to wastewater from process (initial release): 0,05; (final release): 0,05. Local release rate: 0,75 kg/day.

Release fraction to soil from process: 0,00025

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town)

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: CHESAR v3.2-Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	1,372 mg/kg bw/day	0,549	PROC4, PROC9
Worker, long-term, systemic, Inhalation	2,795 mg/m3	0,318	PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC15
Worker, long-term, systemic, Combined routes	N/A	0,867	PROC4, PROC9
Environment			
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Freshwater	0,00474 mg/L	0,615	
Freshwater sediment	0,072 mg/kg dw	0,614	
Marine water	0,000474 mg/L	0,615	
Marine water sediment	0,00724 mg/kg dw	0,614	
Soil	0,016 mg/kg dw	0,827	
Human via environment, Inhalation	0,000004 mg/m3	<0,01	
Human via environment, Oral	0,00024 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, without LEV. Duration: <=8 hours/day. Respiratory protection: PROC1: Not required. PROC2, PROC3, PROC4, PROC5, PROC8b, PROC9, PROC15: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%). PROC8a: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%). Dermal protection: PROC1, PROC2, PROC3, PROC15: No (Effectiveness Dermal: 0%). PROC4, PROC9: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%). PROC5, PROC8a, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). Concentration of substance: Up to 100%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (4): Use at industrial sites - Use as an intermediate

1. Exposure scenario (4)

Short title of the exposure scenario:

Use at industrial sites - Use as an intermediate

List of use descriptors:

Product category (PC): PC0

Process category (PROC): PROC1, PROC2, PROC5, PROC8b, PROC15

Environmental release category (ERC): ERC6a

List of names of contributing worker scenarios and corresponding PROCs:

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions. PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions.

PROC5 Mixing or blending in batch processes. Covers mixing or blending of solid or liquid materials in the context of manufacturing or formulating sectors, as well as upon end use.

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging. PROC15 Use as laboratory reagent. Use of substances at small scale in laboratories (less than or equal to 1 l or 1 kg present at workplace).

Name of contributing environmental scenario and corresponding ERCs:

ERC6a Use of intermediate.

Further explanations:

PC0 Other.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance: Up to 100%.

Physical state: liquid.

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

This information is not relevant for assessment of worker's exposure

Frequency and duration of use/exposure:

Duration: <=8 hours/day

Other given operational conditions affecting workers exposure:

Location: Indoor use. Domain: Industrial use.

Process temperature: <= 40 °C

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation: Basic general ventilation (1-3 air changes per hour): 0%.

Local exhaust ventilation: Not required.

Occupational Health and Safety Management System: Advanced

Conditions and measures related to personal protection, hygiene and health evaluation:

Respiratory protection:

- PROC1: Not required.

PROC2, PROC5, PROC8b, PROC15: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).

Dermal protection:

- PROC1, PROC2, PROC15: No (Effectiveness Dermal: 0%).

- PROC5, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice.

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Maximum daily use at a site: 0,02 ton/day. Maximum annual use at a site: 5 tons/year.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default)

Other given operational conditions affecting environmental exposure:

Industrial use.

Indoor use.

Release fraction to air from process (initial release): 0,05; (final release): 0,05. Local release rate: 1 kg/day.

Release fraction to wastewater from process (initial release): 0,02; (final release): 0,02. Local release rate: 0,4 kg/day.

Release fraction to soil from process: 0,001.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: CHESAR v3.2-Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	1,371 mg/kg bw/day	0,548	PROC5, PROC8b
Worker, long-term, systemic, Inhalation	2,795 mg/m3	0,318	PROC5, PROC8b, PROC15
Worker, long-term, systemic, Combined routes	N/A	0,866	PROC5, PROC8b
Environment			
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Freshwater	0,00254 mg/L	0,33	
Freshwater sediment	0,039 mg/kg dw	0,33	
Marine water	0,000254 mg/L	0,33	
Marine water sediment	0,00389 mg/kg dw	0,33	
Soil	0,00852 mg/kg dw	0,449	
Human via environment, Inhalation	0,000191 mg/m3	<0,01	
Human via environment, Oral	0,00115 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, without LEV. Duration: <=8 hours/day. Respiratory protection: PROC1: Not required. PROC2, PROC5, PROC8b, PROC15: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%). Dermal protection: PROC1, PROC2, PROC15: No (Effectiveness Dermal: 0%). PROC5, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). Concentration of substance: Up to 100%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (5): Formulation - Formulation of fragrance compounds

1. Exposure scenario (5)

Short title of the exposure scenario:

Formulation - Formulation of fragrance compounds

List of use descriptors:

Product category (PC): PC28

Process category (PROC): PROC1, PROC2, PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC15

Environmental release category (ERC): ERC2

List of names of contributing worker scenarios and corresponding PROCs:

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition.

PROC5 Mixing or blending in batch processes. Covers mixing or blending of solid or liquid materials in the context of manufacturing or formulating sectors, as well as upon end use.

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities. Transfer includes loading, filling, dumping, bagging and weighing.

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging. PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing). Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage.

PROC15 Use as laboratory reagent. Use of substances at small scale in laboratories (less than or equal to 1 l or 1 kg present at workplace).

Name of contributing environmental scenario and corresponding ERCs:

ERC2 Formulation into mixture.

Further explanations:

PC28 Perfumes, fragrances.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance: Up to 100%.

Physical state: liquid.

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration: <=8 hours/day

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Process temperature: <= 40 °C

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation: Basic general ventilation (1-3 air changes per hour): 0%.

Local exhaust ventilation: Not required.

Occupational Health and Safety Management System: Advanced.

Conditions and measures related to personal protection, hygiene and health evaluation:

Respiratory protection:

- PROC1: Not required.
- PROC2, PROC3, PROC5, PROC8b, PROC9, PROC15: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).
- PROC8a: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%).

Dermal protection:

- PROC1, PROC2, PROC3, PROC15: No (Effectiveness Dermal: 0%).
- PROC9: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%).
- PROC5, PROC8a, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice.

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Maximum daily use at a site: 0,03 ton/day. Maximum annual use at a site: 10 tons/year.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default)

Other given operational conditions affecting environmental exposure:

Indoor use.

Release fraction to air from process (initial release): 0,025; (final release): 0,025. Local release rate: 0,75 kg/day.

Release fraction to wastewater from process (initial release): 0,02; (final release): 0,02. Local release rate: 0,6 kg/day.

Release fraction to soil from process: 0,0001.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: CHESAR v3.2-Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	1,372 mg/kg bw/day	0,549	PROC9
Worker, long-term, systemic, Inhalation	2,795 mg/m3	0,318	PROC5, PROC8a, PROC8b, PROC9, PROC15

Effect/Compartment	Exposure estimate/PEC	RCR	<u>Notes</u>	
Worker, long-term, systemic, Combined routes	N/A	0,867	PROC9	
Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,0038 mg/L	0,493		
Freshwater sediment	0,058 mg/kg dw	0,492		
Marine water	0,00038 mg/L	0,493		
Marine water sediment	0,0058 mg/kg dw	0,492		
Soil	0,013 mg/kg dw	0,668		
Human via environment, Inhalation	0,000191 mg/m3	<0,01		
Human via environment, Oral	0,00122 mg/kg bw/day	<0,01		-
Human via environment, Combined routes	N/A	<0,01		

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, without LEV. Duration: <=8 hours/day. Respiratory protection: PROC1: Not required. PROC2, PROC3, PROC5, PROC8b, PROC9, PROC15: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%). PROC8a: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%). Dermal protection: PROC1, PROC2, PROC3, PROC15: No (Effectiveness Dermal: 0%). PROC9: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%). PROC5, PROC8a, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). Concentration of substance: Up to 100%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (6): Formulation - Formulation of fragrance products

1. Exposure scenario (6)

Short title of the exposure scenario:

Formulation - Formulation of fragrance products

List of use descriptors:

Product category (PC): PC28

Process category (PROC): PROC2, PROC4, PROC5, PROC8b, PROC15

Environmental release category (ERC): ERC2

List of names of contributing worker scenarios and corresponding PROCs:

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions.

PROC4 Chemical production where opportunity for exposure arises.

PROC5 Mixing or blending in batch processes. Covers mixing or blending of solid or liquid materials in the context of manufacturing or formulating sectors, as well as upon end use.

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging. PROC15 Use as laboratory reagent. Use of substances at small scale in laboratories (less than or equal to 1 l or 1 kg present at workplace).

Further explanations:

PC28 Perfumes, fragrances.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance: Up to 100%.

Physical state: liquid.

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration: <=8 hours/day.

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Process temperature: <= 40 °C.

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation: Basic general ventilation (1-3 air changes per hour): 0%.

Local exhaust ventilation: Not required.

Occupational Health and Safety Management System: Advanced.

Conditions and measures related to personal protection, hygiene and health evaluation:

Respiratory protection: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).

Dermal protection:

- PROC2, PROC15: No (Effectiveness Dermal: 0%).
- PROC4: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%).
- PROC5, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice.

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Maximum daily use at a site: 0,92 ton/day. Maximum annual use at a site: 10 tons/year.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default)

Other given operational conditions affecting environmental exposure:

Indoor use.

Release fraction to air from process (initial release): 0,025; (final release): 0,025. Local release rate: 0,75 kg/day.

Release fraction to wastewater from process (initial release): 0,02; (final release): 0,02. Local release rate: 0,6 kg/day.

Release fraction to soil from process: 0,0001

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: CHESAR v3.2-Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	1,372 mg/kg bw/day	0,549	PROC4
Worker, long-term, systemic, Inhalation	2,795 mg/m3	0,318	PROC4, PROC5, PROC8b, PROC15
Worker, long-term, systemic, Combined routes	N/A	0,867	PROC4
Environment			
Effect/Compartment	Exposure estimate/PEC	RCR	<u>Notes</u>
Freshwater	0,0038 mg/L	0,493	
Freshwater sediment	0,058 mg/kg dw	0,492	
Marine water	0,00038 mg/L	0,493	
Marine water sediment	0,0058 mg/kg dw	0,492	
Soil	0,013 mg/kg dw	0,668	
Human via environment, Inhalation	0,000191 mg/m3	<0,01	
Human via environment, Oral	0,00122 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, without LEV. Duration: <=8 hours/day. Respiratory protection: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%). Dermal protection: PROC2, PROC15: No (Effectiveness Dermal: 0%). PROC4: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%). PROC5, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic

employee training) (Effectiveness Dermal: 90%). Concentration of substance: Up to 100%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (7): Formulation - Formulation of fragranced end-products

1. Exposure scenario (7)

Short title of the exposure scenario:

Formulation - Formulation of fragranced end-products

List of use descriptors:

Product category (PC): PC28

Process category (PROC): PROC1, PROC2, PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15

Environmental release category (ERC): ERC2

List of names of contributing worker scenarios and corresponding PROCs:

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions.

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition.

PROC5 Mixing or blending in batch processes. Covers mixing or blending of solid or liquid materials in the context of manufacturing or formulating sectors, as well as upon end use.

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities. Transfer includes loading, filling, dumping, bagging and weighing.

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging. PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing). Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage.

PROC14 Tabletting, compression, extrusion, pelletisation, granulation. This covers processing of mixtures and/or substances into a defined shape for further use.

PROC15 Use as laboratory reagent. Use of substances at small scale in laboratories (less than or equal to 1 l or 1 kg present at workplace).

Name of contributing environmental scenario and corresponding ERCs:

ERC2 Formulation into mixture

Further explanations:

PC28 Perfumes, fragrances

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance: Up to 100%.

Physical state: liquid.

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration: <=8 hours/day.

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Process temperature: <= 40 °C.

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation: Basic general ventilation (1-3 air changes per hour): 0%.

Local exhaust ventilation: Not required.

Occupational Health and Safety Management System: Advanced.

Conditions and measures related to personal protection, hygiene and health evaluation:

Respiratory protection:

- PROC1: Not required.
- PROC2, PROC3, PROC5, PROC8b, PROC9, PROC14, PROC15: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).
- PROC8a: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%).

Dermal protection:

- PROC1, PROC2, PROC3, PROC15: No (Effectiveness Dermal: 0%).
- PROC9, PROC14: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%).
- PROC5, PROC8a, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice.

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Maximum daily use at a site: 0,03 ton/day. Maximum annual use at a site: 10 tons/year.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default)

Other given operational conditions affecting environmental exposure:

Indoor use

Release fraction to air from process (initial release): 0,025; (final release): 0,025. Local release rate: 0,75 kg/day.

Release fraction to wastewater from process (initial release): 0,02; (final release): 0,02. Local release rate: 0,6 kg/day.

Release fraction to soil from process: 0,0001

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town)

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: CHESAR v3.2-Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	1,372 mg/kg bw/day	0,549	PROC9
Worker, long-term, systemic, Inhalation	2,795 mg/m3	0,318	PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15
Worker, long-term, systemic, Combined routes	N/A	0,867	PROC9
Environment			
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Freshwater	0,0038 mg/L	0,493	
Freshwater sediment	0,058 mg/kg dw	0,492	
Marine water	0,00038 mg/L	0,493	
Marine water sediment	0,0058 mg/kg dw	0,492	
Soil	0,013 mg/kg dw	0,668	
Human via environment, Inhalation	0,000191 mg/m3	<0,01	
Human via environment, Oral	0,00122 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, without LEV. Duration: <=8 hours/day. Respiratory protection: PROC1: Not required. PROC2, PROC3, PROC5, PROC8b, PROC9, PROC14, PROC15: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 95%). PROC9, PROC1, PROC2, PROC3, PROC15: No (Effectiveness Dermal: 0%). PROC9, PROC14: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%). PROC5, PROC8a, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). Concentration of substance: Up to 100%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (8): Use by professional workers - Professional use of polishes and wax blends

1. Exposure scenario (8)

Short title of the exposure scenario:

Use by professional workers - Professional use of polishes and wax blends

List of use descriptors:

Product category (PC): PC31

Process category (PROC): PROC2, PROC8a, PROC9, PROC10.

Environmental release category (ERC): ERC8a

List of names of contributing worker scenarios and corresponding PROCs:

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions.

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities. Transfer includes loading, filling, dumping, bagging and weighing.

PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing). Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage.

PROC10 Roller application or brushing. This includes application of paints, coatings, removers, adhesives or cleaning agents to surfaces with potential exposure arising from splashes.

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)

Further explanations:

PC31 Polishes and wax blends.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance:

- PROC2, PROC8a, PROC9: Up to 100%.

- PROC10: <=10%. Physical state: liquid.

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration: <=8 hours/day

Other given operational conditions affecting workers exposure:

Location: Indoor use. Domain: Professional use. Process temperature: <= 40 °C

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation: Basic general ventilation (1-3 air changes per hour): 0%.

Local exhaust ventilation:

- PROC2, PROC9: Not required.
- PROC8a, PROC10: Yes (80% effectiveness).

Occupational Health and Safety Management System: Basic.

Conditions and measures related to personal protection, hygiene and health evaluation:

Respiratory protection:

- PROC2: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).
- PROC8a, PROC9, PROC10: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%).

Dermal protection:

- PROC2: No (Effectiveness Dermal: 0%).
- PROC8a, PROC9, PROC10: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice.

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Daily wide dispersive use: 0.0000027 tons/day. Amounts used in the EU: 5 tons/year.

Frequency and duration of use:

Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Professional use.

Indoor use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,00275 kg/day.

Release fraction to soil from process: 0,0.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town)

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: CHESAR v3.2-Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Worker, long-term, systemic, Dermal	1,646 mg/kg bw/day	0,658	PROC10	
Worker, long-term, systemic, Inhalation	2,795 mg/m3	0,318	PROC2, PROC9	
Worker, long-term, systemic, Combined routes	N/A	0,866	PROC2	
Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,0000555 mg/L	<0,01		
Freshwater sediment	0,000849 mg/kg dw	<0,01		
Marine water	0,0000053 mg/L	<0,01		
Marine water sediment	0,000081 mg/kg dw	<0,01		
Soil	0,000155 mg/kg dw	<0,01		
Human via environment, Inhalation	0,00000019 mg/m3	<0,01		
Human via environment, Oral	0,00000395 mg/kg bw/day	<0,01		•
Human via environment, Combined routes	N/A	<0,01		

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, PROC8a, PROC10: LEV used. Duration: <=8 hours/day. Respiratory protection: PROC2: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%). PROC8a, PROC9, PROC10: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%). Dermal protection: PROC2: No (Effectiveness Dermal: 0%). PROC8a, PROC9, PROC10: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). Concentration of substance: PROC2, PROC8a, PROC9: Up to 100%. PROC10: <=10%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (9): Use by professional workers - Professional end-use of washing and cleaning products 1. Exposure scenario (9)

Short title of the exposure scenario:

Use by professional workers - Professional end-use of washing and cleaning products

List of use descriptors:

Product category (PC): PC35

Process category (PROC): PROC2, PROC4, PROC5, PROC8a, PROC8b, PROC13

Environmental release category (ERC): ERC8a, ERC8d

List of names of contributing worker scenarios and corresponding PROCs:

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions.

PROC4 Chemical production where opportunity for exposure arises.

PROC5 Mixing or blending in batch processes. Covers mixing or blending of solid or liquid materials in the context of manufacturing or formulating sectors, as well as upon end use.

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities. Transfer includes loading, filling, dumping,

bagging and weighing.

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging. PROC13 Treatment of articles by dipping and pouring.

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

ERC8d Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor)

Further explanations:

PC35 Washing and cleaning products.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance: Up to 100%.

Physical state: liquid.

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration: <=8 hours/day

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Domain: Professional use.

Process temperature: <= 40 °C

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation: Basic general ventilation (1-3 air changes per hour): 0%.

Local exhaust ventilation: Not required.

Occupational Health and Safety Management System: Basic

Conditions and measures related to personal protection, hygiene and health evaluation:

Respiratory protection:

- PROC2, PROC4, PROC5, PROC8b: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).
- PROC8a, PROC13: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%).

Dermal protection:

- PROC2: No (Effectiveness Dermal: 0%).
- PROC4: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%)
- PROC5, PROC8a, PROC8b, PROC13: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Daily wide dispersive use: 0.0000027 tons/day.

Amounts used in the EU: 5 tons/year.

Frequency and duration of use:

Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Professional use.

Indoor/Outdoor use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,00275 kg/day.

Release fraction to soil from process:

- ERC8a: 0,00.
- ERC8d: 0,20

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: CHESAR v3.2-Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	1,372 mg/kg bw/day	0,549	PROC4
Worker, long-term, systemic, Inhalation	2,795 mg/m3	0,318	PROC4, PROC5, PROC8a, PROC8b, PROC13
Worker, long-term, systemic, Combined routes	N/A	0,867	PROC4
Environment			
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Freshwater	0,0000555 mg/L	<0,01	
Freshwater sediment	0,000849 mg/kg dw	<0,01	
Marine water	0,0000053 mg/L	<0,01	
Marine water sediment	0,000081 mg/kg dw	<0,01	
Soil	0,000155 mg/kg dw	<0,01	
Human via environment, Inhalation	0,00000019 mg/m3	<0,01	
Human via environment, Oral	0,00000395 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, without LEV. Duration: <=8 hours/day. Respiratory protection: PROC2, PROC4, PROC5, PROC8b: Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%). PROC8a, PROC13: Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%). Dermal protection: PROC2: No (Effectiveness Dermal: 0%). PROC4: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%). PROC5, PROC8a, PROC8b, PROC13: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). Concentration of substance: Up to 100%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (10): Consumer use - Consumer end-use of biocides

1. Exposure scenario (10)

Short title of the exposure scenario:

Consumer use - Consumer end-use of biocides

List of use descriptors:

Product category (PC): PC8

Environmental release category (ERC): ERC8a, ERC8d

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

ERC8d Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor)

Further explanations:

PC8 Biocidal products.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in product: Up to 0,01%.

Physical state: liquid.

Oral contact foreseen: No.

Spray: No.

Amounts used:

Applied amounts for each use event: 50 g.

Frequency and duration of use/exposure:

Duration covers exposure up to: 8 hours/event. Frequency - covers use frequency: up to 1 time/day.

Human factors not influenced by risk management:

Body parts potentially exposed: Whole body.

Inhalation factor = 1. Dermal transfer factor = 1.

Other given operational conditions affecting consumers exposure:

Location: Indoor use.

Body weight: 60 kg.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Daily wide dispersive use: 0.0000027 tons/day.

Amounts used in the EU: 5 tons/year. Frequency and duration of use:

Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor/Outdoor use.

Consumer use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,00275 kg/day.

Release fraction to soil from process:

- ERC8a: 0,00.

- ERC8d: 0,20

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: TRA Consumer v3.1 (R15).

Assessment method-Environment: EUSES 2.1.2.

Health

Human via environment, Inhalation

Human via environment, Oral

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Consumer, long-term, systemic, Dermal	0,292 mg/kg bw/day	0,327		
Consumer, long-term, systemic, Inhalation	0,000431 mg/m3	<0,01		
Consumer, long-term, systemic, Oral	0 mg/kg bw/day	<0,01		
Consumer, long-term, systemic, Combined routes	N/A	0,327		
Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Effect/Compartment Freshwater	Exposure estimate/PEC 0,0000555 mg/L	RCR <0,01	<u>Notes</u>	
-	· · · · ·		<u>Notes</u>	
Freshwater	0,0000555 mg/L	<0,01	<u>Notes</u>	
Freshwater Freshwater sediment	0,0000555 mg/L 0,000849 mg/kg dw	<0,01 <0,01	<u>Notes</u>	

< 0.01

<0,01

Human via environment, Combined routes <0,01 N/A RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

0,00000019 mg/m3

0,00000395 mg/kg bw/day

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite

technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (11): Consumer use - Consumer end-use of cosmetics

1. Exposure scenario (11)

Short title of the exposure scenario:

Consumer use - Consumer end-use of cosmetics

List of use descriptors:

Product category (PC): PC39

Environmental release category (ERC): ERC8a

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

Further explanations:

PC39 Cosmetics, personal care products.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in product: Up to 0,01%.

Physical state: liquid.

Oral contact foreseen: Yes.

Spray: No.

Amounts used:

Applied amounts for each use event: 50 g.

Frequency and duration of use/exposure:

Duration covers exposure up to: 8 hours/event.

Frequency - covers use frequency: up to 1 time/day.

Human factors not influenced by risk management:

Body parts potentially exposed: Whole body.

Inhalation factor = 1.

Dermal transfer factor = 1.

Oral transfer factor = 1.

Volume of product swallowed: <= 10.0 cm3.

Other given operational conditions affecting consumers exposure:

Location: Indoor use.

Body weight: 60 kg.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Daily wide dispersive use: 0.0000027 tons/day.

Amounts used in the EU: 5 tons/year.

Frequency and duration of use:

Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.

Consumer use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,00275 kg/day.

Release fraction to soil from process: 0,0.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: TRA Consumer v3.1 (R15).

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment Exposure estimate/PEC RCR Notes

Effect/Compartment	Exposure estimate/PEC	RCR	<u>Notes</u>	
Consumer, long-term, systemic, Dermal	0,292 mg/kg bw/day	0,327		
Consumer, long-term, systemic, Inhalation	0,000431 mg/m3	<0,01		
Consumer, long-term, systemic, Oral	0,017 mg/kg bw/day	0,019		
Consumer, long-term, systemic, Combined routes	N/A	0,346		
Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,0000555 mg/L	<0,01		
Freshwater sediment	0,000849 mg/kg dw	<0,01		
Marine water	0,0000053 mg/L	<0,01		
Marine water sediment	0,000081 mg/kg dw	<0,01		
Soil	0,000155 mg/kg dw	<0,01		
Human via environment, Inhalation	0,00000019 mg/m3	<0,01		
Human via environment, Oral	0,00000395 mg/kg bw/day	<0,01		
Human via environment, Combined routes	N/A	<0,01		

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (12): Consumer use - Consumer end-use of washing and cleaning products

1. Exposure scenario (12)

Short title of the exposure scenario:

Consumer use - Consumer end-use of washing and cleaning products

List of use descriptors:

Product category (PC): PC35

Environmental release category (ERC): ERC8d

Name of contributing environmental scenario and corresponding ERCs:

ERC8d Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor).

Further explanations:

PC35 Washing and cleaning products.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in product: Up to 0,01%.

Physical state: liquid.

Oral contact foreseen: No.

Spray: No.

Amounts used:

Applied amounts for each use event: 50 g.

Frequency and duration of use/exposure:

Duration covers exposure up to: 8 hours/event.

Frequency - covers use frequency: up to 1 time/day.

Human factors not influenced by risk management:

Body parts potentially exposed: Whole body.

Inhalation factor = 1.

Dermal transfer factor = 1

Other given operational conditions affecting consumers exposure:

Location: Indoor use.

Body weight: 60 kg.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Daily wide dispersive use: 0.0000027 tons/day.

Amounts used in the EU: 5 tons/year.

Frequency and duration of use:

Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18000 m3/day (default)

Other given operational conditions affecting environmental exposure:

Outdoor use.

Consumer use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

Release fraction to wastewater from process (initial release): 1.00: (final release): 1.00. Local release rate: 0.00275 kg/day.

Release fraction to soil from process: 0,20.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town)

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: TRA Consumer v3.1 (R15).

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Consumer, long-term, systemic, Dermal	0,292 mg/kg bw/day	0,327		
Consumer, long-term, systemic, Inhalation	0,000431 mg/m3	<0,01		
Consumer, long-term, systemic, Oral	0 mg/kg bw/day	<0,01		
Consumer, long-term, systemic, Combined routes	N/A	0,327		
Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,0000555 mg/L	<0,01		
Freshwater sediment	0,000849 mg/kg dw	<0,01		
Marine water	0,0000053 mg/L	<0,01		
Marine water sediment	0,000081 mg/kg dw	<0,01		
Soil	0,000155 mg/kg dw	<0,01		
Human via environment, Inhalation	0,00000019 mg/m3	<0,01		
Human via environment, Oral	0,00000395 mg/kg bw/day	<0,01		
Human via environment, Combined routes	N/A	<0,01	-	-

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (13): Consumer use - Consumer end-use of fragrances

1. Exposure scenario (13)

Short title of the exposure scenario:

Consumer use - Consumer end-use of fragrances

List of use descriptors:

Product category (PC): PC28

Environmental release category (ERC): ERC8a

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

Further explanations:

PC28 Perfumes, fragrances.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance document/ information requirements r12 en.pdf)

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in product: Up to 0,01%.

Physical state: liquid. Oral contact foreseen: No.

Spray: Yes.

Amounts used:

Applied amounts for each use event: 50 g.

Frequency and duration of use/exposure:

Duration covers exposure up to: 8 hours/event.

Frequency - covers use frequency: up to 1 time/day.

Human factors not influenced by risk management:

Body parts potentially exposed: Whole body.

Inhalation factor = 1.

Dermal transfer factor = 1.

Other given operational conditions affecting consumers exposure:

Location: Indoor use. Body weight: 60 kg.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Daily wide dispersive use: 0.0000027 tons/day.

Amounts used in the EU: 5 tons/year.

Frequency and duration of use:

Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.

Consumer use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,00275 kg/day.

Release fraction to soil from process: 0,0.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: TRA Consumer v3.1 (R15).

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Consumer, long-term, systemic, Dermal	0,292 mg/kg bw/day	0,327	
Consumer, long-term, systemic, Inhalation	0,043 mg/m3	0,033	
Consumer, long-term, systemic, Oral	0 mg/kg bw/day	<0,01	
Consumer, long-term, systemic, Combined routes	N/A	0,36	

Environment

environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,0000555 mg/L	<0,01		
Freshwater sediment	0,000849 mg/kg dw	<0,01		
Marine water	0,0000053 mg/L	<0,01		
Marine water sediment	0,000081 mg/kg dw	<0,01		
Soil	0,000155 mg/kg dw	<0,01		
Human via environment, Inhalation	0,00000019 mg/m3	<0,01		
Human via environment, Oral	0,00000395 mg/kg bw/day	<0,01		
Human via environment, Combined routes	N/A	<0,01		

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (14): Consumer use - Consumer end-use of air care products

1. Exposure scenario (14)

Short title of the exposure scenario:

Consumer use - Consumer end-use of air care products

List of use descriptors:

Product category (PC): PC3

Environmental release category (ERC): ERC8a

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

Further explanations:

PC3 Air care products.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information requirements r12 en.pdf).

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in product: Up to 0,01%.

Physical state: liquid. Oral contact foreseen: No.

Spray: Yes.

Amounts used:

Applied amounts for each use event: 50 g.

Frequency and duration of use/exposure:

Duration covers exposure up to: 8 hours/event.

Frequency - covers use frequency: up to 1 time/day

Human factors not influenced by risk management:

Body parts potentially exposed: Whole body.

Inhalation factor = 1.

Dermal transfer factor = 1

Other given operational conditions affecting consumers exposure:

Location: Indoor use. Body weight: 60 kg.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Daily wide dispersive use: 0.0000027 tons/day.

Amounts used in the EU: 5 tons/year.

Frequency and duration of use:

Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.

Consumer use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,00275 kg/day.

Release fraction to soil from process: 0,0.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: TRA Consumer v3.1 (R15).

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	<u>Notes</u>
Consumer, long-term, systemic, Dermal	0,292 mg/kg bw/day	0,327	
Consumer, long-term, systemic, Inhalation	0,043 mg/m3	0,033	
Consumer, long-term, systemic, Oral	0 mg/kg bw/day	<0,01	
Consumer long-term systemic Combined routes	N/A	0.36	

Environment

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,000055 mg/L	<0,01		
Freshwater sediment	0,000849 mg/kg dw	<0,01		
Marine water	0,0000053 mg/L	<0,01		
Marine water sediment	0,000081 mg/kg dw	<0,01		
Soil	0,000155 mg/kg dw	<0,01		
Human via environment, Inhalation	0,00000019 mg/m3	<0,01		
Human via environment, Oral	0,00000395 mg/kg bw/day	<0,01		
Human via environment, Combined routes	N/A	<0,01		

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

4. Guidance to the Downstream User to evaluate whether he works inside the boundaries set by the ES

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (15): Consumer use - Consumer end-use of polishes and wax blends

1. Exposure scenario (15)

Short title of the exposure scenario:

Consumer use - Consumer end-use of polishes and wax blends

List of use descriptors:

Product category (PC): PC31

Environmental release category (ERC): ERC8a

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

Further explanations:

PC31 Polishes and wax blends.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in product: Up to 0,01%.

Physical state: liquid. Oral contact foreseen: No.

Spray: No.

Amounts used:

Applied amounts for each use event: 50 g.

Frequency and duration of use/exposure:

Duration covers exposure up to: 8 hours/event.

Frequency - covers use frequency: up to 1 time/day.

Human factors not influenced by risk management:

Body parts potentially exposed: Whole body.

Inhalation factor = 1.

Dermal transfer factor = 1.

Other given operational conditions affecting consumers exposure:

Location: Indoor use. Body weight: 60 kg.

2.2 Control of environmental exposure

General

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Vapour pressure: 0.358 Pa at 25 °C

Amounts used:

Daily wide dispersive use: 0.0000027 tons/day.

Amounts used in the EU: 5 tons/year.

Frequency and duration of use:

Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use

Consumer use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,00275 kg/day.

Release fraction to soil from process: 0,0.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=87,47%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

External treatment and disposal of waste should comply with applicable local and/or national regulations.

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply:

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: TRA Consumer v3.1 (R15).

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Consumer, long-term, systemic, Dermal	0,292 mg/kg bw/day	0,327		
Consumer, long-term, systemic, Inhalation	0,000431 mg/m3	<0,01		
Consumer, long-term, systemic, Oral	0 mg/kg bw/day	<0,01		
Consumer, long-term, systemic, Combined routes	N/A	0,327		
Environment				

Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,0000555 mg/L	<0,01		
Freshwater sediment	0,000849 mg/kg dw	<0,01		
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Health

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Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.