Safety Data Sheet

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



Revision date: 1/20/2022 Supercedes date: 2/9/2021

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

1.1. Product identifier:

Product trade name: Kalama* Osyrol*

Company product number: OSYROL

REACH registration number: 01-2120763501-60-0002

Substance name: Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-

methoxy-3,7-dimethyl-2-octanol

Substance identification number: EC 947-215-4

Other means of identification: 32178; Methoxyelgenol; Methoxytrimethyl heptanol

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

Uses: Fragrance ingredient. Industrial applications. Intermediate. 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 Limited

Dans Road

Widnes, Cheshire WA8 0RF

United Kingdom

Telephone: +44 (0) 151 423 8000

EU Only Representative: Penman Consulting byba

Avenue des Arts 10 B-1210 Brussels

Belgium

Telephone: +32 (0) 2 403 7239

email: pcbvba10@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 Eye Irritation, category 2, H319

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.

H319 Causes serious eye irritation.

Precautionary statements:

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/eye protection/face protection.

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

easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention. 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% Classification **H Statements** See Notes Reaction mass of (R*,R*)-7-Eye Irrit. 2- Skin Irrit. 2 H315-319 100 methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2octanol

CAS-No. Chemical Name REACH Registration No. **EC/List Number** See Notes Reaction mass of (R*,R*)-7-01-2120763501-60-0002 947-215-4

methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2octanol

ATE CAS-No. **Chemical Name** M-factor **SCLs**

Reaction mass of (R*,R*)-7-Not Available See Notes N/A N/E

methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2-

octanol

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

Notes: OSYROL: Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol (CAS# 87605-57-0) and (R*,S*)-7-methoxy-3,7dimethyl-2-octanol (CAS# 87605-61-6); Alternative CAS# 41890-92-0.

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: Immediately flush eyes with plenty of clean water for an extended time, not less than fifteen (15) minutes. Flush longer if there is any indication of residual chemical in the eye. Ensure adequate flushing of the eyes by separating the eyelids with fingers and roll eyes in a circular motion. If eye irritation persists: Get medical advice/attention.

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: Use water spray, ABC dry chemical, foam or carbon dioxide. Water or foam may cause frothing. Use water to keep fire-exposed containers cool. Water spray may be used to flush spills away from exposures.

Unsuitable: Do not use direct water stream. May spread fire.

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. Closed container may rupture (due to build up in pressure) when exposed to extreme heat.

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. Eliminate ignition sources. Personal Protective Equipment must be worn.

6.2. Environmental precautions:

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

6.3. Methods and material for containment and cleaning up:

Contain by diking with sand, earth or other non-combustible material. Wear proper personal protective clothing and equipment. Absorb spill with an inert material. 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. Do not cut, puncture, or weld on or near the container. 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 inhalation of aerosol, mist, spray, fume or vapor. 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. Do not reuse empty container without commercial cleaning or reconditioning. Shelf life: 24 months. Empty container contains residual product which may exhibit hazards of product.

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):

Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2-octanol

EU OELV

EU IOELV

ACGIH - TWA/Ceiling

ACGIH - STEL

 Chemical Name
 UK WEL
 Ireland OEL

 Reaction mass of (R*.R*)-7-methoxy-3.7-dimethyl-2 N/E
 N/E

octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2-octanol

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

Derived No Effect Levels (DNELs):

Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2-octanol

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Population	Route	Acute (local)	Acute (systemic)	Long Term (local)	Long Term (systemic)
Workers	Inhalation	N/E	N/E	N/E	8,03 mg/m3
Workers	Dermal	N/E	N/E	N/E	2,28 mg/kg bw/day
General population	Inhalation	N/E	N/E	N/E	1,2 mg/m3; 7,2 mg/m3
					(infrequent uses)
General population	Dermal	N/E	N/E	N/E	0,813 mg/kg bw/day;
					4,878 mg/kg bw/day
					(infrequent uses)
General population	Oral	N/E	N/E	N/E	0,813 mg/kg bw/day;
					4,878 mg/kg bw/day
					(infrequent uses)
Human via the environment	Inhalation	N/E	N/E	N/E	1,2 mg/m3
Human via the environment	Oral	N/E	N/E	N/E	0,813 mg/kg bw/day

Predicted No Effect Concentration (PNECs):

Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2-octanol

 Compartment
 PNÉC

 Freshwater
 0,181 mg/L

 Freshwater sediment
 3,62 mg/kg dw

 Marine water
 0,0181 mg/L

 Marine water sediment
 0,362 mg/kg dw

 Soil
 0,062 mg/kg dw

 STP
 10 mg/L

Oral No potential for bioaccumulation

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

The following DNELs have been derived for the assessment of "infrequent uses" which is considered to be 15 days per year or less:

- DNEL inhalation for infrequent use = 7,2 mg/m3.
- DNEL dermal for infrequent use = 4,878 mg/kg bw/day.
- DNEL oral for infrequent use = 4,878 mg/kg bw/day.

8.2. Exposure controls:

Appropriate engineering controls: Always provide effective general and, when necessary, local exhaust ventilation to draw spray, aerosol, fume, mist and vapor 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: Safety glasses or goggles required.

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). 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: Respiratory protection is not needed with proper ventilation. In case of insufficient ventilation, wear suitable respiratory equipment.

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: Liquid

Colour: Clear, Colorless
Odour: Characteristic
Odour threshold: Not Available
Melting point/Freezing point: <-20°C (<-4°F)
Poiling point °C: 246°C

Boiling point °C: 246 °C Boiling point °F: 475 °F

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

UEL: Not Available

2.3 @ 35°C (OECD 117)

Flash point: >110 °C (>230 °F) Closed Cup

Auto-ignition temperature:282 °C (540 °F)Decomposition temperature:Not AvailablepH:Not AvailableKinematic viscosity:Not AvailableSolubility in water:12.04 g/L @ 20°C

Partition coefficient n-octanol/water (log

value):

Vapour pressure: 604 Pa @ 20°C; 631 Pa @ 25°C

Density and/or relative density:0.899-0.902Relative vapour density:Not AvailableParticle characteristics:Not Applicable% Volatile by weight:Not AvailableVOC:Not Available

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: Not Available

SECTION 10: Stability and reactivity

10.1. Reactivity:

None known.

10.2. Chemical stability:

This product is stable.

10.3. Possibility of hazardous reactions:

Hazardous polymerization will not occur.

10.4. Conditions to avoid:

Excessive heat and ignition sources.

10.5. Incompatible materials:

Avoid contact with strong oxidizing agents.

10.6. Hazardous decomposition products:

methoxy-3,7-dimethyl-2-octanol

methoxy-3,7-dimethyl-2-octanol

Carbon dioxide, carbon monoxide and hydrocarbons.

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).

Chemical NameInhalation LC50SpeciesOral LD50SpeciesDermal LD50SpeciesReaction mass of (R*,R*)-7-methoxy-3,7-N/EN/E>2000 mg/kgRat/ adult>2000 mg/kgRat/ adultdimethyl-2-octanol and (R*,S*)-7-female

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

 Chemical Name
 Skin irritation
 Species

 Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7 Irritant (OECD 439)
 In-Vitro

Serious eye damage/irritation: Causes serious eye irritation - Category 2.

Chemical Name Eye irritation Species

 $\label{eq:chemical Name} {\begin{tabular}{ll} \textbf{Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-} \end{tabular}$

methoxy-3,7-dimethyl-2-octanol

Eye irritation Irritant (OECD 438 & 492) Species In-Vitro

Respiratory or skin sensitization: Not classified (based on available data, the classification criteria are not met).

Chemical Name

Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2-octanol

Skin sensitisation Non-sensitizer Species

Mouse/Local lymph node assay

Carcinogenicity: Not classified (no relevant information found).

Germ cell mutagenicity: Not classified (based on available data, the classification criteria are not met). Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol: In vitro testing showed no mutagenic activity.

Reproductive toxicity: Not classified (based on available data, the classification criteria are not met). Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2-octanol: Reproductive toxicity, oral study in rats: NOAEL (no-observed adverse-effect-level) 488 mg/kg bw/day (OECD 422).

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). Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2-octanol: Repeated dose study, oral, rats (OECD 422): NOAEL (no-observed-adverse-effect-level)=488 mg/kg/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: Causes serious eye irritation.

Skin: Causes skin irritation.

Inhalation: High airborne concentrations of vapors resulting from heating, misting or spraying may cause irritation of the respiratory tract and mucous membranes.

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
Reaction mass of (R*,R*)-7- methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2- octanol	Fish	LC50 208 mg/L (96 hours) (calculated)	N/E	N/E
Reaction mass of (R*,R*)-7- methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2- octanol	Invertebrates	EC50 >100 mg/L (48 hours) (OECD 202)	N/E	N/E
Reaction mass of (R*,R*)-7- methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2- octanol	Algae	EC50 181 mg/L (72 hours) (calculated)	N/E	N/E
Reaction mass of (R*,R*)-7- methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2- octanol	Micro-organisms	EC50 >1000 mg/L (3 hours)		

12.2. Persistence and degradability:

Chemical Name

Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2-octanol

Biodegradation

Not readily biodegradable (OECD 301D); Inherently biodegradable (OECD 301F)

12.3. Bioaccumulative potential:

<u>Chemical Name</u> Reaction mass of (R*,R*)-7-methoxy-3,7dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7dimethyl-2-octanol Bioconcentration Factor (BCF)
N/E

Log Kow

2.3 @ 35°C (OECD 117)

12.4. Mobility in soil:

No specific information available.

<u>Chemical Name</u> Reaction mass of (R*,R*)-7-methoxy-3,7dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7dimethyl-2-octanol Mobility in soil (Koc/Kow)

N/E

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) 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:

Regulation	<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
Philippines Inventory of Chemicals and Chemical Substances (PICCS):	Υ
Taiwan Inventory of Existing Chemicals:	Υ
U.S. Toxic Substances Control Act (TSCA) (Active):	Υ

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.

Chemical inventory notes: OSYROL: Alternative CAS# 41890-92-0.

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):

H315 Causes skin irritation.
H319 Causes serious eye irritation.

Reason for revision: Changes in Section(s): 1

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 Emerald Kalama Chemical, LLC 1499 SE Tech Center Place, Suite 300 Vancouver, WA 98683

United States

Annex

Exposure Scenarios

Substance information:

Name of substance: Reaction mass of (R*,R*)-7-methoxy-3,7-dimethyl-2-octanol and (R*,S*)-7-methoxy-3,7-dimethyl-2-octanol.

EC# 947-215-4

REACH Registration number: 01-2120763501-60-0002

List of exposure scenarios:

ES1: Use as an intermediate

ES2: Formulation - GES1 Formulation of fragrance compounds

ES3: Formulation - GES2 Formulation of fragranced end-products

ES4: Use at industrial sites - GES3 Industrial end-use of washing and cleaning products

ES5: Use by professional workers - GES4 Professional end use of washing and cleaning products

ES6: Use by professional workers - GES5 Professional end-use of polishes and wax blends

ES7: Consumer use - GES6 Consumer end-use of washing and cleaning products

ES8: Consumer use - GES7 Consumer end-use of air care products

ES9: Consumer use - GES8 Consumer end-use of biocides

ES10: Consumer use - GES9 Consumer end-use of polishes and wax blends

ES11: Consumer use - GES10 Consumer end-use of cosmetics

General remarks:

Exposure scenarios are based on the following: Generic Exposure Scenarios (GES) and specific Exposure Scenarios (SpERCs) from the Industry Guidance Document REACH Exposure Scenarios for Fragrance Substances (version 2.1, 11 December 2012) developed by the International Fragrance Association (IFRA). AISE has developed Specific Consumers Exposure Determinants (SCEDs) to facilitate consumer exposure assessments for a range of consumer products including cleaning and air care products, in line with guidance developed by the DUCC/CONCAWE task force under the CSR/ES Roadmap (2015).

The first tier environmental exposure assessments have at first instance been performed using EUSES v2.1.2 which is part of Chemical Safety Assessment and Reporting tool version 3.3 (CHESAR v3.3). Higher tier assessments have been performed if safe use was not demonstrated using first tier assessments. In these cases Specific Environmental Release Categories (SpERCs) have been used.

The worker dermal and inhalation exposure assessments for industrial and professional uses have been performed using ECETOC TRA Worker v3 model integrated in the Chemical Safety Assessment and Reporting tool (CHESAR v3.3) or the Advanced REACH tool (ART v1.5) (inhalation exposures). The RiskofDerm Tier 2 model was used to refine dermal exposure estimates, if necessary.

Consumer exposure assessments have been performed using ECETOC TRA v3.1 (R15) model (consumer module) in which:

- Fragrance concentration in fragranced end-product from the IFRA guidance (2012) is used at Tier 1.5 level consumer risk assessment;
- If necessary, further parameters are refined (Refined Tier 1.5) using the table of habits and practices for consumer products in western Europe from AISE (2009);
- If Tier 2 refinement is necessary, ConsExpo v5.0 b01 according to the product sub category specific fact sheet or ECETOC TRA v3.1 with Specific Consumer Exposure Determinants (SCED) (e.g. AISE REACT 1.0 Consumer tool) is used.
- DNELs have been derived for assessment of "infrequent" uses which are considered to be 15 days per year of less.

This substance is categorized in the "low hazard" band according to ECHA Chemical Safety Assessment Guidance Part E Table E.3-1). The following operational conditions (OC) and risk management measures (RMM) are recommended for substances considered to be "low hazard":

- Minimisation of manual phases/work tasks;
- Work procedures minimising splashes and spills;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;
- Management/supervision in place to check that the RMMs in place are being used correctly and OCs are followed;
- Training for staff on good practice
- Good standard of personal hygiene
- The following personal protective equipment is recommended: chemical goggles, face shield, substance/task appropriate gloves and full skin coverage with appropriate light-weight barrier materials.

Exposure scenario (1): Use as an intermediate

1. Exposure scenario (1)

Short title of the exposure scenario:

Use as an intermediate

List of use descriptors:

Sector of use category (SU): SU8, SU9

Process category (PROC): PROC1, PROC2, PROC3, PROC4, 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.

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.

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 laboratory (< 1 l or 1 kg present at workplace).

Name of contributing environmental scenario and corresponding ERCs:

ERC6a Use of intermediate.

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). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see http://www.cefic.org/Industry-support/Implementing-reach/Libraries/

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:

- PROC1, PROC2, PROC15: <=100%
- PROC8b: <=25%
- PROC3, PROC4: <=1%

Physical state: liquid.

Vapour pressure: 631 Pa at 25 °C; 1660 Pa @ 40°C; 1680 Pa @ 80°C; 16400 Pa @ 150°C.

Amounts used:

Application rate (for inhalation exposure): Unless otherwise stated, not specified.

- PROC2: <100 L/minute.
- PROC8b: 1-10 L/minute

Frequency and duration of use/exposure:

Duration of activity:

- PROC1, PROC2, PROC4: <=1 hour/day.
- PROC3, PROC8b, PROC15: <=15 minutes/day.

Human factors not influenced by risk management:

Exposed skin surface:

- PROC1, PROC3, PROC15: 240 cm2 (one hand, face side only).
- PROC2. PROC4: 480 cm2 (two hands, face side only).
- PROC8b: 960 cm2 (two hands)

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Domain: Industrial use.

Process temperature: - PROC1: <= 150 °C.

- PROC2: <= 80°C.
- PROC3, PROC4, PROC15: <= 40°C.
- PROC8b: <= 90°C.

Assessment tool used:

- PROC1, PROC3, PROC4: ECETOC TRA Worker v3 for inhalation and dermal exposure.
- PROC2, PROC8b, PROC15: ECETOC TRA Worker v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure.

Technical conditions and measures at process level (source) to prevent release:

Activity class - subclass (ART v1.5):

- PROC2: Activities with open liquid surfaces and open reservoirs activities with agitated surfaces. Activities with agitated surfaces; open surface <0.1 m2. Containment: Low level containment (90% reduction).
- PROC8b: Transfer of liquid products falling liquids; splash loading. Containment: handling that reduces contact between product and adjacent air.
- PROC15: Handling of contaminated objects: Level of contamination: 10-90% of surface; Activities with treated/contaminated objects (surface <0.1 m2)

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

General ventilation:

- PROC1, PROC2, PROC3, PROC4, PROC8b: Basic general ventilation (1-3 air changes per hour): 0%.
- PROC15: Good general ventilation (3-5 air changes per hour): 30%.

Containment:

- PROC1: Closed system (minimal contact during routine operations).
- PROC2: Closed continuous process with occasional controlled exposure.
- PROC3: Closed batch process with occasional controlled exposure.
- PROC4, PROC8b: Semi-closed process with occasional controlled exposure.
- PROC15: No.

Local exhaust ventilation: Not required.

Local exhaust ventilation (for dermal): Not required.

Occupational Health and Safety Management System: Advanced

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

Respiratory protection: Not required.

Eye protection: Yes (chemical resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact). Dermal protection:

- PROC1, PROC2, PROC3, PROC4, PROC15: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (minimum efficiency dermal: 90%).
- PROC8b: Yes (chemically resistant gloves conforming to EN374 with specific activity training) (minimum efficiency 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.

For tasks where potential splashes may arise, the following personal protective equipment is recommended: face shield, substance/task appropriate gloves and full skin coverage with appropriate light-weight barrier materials (e.g. coveralls).

2.2 Control of environmental exposure

General:

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

On-site wastewater treatment required.

Product characteristics:

Physical state: liquid.

Amounts used:

Maximum daily use at a site: 1.3 ton/day. Maximum annual use at a site: 26 tons/year.

Percentage of tonnage used at regional scale: 100 %.

Frequency and duration of use:

Emission days: 365 days/year (main site); 250 days/year (other sites).

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): 0,05; (final release): 0,05. Local release rate: 65 kg/day.

Release fraction to wastewater from process: (final release): 0,0. Local release rate: 0 kg/day (main site)(measured release rate); (initial release): 0,02; (final release): 0,00002. Local release rate: 0,026 kg/day (other sites).

Release fraction to soil from process (final release): 0,001.

Type of process: Application of solvent borne of water-borne products.

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

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

On-site treatment of wastewater:

- Main site: industrial biological on-site STP with measured release rate.

- Other sites: If discharging to municipal sewage treatment plant, provide onsite wastewater efficiency of Effectiveness Water: 99.9%.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Effectiveness Water: 9,457%).

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

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

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

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: PROC1, PROC3, PROC4: ECETOC TRA v3. PROC2, PROC8b, PROC15: ECETOC TRA v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	<u>Notes</u>	
Worker, long-term, systemic, Dermal	0,411 mg/kg bw/day	0,18	PROC8b	
Worker, long-term, systemic, Inhalation	3,138 mg/m3	0,391	PROC4	
Worker, long-term, systemic, Combined routes	N/A	0,454	PROC8b	
Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,00122 mg/L	<0,01	ERC6a (other sites)	
Freshwater sediment	0,.025 mg/kg dw	<0,01	ERC6a (other sites)	
Marine water	0,000124 mg/L	<0,01	ERC6a (other sites)	
Marine water sediment	0,00248 mg/kg dw	<0,01	ERC6a (other sites)	
Soil	0,00244 mg/kg dw	0,039	ERC6a (other sites)	
STP	0,012 mg/L	<0,01	ERC6a (other sites)	
Human via environment, Inhalation	0,000995 mg/m3	<0,01	ERC6a (other sites)	•
Human via environment, Oral	0,00006 mg/kg bw/day	<0,01	ERC6a (other sites)	
Human via environment. Combined routes	N/A	<0.01	FRC6a (other sites)	

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, with gloves, no respirator required. Duration of activity: PROC1, PROC2, PROC4: <=1 hour/day. PROC3, PROC8b, PROC15: <=15 minutes/day. Concentration of substance: PROC1, PROC2, PROC15: <=100%. PROC8b: <=25%. PROC3, PROC4: <=1%.

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): Formulation - GES1 Formulation of fragrance compounds

1. Exposure scenario (2)

Short title of the exposure scenario:

Formulation - GES1 Formulation of fragrance compounds

List of use descriptors:

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

Environmental release category (ERC): ERC2 (SpERC IFRA 2.1a.v1, 2.1b.v1)

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. 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 laboratory (< 1 l or 1 kg present at workplace).

Name of contributing environmental scenario and corresponding ERCs:

ERC2 Formulation into mixture.

SpERC IFRA 2.1(a): Formulation of fragrance compounds at large/medium sites; SpERC IFRA 2.1(b): Formulation of fragrance compounds at small sites.

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). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see http://www.cefic.org/Industry-support/Implementing-reach/Libraries/.

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:

- PROC1, PROC3, PROC5, PROC15: <=100%
- PROC8a, PROC8b, PROC9: <=25%

Physical state: liquid.

Vapour pressure: 631 Pa at 25 °C; 1660 Pa @ 40°C.

Amounts used:

Application rate (for inhalation exposure): Unless otherwise stated, not specified.

- PROC8a, PROC9: 1-10 L/minute.
- PROC8b: 10-100 L/minute.

Frequency and duration of use/exposure:

Duration of activity:

- PROC1, PROC3: <=8 hours/day.
- PROC5, PROC8a: <=4 hours/day (duration of exposure for workers: <= 1 hour/day).
- PROC8b, PROC9: <=1 hour/day.
- PROC15: <=15 minutes/day

Human factors not influenced by risk management:

Exposed skin surface:

- PROC1, PROC3, PROC5, PROC15: 240 cm2 (one hand, face side only).
- PROC9: 480 cm2 (two hands, face side only).
- PROC8a, PROC8b: 960 cm2 (two hands).

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Domain: Industrial use.

Process temperature:

- PROC1, PROC9, PROC15: <= 40 °C.
- PROC3, PROC5, PROC8a, PROC8b: <= 25 °C.

Assessment tool used:

- PROC1: ECETOC TRA Worker v3 for inhalation and dermal exposure.
- PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC15: ECETOC TRA Worker v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure.

Technical conditions and measures at process level (source) to prevent release:

Activity class - subclass (ART v1.5):

- PROC3: Activities with open liquid surfaces and open reservoirs activities with relatively undisturbed surfaces. Activities with agitated surfaces; open surface <0.1 m2. Containment: Low level containment (90% reduction).
- PROC5: Activities with open liquid surfaces and open reservoirs activities with relatively undisturbed surfaces. Activities with agitated surfaces; open surface <0.1 m2. Containment: open process.
- PROC8a: Transfer of liquid products falling liquids; splash loading. Containment: open process. Handling of contaminated objects: Activities with treated/contaminated objects (surface 0.3- 1 m2).
- PROC8b: Transfer of liquid products falling liquids; splash loading. Containment: handling that reduces contact between product and adjacent air.
- PROC9: Transfer of liquid products bottom loading.
- PROC15: Handling of contaminated objects: Level of contamination: 10-90% of surface; Activities with treated/contaminated objects (surface <0.1 m2). Containment: open process.

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

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

Containment:

- PROC1: Closed system (minimal contact during routine operations).
- PROC3: Closed batch process with occasional controlled exposure.
- PROC8b, PROC9: Semi-closed process with occasional controlled exposure.
- PROC5, PROC8a, PROC15: No.

Local exhaust ventilation: Not required.

Local exhaust ventilation (for dermal): Not required.

Occupational Health and Safety Management System: Advanced.

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

Respiratory protection: Not required.

Eye protection: Yes (chemical resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact). Dermal protection:

- PROC1, PROC3, PROC5, PROC6, PROC9, PROC15: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (minimum efficiency dermal: 90%).
- PROC8a: Yes (chemically resistant gloves conforming to EN374 with specific activity training) (minimum efficiency 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.

For tasks where potential splashes may arise, the following personal protective equipment is recommended: face shield, substance/task appropriate gloves and full skin coverage with appropriate light-weight barrier materials (e.g. coveralls).

2.2 Control of environmental exposure

General:

Environmental release may vary depending on the size of the compounding site according to IFRA guideline (2012). It is not more than 0.5% of the use volume for smaller compounding sites, whereas for large/medium sites it is not more than 0.2%.

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

Product characteristics:

Physical state: liquid.

Amounts used:

Maximum daily use at a site: 0,026 tons/day (large/medium site); 0,00021 tons/day (small site).

Maximum annual use at a site: 6,5 tons/year (large/medium site); 0,052 tons/year (small site).

Percentage of tonnage used at regional scale: 80 % (large/medium site); 2 % (small site).

Frequency and duration of use:

Emission days: <=250 days/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): 0.025; (final release): 0.025. Local release rate: 0,65 kg/day (large/medium site)(SpERC IFRA 2.1a.v1), 0,00525 kg/day (small site)(SpERC IFRA 2.1b.v1).

Release fraction to wastewater from process: (initial release): 0,002; (final release): 0,002. Local release rate: 0,052 kg/day (large/medium site) (SpERC IFRA 2.1a.v1); (initial release): 0,005; (final release): 0,005. Local release rate: 0,00105 kg/day (small site)(SpERC IFRA 2.1b.v1). Release fraction to soil from process (final release): 0.

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 (Effectiveness Water: 9,457%).

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: PROC1: ECETOC TRA v3. PROC3, PROC5, PROC8a, PROC9, PROC9, PROC15: ECETOC TRA v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	<u>Notes</u>
Worker, long-term, systemic, Dermal	0,823 mg/kg bw/day	0,361	PROC5
Worker, long-term, systemic, Inhalation	2,8 mg/m3	0,349	PROC8a
Worker, long-term, systemic, Combined routes	N/A	0,485	PROC5
Environment			
Effect/Compartment	Exposure estimate/PEC	RCR	<u>Notes</u>
Freshwater	0,0024 mg/L (a)/ 0,0000949 mg/L (b)	0,013(a)/ <0,01 (b)	(a) large/medium site/ (b) small site
Freshwater sediment	0,048 mg/kg dw (a)/ 0,0019 mg/kg dw (b)	0,013(a)/ <0,01 (b)	(a) large/medium site/ (b) small site
Marine water	0,000241 mg/L (a)/ 0,0000107 mg/L (b)	0,013(a)/ <0,01 (b)	(a) large/medium site/ (b) small site
Marine water sediment	0,00484 mg/kg dw (a)/ 0,000214 mg/kg dw (b)	0,013(a)/ <0,01 (b)	(a) large/medium site/ (b) small site
Soil	0,00275 mg/kg dw (a)/ 0,0000636 mg/kg dw (b)	0,044 (a) / <0,01 (b)	(a) large/medium site/ (b) small site
STP	0,024 mg/L (a)/ 0,000475 mg/L (b)	<0,01 (a)/ <0,01 (b)	(a) large/medium site/ (b) small site
Human via environment, Inhalation	0,000129 mg/m3 (a) / 0,00000578 mg/m3 (b)	<0,01 (a) / <0,01 (b)	(a) large/medium site/ (b) small site
Human via environment, Oral	0,000111 mg/kg bw/day (a) / 0,00000504 mg/kg bw/day (b)	<0,01 (a) / <0,01 (b)	(a) large/medium site/ (b) small site
Human via environment, Combined routes	N/A	<0,01	(a) large/medium site/ (b) small site

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, with gloves, no respirator required. Duration of activity: PROC1, PROC3: <=8 hours/day. PROC5, PROC8a: <=4 hours/day (duration of exposure for workers: <= 1 hour/day). PROC8b, PROC9: <=1 hour/day. PROC15: <=15 minutes/day. Concentration of substance: PROC1, PROC3, PROC5, PROC15: <=100%. PROC8a, PROC9b, PROC9: <=25%.

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): Formulation - GES2 Formulation of fragranced end-products

1. Exposure scenario (3)

Short title of the exposure scenario:

Formulation - GES2 Formulation of fragranced end-products

List of use descriptors:

Process category (PROC): PROC1, PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15 Environmental release category (ERC): ERC2 (SpERC AISE and Cosmetics Europe (CE)).

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. 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.

SpERC:

- IFRA SG-1: AISE Granular and low viscosity liquids (large site)(AISE 2.1.a,g).
- IFRA SG-2: AISE Granular and low viscosity liquids (medium site)(AISE 2.1.b,h).
- IFRA SG-3: AISE Granular and low viscosity liquids (small site)(AISE 2.1.c,i).
- IFRA SG-4: AISE High viscosity liquids+CE/AISE Solid products+CE Low viscosity liquids (large site)(AISE 2.1.j+CE/AISE 2.3.a+CE2.1.a).
- IFRA SG-5: AISE High viscosity liquids+CE/AISE Solid products+CE Low viscosity liquids (medium site)(AISE 2.1.k+CE/AISE 2.3.b+CE2.1.b).
- IFRA SG-6: AISE High viscosity liquids+CE/AISE Solid products+CE Low viscosity liquids (small site)(AISE 2.1.I+CE/AISE 2.3.c+CE2.1.c).
- IFRA SG-7: AISE + ČE Fine fragrances (cleaning with solvent)(large/medium/small site)(CE 2.2a-c).
- IFRA SG-8: ERC2 default (large/medium/small site)(CE 2.1.d-j)

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). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see http://www.cefic.org/Industry-support/Implementing-reach/Libraries/.

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:

- PROC1: <=100%
- PROC3, PROC5, PROC8b, PROC15, PROC15: <=25%
- PROC8a, PROC9, PROC14: <=1%

Physical state: liquid.

Vapour pressure: 631 Pa at 25 °C; 1660 Pa @ 40°C.

Amounts used:

Application rate (for inhalation exposure): Unless otherwise stated, not specified.

- PROC8a, PROC8b: 1-10 L/minute.
- PROC9: 10-100 L/minute.

Frequency and duration of use/exposure:

Duration of activity:

- PROC1, PROC14: <=8 hours/day.
- PROC3, PROC8a: <=4 hours/day.
- PROC5, PROC8b, PROC9: <=1 hour/day.
- PROC15: <=15 minutes/day.

Human factors not influenced by risk management:

Exposed skin surface:

- PROC1, PROC3, PROC15: 240 cm2 (one hand, face side only).
- PROC5, PROC9, PROC14: 480 cm2 (two hands, face side only).
- PROC8a, PROC8b: 960 cm2 (two hands)

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Domain: Industrial use.

Process temperature:

- PROC1, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15: <= 40 °C.
- PROC3: <= 25 °C.

Assessment tool used:

- PROC1: ECETOC TRA Worker v3 for inhalation and dermal exposure.
- PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15: ECETOC TRA Worker v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure.

Technical conditions and measures at process level (source) to prevent release:

Activity class - subclass (ART v1.5):

- PROC3: Activities with open liquid surfaces and open reservoirs activities with relatively undisturbed surfaces. Activities with agitated surfaces; open surface 0.1-0.3 m2. Containment: Low level containment (90% reduction).
- PROC5: Activities with open liquid surfaces and open reservoirs activities with agitated surfaces. Activities with agitated surfaces; open surface 0.1-0.3 m2. Containment: open process.
- PROC8a: Transfer of liquid products falling liquids; splash loading. Containment: open process.
- PROC8b: Transfer of liquid products falling liquids; splash loading. Containment: handling that reduces contact between product and adjacent air.
- PROC9: Transfer of liquid products bottom loading.
- PROC14: Compressing of powders, granules or pelletized material. Containment: open process.
- PROC15: Handling of contaminated objects: Level of contamination: >90% of surface; Activities with treated/contaminated objects (surface <0.1 m2).

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

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

Containment:

- PROC1: Closed system (minimal contact during routine operations).
- PROC3: Closed batch process with occasional controlled exposure.
- PROC8b, PROC9: Semi-closed process with occasional controlled exposure.
 PROC5, PROC8a, PROC14, PROC15: No.

Local exhaust ventilation: Not required.

Local exhaust ventilation (for dermal): Not required.

Occupational Health and Safety Management System: Advanced

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

Respiratory protection: Not required.

Eye protection: Yes (chemical resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact). Dermal protection:

- PROC8a, PROC9, PROC14: No (Effectiveness Dermal: 0%).

- PROC1, PROC3, PROC5, PROC8b, PROC15: 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.

For tasks where potential splashes may arise, the following personal protective equipment is recommended: face shield, substance/task appropriate gloves and full skin coverage with appropriate light-weight barrier materials (e.g. coveralls).

2.2 Control of environmental exposure

General:

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

Product characteristics:

Physical state: liquid.

Amounts used:

Maximum daily use at a site:

- IFRA SG-1: 0,047 tons/day.
- IFRA SG-2: 0,019 tons/day.
- IFRA SG-3: 0,0001 tons/day.
- IFRA SG-4: 0,14 tons/day.
- IFRA SG-5: 0,0073 tons/day
- IFRA SG-6: 0,000073 tons/day.
- IFRA SG-7: 0,021 tons/day.
- IFRA SG-8: 0,0021 tons/day.

Maximum annual use at a site:

- IFRA SG-1: 11,7 tons/year.
- IFRA SG-2: 4,7 tons/year.
- IFRA SG-3: 0,025 tons/year.
- IFRA SG-4: 3,4 tons/year.
- IFRA SG-5: 1,8 tons/year.
- IFRA SG-6: 0,018 tons/year.
- IFRA SG-7: 5,2 tons/year. - IFRA SG-8: 0,52 tons/year.
- Percentage of tonnage used at regional scale:
- IFRA SG-1: 45 %.
- IFRA SG-2: 18%.
- IFRA SG-3: 1,4 %.
- IFRA SG-4: 13 %.
- IFRA SG-5: 7 %.
- IFRA SG-6: 0,7 %.
- IFRA SG-7: 20 %.
- IFRA SG-8: 2 %.

Frequency and duration of use:

Emission days: 250 days/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: Unless otherwise stated, (initial release): 0,0; (final release): 0,0. Local release rate: 0 kg/day. IFRA SG-8: (initial release): 0,025; (final release): 0,025. Local release rate: 0,053 kg/day.

Release fraction to wastewater from process:

- IFRA SG-1: (initial release): 0,0001; (final release): 0,0001. Local release rate: 0,00468 kg/day.
- IFRA SG-2: (initial release): 0,001; (final release): 0,001. Local release rate: 0,019 kg/day.
- IFRA SG-3: (initial release): 0,002; (final release): 0,002. Local release rate: 0,0002 kg/day. IFRA SG-4: (initial release): 0,001; (final release): 0,001. Local release rate: 0,135 kg/day. IFRA SG-5: (initial release): 0,002; (final release): 0,002. Local release rate: 0,015 kg/day.

- IFRA SG-6: (initial release): 0,004; (final release): 0,004. Local release rate: 0,000292 kg/day.
- IFRA SG-7: (initial release): 0,0; (final release): 0,0. Local release rate: 0 kg/day.
- IFRA SG-8: (initial release): 0.02: (final release): 0.02. Local release rate: 0.042 kg/day.

Release fraction to soil from process: Unless otherwise stated, (final release): 0,0. IFRA SG-8: (final release): 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).

Process efficiency: Process optimized for highly efficient use of raw materials (very minimal environmental release).

Typical measures reducing emissions to waste water may include may include:

- Closed automated process and/or Closed transfer system and/or Closed batch systems and/or Semi-closed transfer system and/or Batch production of final product;
- Centralized process control:
- Re-use of process grey water for cleaning;
- Optimized and/or automated systems for the transport and handling of raw materials that minimize overall exposure levels and incidental spills;
- Reduced number of transfer and cleaning operations through manufacturing of different products from one premix (masterbatch) to which certain ingredients are added to yield the final products;
- Dedicated storage tanks for raw materials, premixes and final products;
- Recovery of materials through recycling residues of granular detergents in cleaning steps at packaging or transfer lines into the slurries. Equipment cleaning:
- IFRA SG-1, IFRA SG-2: Residues of granular detergents recovered in cleaning steps at packaging or transfer lines are recycled into the slurries. Equipment cleaning with minimized emissions to wastewater. Typically implemented measures for reducing emissions to waste water may include: Dry cleaning of equipment (e.g. use of absorbent materials and vacuum cleaning including incineration of resulting solid waste); Cleaning involving so-called pigs; Cleaning involving so-called "cleaning in place" (CIP System); Steam cleaning; Manual removal of residual products adhering to equipment (e.g. by manual scrubbing, vacuum cleaning, etc.); Use of two-liner systems (i.e. single use disposable reactor cover that is incinerated after use as solid waste).
- IFRA SG-3: Residues of granular detergents recovered in cleaning steps at packaging or transfer lines are recycled into the slurries. Equipment cleaned with water, washing disposed of with wastewater.
- IFRA SG-4, IFRA SG-5: Equipment cleaning with minimized emissions to wastewater. Typically implemented measures for reducing emissions to waste water may include: Dry cleaning of equipment (e.g. use of absorbent materials and vacuum cleaning including incineration of resulting solid waste); Cleaning involving so-called pigs; Cleaning involving so-called ""cleaning in place"" (CIP System); Steam cleaning; Manual removal of residual products adhering to equipment (e.g. by manual scrubbing, vacuum cleaning, etc.); Use of two-liner systems (i.e. single use disposable reactor cover that is incinerated after use as solid waste).
- IFRA SG-6, IFRA SG-8: Equipment cleaned with water, washing disposed of with wastewater.
- IFRA SG-7: Equipment cleaned with organic solvent, washings are collected and disposed of as solvent waste.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Effectiveness Water: 9,457%).

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

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

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

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.

General good practice: Trained staff, spill protection including waste reuse.

3. Exposure estimation and reference to its source

Assessment method-Health: PROC1: ECETOC TRA v3. PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15: ECETOC TRA v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2. Only highest figures are presented here.

Health

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Worker, long-term, systemic, Dermal	0,823 mg/kg bw/day	0,361	PROC8a	
Worker, long-term, systemic, Inhalation	2 mg/m3	0,249	PROC3, PROC5	
Worker, long-term, systemic, Combined routes	N/A	0,451	PROC8a	
Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,00616 mg/L	0,034	ERC2 (IFRA SG-4)	
Freshwater sediment	0,123 mg/kg dw	0,034	ERC2 (IFRA SG-4)	
Marine water	0,000617 mg/L	0,034	ERC2 (IFRA SG-4)	
Marine water sediment	0,012 mg/kg dw	0,034	ERC2 (IFRA SG-4)	
Soil	0,00677 mg/kg dw	0,109	ERC2 (IFRA SG-4)	
STP	0,061 mg/L	<0,01	ERC2 (IFRA SG-4)	
Human via environment, Inhalation	0,0000147 mg/m3	<0,01	ERC2 (IFRA SG-8)	
Human via environment, Oral	0,0000861 mg/kg bw/day	<0,01	ERC2 (IFRA SG-8)	
Human via environment, Combined routes	N/A	<0,01	ERC2 (IFRA SG-8)	

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, with gloves (PROC1, PROC3, PROC8b, PROC15), no respirator required. Duration of activity: PROC1, PROC14: <=8 hours/day. PROC3, PROC8a: <=4 hours/day. PROC5, PROC8b, PROC9: <=1 hour/day. PROC15: <=15 minutes/day. Concentration of substance: PROC1: <=100%. PROC3, PROC3, PROC3, PROC3, PROC6b, PROC8b, PROC15; PROC15: <=25%. PROC8a, PROC9, PROC14: <=1%.

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 - GES3 Industrial end-use of washing and cleaning products

1. Exposure scenario (4)

Short title of the exposure scenario:

Use at industrial sites - GES3 Industrial end-use of washing and cleaning products

List of use descriptors:

Product category (PC): PC35

Process category (PROC): PROC1, PROC2, PROC4, PROC7, PROC8b, PROC10, PROC13

Environmental release category (ERC): ERC4 (SpERC AISE 4.1.v.2)

List of names of contributing worker scenarios and corresponding PROCs:

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CS2: PROC1 (AISE P801, P805).
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CS3: PROC2 (AISE P101, P104, P107, P110).

CS4: PROC4 (AISE P810)

CS5: PROC4 (AISE P707, P708, P709, P712, P802).

CS6: PROC4 (AISE P904, P905).

CS7: PROC7 (AISE P710).

CS8: PROC7 (AISE P711, P714). CS9: PROC7 (AISE P806).

CS10: PROC7 (AISE P803, P807, P809, P811).

CS11: PROC7 (AISE P906, P907).

CS12: PROC8b (AISE P101, P104, P107, P110, P801, P802, P803, P805).

CS13: PROC8b (AISE P904, P905, P906, P907).

CS14: PROC8b (AISE P707, P708, P709, P710, P712, P807, P811).

CS15: PROC8b (AISE P711, P713, P714).

CS16: PROC8b (AISE P809, P810).

CS17: PROC8b (AISE P806)

CS18: PROC10 (AISE P711, P713, P714).

CS19: PROC13 (AISE P804).

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.

PROC4 Chemical production where opportunity for exposure arises.

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.

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:

CS1: ERC4.

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

SpERC AISE 4.1.v.2: Industrial Use of Water Borne Processing Aids.

Further explanations:

PC35 Washing and cleaning products.

Industrial use of Laundry products:

- AISE P101 Laundry detergent: Automatic process (PROC2, PROC8b).
- AISE P104 Conditioner (softener/starch): Automatic process (PROC2, PROC8b).
- AISE P107 Laundry aid (gasing): Automatic process (PROC2, PROC8b).
- AISE P110 Laundry aid (non-gasing): Automatic process (PROC2, PROC8b).

Industrial use of Vehicle cleaning Products:

- AISE P707 Train cleaner: Semi-Automatic process (PROC4, PROC8b)
- AISE P708 Aeroplane cleaner: Semi-Automatic process (PROC4, PROC8b).
- AISE P709 Car wash product: Semi-Automatic process (PROC4, PROC8b).
- AISE P710 Car wash product: Spray and rinse process (PROC7, PROC8b).
- AISE P711 Car wash product: Spray and wipe manual process (PROC7, PROC8b, PROC10)
- AISE P712 Dewaxing product: Semi-Automatic process (PROC4, PROC8b).
- AISE P713 Boat cleaning: Semi-Automatic process (PROC8b, PROC10).
- AISE P714 Boat cleaning: Spray and wipe manual process (PROC7, PROC8b, PROC10).

Industrial use of Food beverage and pharmacos products:

- AISE P801 Food process cleaner: Cleaning In Place process (PROC1, PROC8b)
- AISE P802 Food process cleaner: Semi closed cleaning process (PROC4, PROC8b).
- AISE P803 Chain maintenance product: Automatic spray process (PROC7, PROC8b).
- AISE P804 Chain maintenance product: Automatic drip and brush process (PROC13).
- AISE P805 Defoaming product: Automatic process (PROC1, PROC8b)
- AISE P806 Foam cleaner: Semi-Automatic with venting process (PROC7, PROC8b).
- AISE P807 Foam cleaner: Semi-Automatic without venting process (PROC7, PROC8b).
- AISE P809 Animal housing care: Semi-Automatic process (PROC7, PROC8b).
- AISE P810 Disinfection product: Semi-Automatic process (PROC4, PROC8b)
- AISE P811 Disinfection product: Fogging and gassing Semi-automatic process (PROC7, PROC8b).

Industrial use of Water treatment products:

- AISE P904 Preservation and sanitation agent: drink and pool water (PROC4, PROC8b).
- AISE P905 Preservation and sanitation agent: waste water (PROC4, PROC8b).

Industrial Use of Facade/surface Cleaning Products:

- AISE P906 Facade/surface cleaner: High pressure process (PROC7, PROC8b).
- AISE P907 Facade/surface cleaner: Medium pressure process (PROC7, PROC8b).

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). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see http://www.cefic.org/Industry-support/Implementing-reach/Libraries/.

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: <=1%.

Physical state: liquid.

Vapour pressure: 447.3 Pa @ 20 °C; 631 Pa at 25 °C; 1660 Pa @ 40°C.

Amounts used:

Application rate (for inhalation exposure): Unless otherwise stated, not specified.

- PROC7 (CS7, CS10): moderate application rate (0.3-3 L/minute).
- PROC7 (CS8, CS11): high application rate (>3 L/minute)
- PROC8b (CS14): <1000 L/minute.
- PROC8b (CS16): 10-100 L/minute.

Frequency and duration of use/exposure:

Duration of activity:

- PROC1, PROC2, PROC4, PROC7 (CS9-CS11), PROC8b (CS13, CS17), PROC13: <=8 hours/day.
- PROC7 (CS7, CS8), PROC8b (CS14-CS16): <=1 hour/day.
- PROC10: <=4 hours/day.
- PROC8b (CS12): <=15 minutes/day.

Human factors not influenced by risk management:

Exposed skin surface:

- PROC1: 240 cm2 (one hand, face side only).
- PROC2, PROC4, PROC13: 480 cm2 (two hands, face side only).
- PROC8b, PROC10: 960 cm2 (two hands).
- PROC7: 1500 cm2 (two hands and upper wrists).

Other given operational conditions affecting workers exposure:

Location:

- PROC1, PROC2, PROC13: Indoor use.
- PROC4, PROC7, PROC8b: Indoor/outdoor use.
- PROC10: Outdoor use.

Domain: Industrial use.

Process temperature:

- PROC1, PROC2, PROC4, PROC7 (CS7, CS8), PROC8b (CS12, CS14-CS17), PROC13: <= 40 °C.
- PROC7 (CS9-CS11), PROC10: <= 25 °C.
- PROC8b (CS13): 20 °C.

Assessment tool used:

- PROC1, PROC7 (CS8), PROC8b (CS12, CS13, CS15, CS17), PROC13: ECETOC TRA Worker v3 for inhalation and dermal exposure.
- PROC2, PROC4, PROC7 (CS7, CS9-CS11), PROC8b (CS14, CS16), PROC10: ECETOC TRA Worker v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure.

Technical conditions and measures at process level (source) to prevent release:

Activity class - subclass (ART v1.5):

- PROC2: Activities with open liquid surfaces and open reservoirs activities with relatively undisturbed surfaces. Open surface 0.1-0.3 m2.
- PROC4: Activities with open liquid surfaces and open reservoirs activities with agitated surfaces. Activities with agitated surfaces; open surface 0.1-0.3 m2. No segregation.
- PROC7 (CS7, CS8): Spray application of liquids surface spraying of liquids. Spray direction: Spraying in any direction (including upwards). Located in breathing zone of the worker.
- PROC7 (CS9): Spray application of liquids spraying of liquids in a space. Located in breathing zone of the worker.
- PROC7 (CS10): Spray application of liquids surface spraying of liquids. Spray direction: Only horizontal or downward spraying. Located in breathing zone of the worker.
- PROC7 (CS11): Spray application of liquids surface spraying of liquids. Spray technique: Spraying with high compressed air use. Spray direction: Spraying in any direction (including upwards). Not located in breathing zone of the worker.
- PROC8b (CS14, CS16): Transfer of liquid products falling liquids; splash loading. Containment: handling that reduces contact between product and adjacent air.
- PROC10: Spreading of liquid products. Spreading of liquids at surfaces or work pieces: >3 m2/hour.

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

General ventilation: Basic general ventilation (1-3 air changes per hour): 0% (indoor use). Outdoors (outdoor use). Containment:

- PROC1: Closed system (minimal contact during routine operations).
- PROC2: Closed continuous process with occasional controlled exposure.
- PROC4, PROC8b: Semi-closed process with occasional controlled exposure.
- PROC7, PROC10, PROC13: No.

Local exhaust ventilation: Unless otherwise stated, Not required.

- PROC13: Yes (90% effectiveness).
- PROC7 (CS9), PROC8b (CS17): Yes (95% effectiveness).

Local exhaust ventilation (for dermal): Unless otherwise stated, Not required.

- PROC13: Yes (90% effectiveness).

Occupational Health and Safety Management System: Advanced

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

Respiratory protection: Unless otherwise stated, Not required.

- PROC7 (CS7, CS8, CS10): Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).
- PROC7 (CS11): Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%).

Eye protection: Yes (chemical resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact). Dermal protection:

- PROC1, PROC2, PROC4, PROC8b (CS16): No (Effectiveness Dermal: 0%).
- PROC7, PROC8b (CS12-CS15, CS17), PROC10, 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.

For tasks where potential splashes may arise, the following personal protective equipment is recommended: face shield, substance/task appropriate gloves and full skin coverage with appropriate light-weight barrier materials (e.g. coveralls).

2.2 Control of environmental exposure

General:

Industrial use is considered as wide dispersive use together with the other end-uses of fragranced products. Industrial end-use products are similar to those used by professionals and consumers and releases will be to the waste water stream (IFRA 2012).

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

Product characteristics:

Physical state: liquid.

Amounts used:

Maximum daily use at a site: 0,0000021 ton/day. Maximum annual use at a site: 0,00078 tons/year. Percentage of tonnage used at regional scale: 4 %.

Frequency and duration of use:

Emission days: 220 days/year.

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:

Industrial use.

Indoor use.

Release fraction to air from process (initial release): 0,0; (final release): 0,0. Local release rate: 0 kg/day (SpERC AISE 4.1.v2).

Release fraction to wastewater from process (initial release): 1.0; (final release): 1.0. Local release rate: 0,00214 kg/day (SpERC AISE 4.1.v2) Release fraction to soil from process (final release): 0.0 (SpERC AISE 4.1.v2).

Type of process: Substance applied in aqueous process solution with negligible volatilization.

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

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

Process efficiency: Optimized water use due to e.g.: Re-use of rinsing water.

Chemical waste - discontinuous and continuous generation: Spent fluid discharged to wastewater.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Effectiveness Water: 9,457%).

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: PROC1, PROC7 (CS8), PROC8b (CS12, CS13, CS15, CS17), PROC13: ECETOC TRA v3. PROC2, PROC4, PROC7 (CS7, CS9-CS11), PROC8b (CS14, CS16), PROC10: ECETOC TRA v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	<u>Notes</u>	
Worker, long-term, systemic, Dermal	0,686 mg/kg bw/day	0,301	PROC4	
Worker, long-term, systemic, Inhalation	3,923 mg/m3	0,489	PROC13	

Effect/Compartment	Exposure estimate/PEC	RCR	Notes	
Worker, long-term, systemic, Combined routes	N/A	0,537	PROC7 (CS9)	
Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,000144 mg/L	<0,01		
Freshwater sediment	0,00289 mg/kg dw	<0,01		
Marine water	0,0000156 mg/L	<0,01		
Marine water sediment	0,000313 mg/kg dw	<0,01		
Soil	0,000117 mg/kg dw	<0,01		
STP	0,000969 mg/L	<0,01		
Human via environment, Inhalation	0,00000484 mg/m3	<0,01		
Human via environment, Oral	0,00000896 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/outdoor use, PROC7 (CS9), PROC8b (CS17) PROC13: LEV used, PROC7, PROC8b (CS12-CS15, CS17), PROC10, PROC13: with gloves. Duration of activity: PROC1, PROC2, PROC4, PROC7 (CS9-CS11), PROC8b (CS13, CS17), PROC13: <=8 hours/day. PROC7 (CS7, CS8), PROC8b (CS14-CS16): <=1 hour/day. PROC10: <=4 hours/day. PROC8b (CS12): <=15 minutes/day. Respiratory protection: PROC7 (CS7, CS8, CS10): Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%). PROC7 (CS11): Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%). Concentration of substance: <=1%.

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): Use by professional workers - GES4 Professional end use of washing and cleaning products 1. Exposure scenario (5)

Short title of the exposure scenario:

Use by professional workers - GES4 Professional end use of washing and cleaning products

List of use descriptors:

Product category (PC): PC35

Process category (PROC): PROC1, PROC2, PROC4, PROC8a, PROC8b, PROC10, PROC11, PROC13

Environmental release category (ERC): ERC8a

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List of names of contributing worker scenarios and corresponding PROCs:
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CS2: PROC1 (AISE P102, P105, P108, P111, P203, P204, P1101).
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CS3: PROC2 (AISE P202).

CS4: PROC4 (AISE P112).

CS5: PROC4 (AISE P701, P704).

CS6: PROC8a (AISE P102, P105, P108, P111, P112, P203, P204, P309, P1101, P1102).

CS7: PROC8a (AISE P901, P902).

CS8: PROC8a (AISE P201).

CS9: PROC8a (AISE P301, P302, P303, P304, P305, P306, P312, P401, P402, P403, P409, P410, P808, P1104).

CS10: PROC8a (AISE P103, P308, P314, P315, P404, P405, P701, P702, P704, P1103).

CS11: PROC8a (AISE P703, P705, P706).

CS12: PROC8b (AISE P202).

CS13: PROC10 (AISE P310).

CS14: PROC10 (AISE P103, P201, P317, P411).

CS15: PROC10 ((AISE P307)

CS16: PROC10 (AISE P113, P301, P302, P303, P304, P305, P403).

CS17: PROC10 (AISE P306, P312, P313, P314, P315, P316, P401, P402, P405, P409, P410, P808, P1103, P1104).

CS18: PROC10 (AISE P308, P311, P404).

CS19: PROC10 (AISE P703, P705, P706).

CS20: PROC10 (AISE P902).

CS21: PROC11 (AISE P113, P302, P304, P306, P313, P315, P402, P411, P702, P1104).

CS22: PROC11 (AISE P308, P311).

CS23: PROC11 (AISE P703, P706).

CS24: PROC11 (AISE P902).

CS25: PROC11 (AISE P901).

CS26: PROC13 (AISE P606, P607)

CS27: PROC13 (AISE P309, P1102).

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.

PROC4 Chemical production where opportunity for exposure arises.

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.

PROC11 Non 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.

PROC13 Treatment of articles by dipping and pouring.

Name of contributing environmental scenario and corresponding ERCs:

CS1: ERC8a.

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

Further explanations:

PC35 Washing and cleaning products.

Professional Use of Laundry products:

- AISE P102 Laundry detergent: Semi-automatic process (PROC1, PROC8a).
- AISE P103 Laundry detergent: Manual process (PROC8a, PROC10)
- AISE P105 Conditioner (softener/starch): Semi-automatic process (PROC1, PROC8a).
- AISE P108 Laundry aid (gasing): Semi-automatic process (PROC1, PROC8a)
- AISE P111 Laundry aid (non-gasing): Semi-automatic process (PROC1, PROC8a).
- AISE P112 Laundry aid (non-gasing): Manual process (PROC4, PROC8a).
- AISE P113 Prespotter/Stain remover: Manual process (PROC10, PROC11).

Professional Use of Dishwash products:

- AISE P201 Dishwash product: Manual process (PROC8a, PROC10).
- AISE P202 Rinse aid: Automatic process (PROC2, PROC8b).
- AISE P203 Dishwash product: Semi-automatic process (PROC1, PROC8a).
- AISE P204 Rinse aid: Semi-automatic process (PROC1, PROC8a).

Professional Use of General surface cleaning products:

- AISE P301 General purpose cleaner: Manual process (PROC8a, PROC10).
- AISE P302 General purpose cleaner: Spray and wipe manual process (PROC8a, PROC10, PROC11).
- AISE P303 Kitchen cleaner: Manual process (PROC8a, PROC10).
- AISE P304 Kitchen cleaner: Spray and wipe manual process (PROC8a, PROC10, PROC11).
- AISE P305 Sanitary cleaner: Manual process (PROC8a, PROC10)
- AISE P306 Sanitary cleaner: Spray and wipe manual process (PROC8a, PROC10, PROC11).
- AISE P307 Descaling agent: Manual process (PROC10).
- AISE P308 Descaling agent: Spray and rinse manual process (PROC8a, PROC10, PROC11).
- AISE P309 General surface cleaning: Dipping process: (PROC8a, PROC13).
- AISE P310 Oven/Grill cleaner: Manual process (PROC10).
- AISE P311 Oven/Grill Cleaner: Spray and wipe manual process (PROC10, PROC11).
- AISE P312 Glass cleaner: Manual process (PROC8a, PROC10).
- AISE P313 Glass cleaner: Spray and wipe manual process (PROC10, PROC11).
- AISE P314 Surface disinfectant: Manual process (PROC8a, PROC10)
- AISE P315 Surface disinfectant: Spray and rinse manual process (PROC8a, PROC10, PROC11).
- AISE P316 Metal cleaning agent: Manual process (PROC10).
- AISE P317 Surface cleaning: Wet wipes manual process (PROC10).

Professional Use of Floor care products:

- AISE P401 Floor cleaner: Semi-Automatic process (PROC8a, PROC10).
- AISE P402 Floor cleaner: Spray and wipe manual process (PROC8a, PROC10, PROC11).
- AISE P403 Floor cleaner: Manual process (PROC8a, PROC10).
- AISE P404 Floor stripper: Manual process (PROC8a, PROC10).
- AISE P405 Floor stripper: Semi-Automatic process (PROC8a, PROC10).
- AISE P409 Carpet cleaner: Manual process (PROC8a, PROC10).
- AISE P410 Carpet cleaner: Semi-Automatic process (PROC8a, PROC10).
- AISE P411 Carpet cleaner: Prespotter, brush manual process (PROC10, PROC11).

Professional Use of Maintenance Products:

- AISE P606 Drain unblocker: Manual process (PROC13).
- AISE P607 Drain cleaner: Manual process (PROC13).

Professional Use of Vehicle cleaning Products:

- AISE P701 Car wash product: Semi-Automatic process (PROC4, PROC8a).
- AISE P702 Car wash product: Spray manual process (PROC8a, PROC11).
- AISE P703 Car wash product: Spray and wipe manual process (PROC8a, PROC10, PROC11).
- AISE P704 Dewaxing product: Semi-Automatic process (PROC4, PROC8a).
- AISE P705 Boat cleaner: Manual process (PROC8a, PROC10)
- AISE P706 Boat cleaner: Spray and wipe manual process (PROC8a, PROC10, PROC11).

Professional Use of Food beverage and pharmacos products:

- AISE P808 Animal housing care: Manual process (PROC8a, PROC10).

Professional Use of Facade/surface Cleaning Products:

- AISE P901 Facade/surface cleaner: High pressure process (PROC8a, PROC11).
- AISE P902 Facade/surface cleaner: Medium pressure process (PROC8a, PROC10, PROC11).

Professional Use of Medical Devices:

- AISE P1101 Medical devices: Semi-automatic process (PROC1, PROC8a).
- AISE P1102 Medical devices: Dipping process (PROC8a, PROC13).
- AISE P1103 Medical devices: Manual process (PROC8a, PROC10).
- AISE P1104 Medical devices: Spray and wipe manual process (PROC8a, PROC10, PROC11).

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). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental

Release Categories (SpERCs), see http://www.cefic.org/Industry-support/Implementing-reach/Libraries/.

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: Unless otherwise stated, covers concentrations <=1%. PROC11 (CS25): <=0,5%.

Physical state: liquid.

Vapour pressure: 631 Pa at 25 °C; 1660 Pa @ 40°C.

Amounts used:

Application rate (for inhalation exposure): Unless otherwise stated, not specified.

- PROC8a (CS6): flow transfer <100 L/minute.
- PROC8a (CS8, CS9): flow transfer <10 L/minute; use rate 10 L/minute.
- PROC8a (CS10, CS11): 100-1000 L/minute.
- PROC10 (CS14, CS16, CS17, CS19): <=0,1 L/minute (brushing).
- PROC11 (C21-C23): moderate application rate (0.3-3 L/minute).
- PROC11 (CS24, CS25): high application rate (>3 L/minute); use rate <10 kg/minute.

Frequency and duration of use/exposure:

Duration of activity:

- PROC1, PROC2, PROC4 (CS5), PROC10 (CS16-CS20), PROC13: <=8 hours/day.
- PROC11 (CS25): <=4 hours/day.
- PROC8a (CS7, CS9-CS11), PROC10 (CS13-CS15), PROC11 (CS21-CS24): <=1 hour/day.
- PROC4 (CS4), PROC8a (CS6, CS8), PROC8b: <=15 minutes/day.

Duration covers exposure (inhalation):

- PROC10 (CS19): <=4 hours/day.
- PROC11 (CS21-CS23): <=15 minutes/day.

Human factors not influenced by risk management:

Exposed skin surface:

- PROC1: 240 cm2 (one hand, face side only).
- PROC2, PROC4, PROC13: 480 cm2 (two hands, face side only).
- PROC8a, PROC8b, PROC10: 960 cm2 (two hands).
- PROC11: 1500 cm2 (two hands and upper wrists)

Other given operational conditions affecting workers exposure:

Location:

- PROC1, PROC2, PROC8b, PROC13: Indoor use.
- PROC4, PROC8a, PROC10, PROC11: Indoor/outdoor use.

Domain: Professional use.

Process temperature:

- PROC1, PROC2, PROC4 (CS4), PROC8a (CS6-CS8, CS10, CS11), PROC8b, PROC10 (CS13), PROC13: <= 40 °C.
- PROC4 (CS5), PROC8a (CS9), PROC10 (CS14-CS20), PROC11: <= 25 °C.

Assessment tool used:

- PROC1, PROC4 (CS4), PROC8a (C7), PROC8b: ECETOC TRA Worker v3 for inhalation and dermal exposure.
- PROC2, PROC4 (CS5), PROC8a (CS6, CS8, CS10, CS11), PROC10 (CS13, CS15, CS18, CS20), PROC11 (CS21, CS22, CS24), PROC13: ECETOC TRA Worker v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure.
- PROC8a (CS9), PROC10 (CS14, CS16, CS17, CS19), PROC11 (CS23, CS25): RiskofDerm Tier 2 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure.

Technical conditions and measures at process level (source) to prevent release:

Activity class - subclass (ART v1.5):

- PROC2: Activities with open liquid surfaces and open reservoirs activities with relatively undisturbed surfaces. Activities with agitated surfaces; open surface 1-3 m2. Containment: Low level containment (90% reduction).
- PROC4 (CS5): Activities with open liquid surfaces and open reservoirs activities with relatively undisturbed surfaces. Activities with agitated surfaces; open surface 0.1-0.3 m2. Containment: open process.
- PROC8a (CS6, CS8-CS11): Transfer of liquid products falling liquids; splash loading. Containment: open process.
- PROC10 (CS13): Spreading of liquid products. Spreading of liquids at surfaces or work pieces: 0,3-1 m2/hour.
- PROC10 (CS14, CS16, CS17, CS19): Spreading of liquid products. Spreading of liquids at surfaces or work pieces: >3 m2/hour. Located in breathing zone of the worker. Tools with handles <30 cm in length.
- PROC10 (CS15, CS18, CS20): Spreading of liquid products. Spreading of liquids at surfaces or work pieces: >3 m2/hour. Located in breathing zone of the worker.
- PROC11 (CS21-CS23): Spray application of liquids surface spraying of liquids. Spray technique: Spraying with no or low compressed air use. Spray direction: Spraying in any direction (including upwards). Located in breathing zone of the worker.
- PROC11 (CS24): Spreading of liquid products. Spray technique: Spraying with no or low compressed air use. Spray direction: Spraying in any direction (including upwards).
- PROC11 (CS25): Spray application of liquids surface spraying of liquids. Spray technique: Spraying with high compressed air use. Spray direction: Spraying in any direction (including upwards). Not located in breathing zone of the worker. Large workrooms only. Direction of air flow: away from the worker.
- PROC13: Handling of contaminated objects: Level of contamination: 10-90% of surface; Activities with treated/contaminated objects (surface 0,3-1 m2).

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

General ventilation: Basic general ventilation (1-3 air changes per hour): 0% (indoor use). Outdoors (outdoor use). Containment:

- PROC1: Closed system (minimal contact during routine operations).
- PROC2: Closed continuous process with occasional controlled exposure.

- PROC4, PROC8b: Semi-closed process with occasional controlled exposure.
- PROC8a, PROC10, PROC11, PROC13: No.

Local exhaust ventilation: Not required.

Local exhaust ventilation (for dermal): Not required.

Occupational Health and Safety Management System: Basic.

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

Respiratory protection: Unless otherwise stated, Not required.

- PROC8a (CS7), PROC10 (CS16-CS18, CS20), PROC11 (CS24): Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).
- PROC11 (CS25): Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%).

Eye protection: Yes (chemical resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact). Dermal protection:

- PROC1, PROC2, PROC4 (CS5), PROC8a (CS8, CS9), PROC10 (CS14, CS16, CS17, CS19): No (Effectiveness Dermal: 0%).
- PROC13 (CS26): Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%).
- PROC4 (CS4), PROC8a (CS6, CS7, CS10, CS11), PROC8b, PROC10 (CS13, CS15, CS18, CS20), PROC11 (CS21-CS24), PROC13 (CS27):

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

- PROC11 (CS25): 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.

For tasks where potential splashes may arise, the following personal protective equipment is recommended: face shield, substance/task appropriate gloves and full skin coverage with appropriate light-weight barrier materials (e.g. coveralls).

2.2 Control of environmental exposure

General:

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

Product characteristics:

Physical state: liquid.

Amounts used:

Daily wide dispersive use: 0.0000021 tons/day. Fraction of the main local source: 0.00075. Percentage of tonnage used at regional scale: 4 %.

Frequency and duration of use:

Emission days: <=365 days/year.

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 use.

Professional use.

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

Release fraction to wastewater from process (initial release): 1.0; (final release): 1.0. Local release rate: 0,00214 kg/day.

Release fraction to soil from process (final release): 0,0.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Effectiveness Water: 9,457%).

Size of municipal sewage system/treatment plant: >=20000 m3/day.

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

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

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: PROC1, PROC4 (CS4), PROC8a (C7), PROC8b: ECETOC TRA Worker v3 for inhalation and dermal exposure. PROC2, PROC4 (CS5), PROC8a (CS6, CS8, CS10, CS11), PROC10 (CS13, CS15, CS18, CS20)), PROC11 (CS21, CS22, CS24), PROC13: ECETOC TRA Worker v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure. PROC8a (CS9), PROC10 (CS14, CS16, CS17, CS19), PROC11 (CS23, CS25): RiskofDerm Tier 2 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure. 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	0,71 mg/kg bw/day	0,311	PROC8a (CS9)	
Worker, long-term, systemic, Inhalation	3.923 mg/m3	0,489	PROC4 (CS4), PROC8b	
Worker, long-term, systemic, Combined routes	N/A	0,5	PROC4 (CS5)	
Environment				

Effect/Compartment Exposure estimate/PEC RCR Notes

Effect/Compartment	Exposure estimate/PEC	RCR	<u>Notes</u>	
Freshwater	0,000144 mg/L	<0,01		
Freshwater sediment	0,00289 mg/kg dw	<0,01		
Marine water	0,0000156 mg/L	<0,01		
Marine water sediment	0,000313 mg/kg dw	<0,01		
Soil	0,000117 mg/kg dw	<0,01		
STP	0,000969 mg/L	<0,01		
Human via environment, Inhalation	0,00000484 mg/m3	<0,01		
Human via environment, Oral	0,00000897 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/outdoor use, without LEV, PROC4, PROC8a, PROC8b, PROC10, PROC11, PROC13: with gloves. Duration of activity: PROC1, PROC2, PROC4 (CS5), PROC10 (CS16-CS20), PROC13: <=8 hours/day. PROC11 (CS25): <=4 hours/day. PROC8a (CS7, CS9-CS11), PROC10 (CS13-CS15), PROC11 (CS21-CS24): <=1 hour/day. PROC4 (CS4), PROC8a (CS6, CS8), PROC8b: <=15 minutes/day. Respiratory protection: PROC8a (CS7), PROC10 (CS16-CS18, CS20), PROC11 (CS24): Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%). PROC11 (CS25): Yes (Respirator with APF of 20) (Effectiveness Inhalation: 95%). Concentration of substance: Unless otherwise stated, covers concentrations <=1%. PROC11 (CS25): <=0,5%.

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): Use by professional workers - GES5 Professional end-use of polishes and wax blends 1. Exposure scenario (6)

Short title of the exposure scenario:

Use by professional workers - GES5 Professional end-use of polishes and wax blends

List of use descriptors:

Product category (PC): PC31

Process category (PROC): PROC2, PROC8b, PROC10, PROC11

Environmental release category (ERC): ERC8a

List of names of contributing worker scenarios and corresponding PROCs:

CS2: PROC2 (AISE P605).

CS3: PROC8b (AISE P605).

CS4: PROC10 (AISE P601, P602 (wipe), P603, P604 (wipe), P609 (wipe)).

CS5: PROC10 (AISE P406, P407, P408 (wipe), P608).

CS6: PROC11 (AISE P602 (spray), P604 (spray), P609 (spray)).

CS7: PROC11 (AISE P408 (spray)).

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

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.

PROC11 Non 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.

Name of contributing environmental scenario and corresponding ERCs:

CS1: ERC8a.

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

Further explanations:

PC31 Polishes and wax blends.

Professional Use of Floor care products:

- AISE P406 Polish/impregnating agent: Manual process (PROC10).
- AISE P407 Polish/impregnating agent: Semi-Automatic process (PROC10).
- AISE P408 Polish/impregnating agent: Spray and wipe manual process (PROC10, PROC11).

Professional Use of Maintenance Products:

- AISE P601 Wooden Furniture care product: Manual process (PROC10).
- AISE P602 Wooden Furniture care product: Spray and wipe manual process (PROC10, PROC11).
- AISE P603 Leather care product: Manual process (PROC10).
- AISE P604 Leather care product: Spray and wipe manual process (PROC10, PROC11).
- AISE P605 Leather care product: Semi-automatic process (PROC2, PROC8b).
- AISE P608 Stainless steel care: Manual process (PROC10).
- AISE P609 Stainless steel care: Spray and wipe manual process (PROC10, PROC11)

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). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see http://www.cefic.org/Industry-support/Implementing-reach/Libraries/.

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: <=1%.

Physical state: liquid.

Vapour pressure: 631 Pa at 25 °C; 1660 Pa @ 40°C.

Amounts used:

Application rate (for inhalation exposure): Unless otherwise stated, not specified.

- PROC8b: flow transfer 10-100 L/minute.
- PROC10 (CS4, CS5): <=0,1 L/minute (brushing).
- PROC11 (CS6): low application rate (0,03-0,3 L/minute).
- PROC11 (CS7): low application rate (0,03-0,3 L/minute); use rate <=0,3 L/minute.

Frequency and duration of use/exposure:

Duration of activity:

- PROC2, PROC8b, PROC10 (CS5): <=8 hours/day.
- PROC11 (CS7): <=1 hour/day.
- PROC10 (CS4): <=4 hours/day.
- PROC11 (CS6): <=15 minutes/day

Human factors not influenced by risk management:

Exposed skin surface:

- PROC2: 480 cm2 (two hands, face side only).
- PROC8b, PROC10: 960 cm2 (two hands).
- PROC11: 1500 cm2 (two hands and upper wrists)

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Domain: Professional use.

Process temperature:

- PROC2, PROC8b, PROC10 (CS4): <= 40 °C.
- PROC10 (CS5), PROC11: <= 25 °C.

Assessment tool used:

- PROC2, PROC8b: ECETOC TRA Worker v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure.
- PROC10, PROC11: RiskofDerm Tier 2 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure.

Technical conditions and measures at process level (source) to prevent release:

Activity class - subclass (ART v1.5):

- PROC2: Activities with open liquid surfaces and open reservoirs activities with relatively undisturbed surfaces. Activities with agitated surfaces; open surface 0,3-1 m2. Containment: Low level containment (90% reduction).
- PROC8b: Transfer of liquid products falling liquids; splash loading. Containment: handling that reduces contact between product and adjacent air.
- PROC10 (CS4, CS5): Spreading of liquid products. Spreading of liquids at surfaces or work pieces: 0,3-1 m2/hour. Located in breathing zone of the worker. Tools with handles <30 cm in length.
- PROC11 (CS6): Spray application of liquids surface spraying of liquids. Spray technique: Spraying with no or low compressed air use. Spray direction: Spraying in any direction (including upwards). Located in breathing zone of the worker.
- PROC11 (CS7): Spray application of liquids surface spraying of liquids. Spray technique: Spraying with no or low compressed air use. Spray direction: Downward only. Located in breathing zone of the worker.

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

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

Containment:

- PROC2: Closed continuous process with occasional controlled exposure.
- PROC8b: Semi-closed process with occasional controlled exposure.
- PROC10, PROC11: No.

Local exhaust ventilation: Not required.

Local exhaust ventilation (for dermal): Not required.

Occupational Health and Safety Management System: Basic.

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

Respiratory protection: Not required.

Eye protection: Yes (chemical resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact). Dermal protection:

- PROC2, PROC10, PROC11: No (Effectiveness Dermal: 0%)
- 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.

For tasks where potential splashes may arise, the following personal protective equipment is recommended: face shield, substance/task appropriate gloves and full skin coverage with appropriate light-weight barrier materials (e.g. coveralls).

2.2 Control of environmental exposure

General:

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

Product characteristics:

Physical state: liquid.

Amounts used:

Daily wide dispersive use: 0.0000021 tons/day. Fraction of the main local source: 0.00075. Percentage of tonnage used at regional scale: 4 %.

Frequency and duration of use:

Emission days: <=365 days/year.

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 use.

Professional use.

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

Release fraction to wastewater from process (initial release): 1.0; (final release): 1.0. Local release rate: 0,00214 kg/day.

Release fraction to soil from process (final release): 0,0.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Effectiveness Water: 9,457%).

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

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

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

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: PROC2, PROC8b: ECETOC TRA Worker v3 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure. PROC10, PROC11: RiskofDerm Tier 2 for dermal exposures. Advanced REACH Tool (ART v1.5) for inhalation exposure. 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	0,8 mg/kg bw/day	0,351	PROC11 (CS7)	
Worker, long-term, systemic, Inhalation	2,4 mg/m3	0,299	PROC10 (CS4)	
Worker, long-term, systemic, Combined routes	N/A	0,439	PROC10 (CS5)	
Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,000144 mg/L	<0,01		
Freshwater sediment	0,00289 mg/kg dw	<0,01		
Marine water	0,0000156 mg/L	<0,01		
Marine water sediment	0,000313 mg/kg dw	<0,01		
Soil	0,000117 mg/kg dw	<0,01		
STP	0,000969 mg/L	<0,01		
Human via environment, Inhalation	0,00000484 mg/m3	<0,01		
Human via environment, Oral	0,00000897 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, with gloves (PROC8b), no respirator required. Duration of activity: PROC2, PROC8b, PROC10 (CS5): <=8 hours/day. PROC11 (CS7): <=1 hour/day. PROC10 (CS4): <=4 hours/day. PROC11 (CS6): <=15 minutes/day. Concentration of substance: <=1%.

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): Consumer use - GES6 Consumer end-use of washing and cleaning products

1. Exposure scenario (7)

Short title of the exposure scenario:

Consumer use - GES6 Consumer end-use of washing and cleaning products

List of use descriptors:

Product category (PC): PC35

Environmental release category (ERC): ERC8a, ERC8d

Name of contributing environmental scenario and corresponding ERCs:

CS1: ERC8a, ERC8d.

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:

- Laundry and dish washing products:
- CS2: AISE C1 Laundry regular (powder, liquid);
- CS3: AISE C2 Laundry compact (powder, liquid/gel, tablet);
- CS4: AISE C3 Fabric conditioners (liquid regular, liquid concentrate);
- CS5: AISE C4 Laundry additives (powder bleach, liquid bleach, tablet);
- CS6: AISE C5 Hand dishwashing (liquid regular, liquid concentrate);
- CS7: AISE C6 Machine dishwashing (powder, liquid, tablet);
- CS8: AISE C12 Laundry aids (ironing aids-starch spray, ironing aids-other).
- Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners):
 - CS9: AISE C7 Surface cleaners (liquid);
- CS10: AISE C8 Toilet cleaners (powder, liquid, gel, tablet);
- CS11: AISE C11 Carpet cleaners (liquid);
- CS12: AISE C15 Wipes (bathroom, kitchen, floor);
- CS13: AISE C21 High pressure washers/cleaners (liquid),
- CS14: AISE C22 Automotive care (liquid).
- Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners):
 - CS15: AISE C7 Surface cleaners (spray neat);
- CS16: AISE C10 Oven cleaners (trigger spray);
- CS17: AISE C11 Carpet cleaners (spray);
- CS18: AISE C22 Automotive care (spray).

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). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see http://www.cefic.org/Industry-support/Implementing-reach/Libraries/.

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in mixture:

- CS2, CS3, CS5-CS7: <= 0,05%
- CS4, CS8-CS10, CS12, CS13, CS15-CS17: <= 0,1%.
- CS11: <=0,015%.
- CS14: <=0,15%.
- CS18: <=0,25%.

Physical state: liquid.

Vapour pressure: 631 Pa at 25 °C

Exposure via inhalation route: Yes.

Exposure via dermal route: Yes.

Oral contact foreseen: No.

Spray: CS2-CS14: No. CS15-CS18: Yes

Amounts used:

Applied amounts for each use event:

- CS2: 150 g.
- CS3: 90 g.
- CS4: 135 g.
- CS5: 70 g.
- CS6, CS7, CS13: 50 g.
- CS8: 10 g. - CS9: 60 g.
- CS10. CS16, CS17: 35 g. - CS11: 250 g.
- CS12: 26 g.
- CS14: 200 g.
- CS15: 30 g.
- CS18: 16,2 g; Inhalation mass generation rate 0,8 g/sec; Dermal contact rate 46 mg/min for 24,6 sec (0,41 min)

Frequency and duration of use/exposure:

Duration covers exposure up to:

- CS2-CS5: 1 hour/event. Exposure time per event: 0,17 hour/event.
- CS6: 1 hour/event. Exposure time per event: 0,5 hour/event.
- CS7: 1 hour/event. Exposure time per event: 0,017 hour/event.
- CS8: 1 hour/event.
- CS9, CS11, CS15: 0.33 hour/event.

- CS10: 0,017 hour/event.
- CS12: 0,083 hour/event.
- CS13, CS14: 5 hours/event.
- CS16, CS17: 4 hours/event.
- CS18: 1 hour/event (inhalation), 0,41 minutes/event (dermal). Exposure time per event: 5 hours/event.

Frequency - covers use frequency: Unless otherwise stated, up to 1 time/day; frequent use per year.

- CS6: up to 2 times/day; frequent use per year.
- CS13, CS14, CS18: up to 1 time/day; infrequent use per year.

Human factors not influenced by risk management:

Exposed skin surface: Hands. Inhalation factor = 1. Dermal transfer factor=1.

Other given operational conditions affecting consumers exposure:

Location: Indoor use.

Body weight: Unless otherwise stated, 60 kg.

- CŚ7: 8.7 kg (child).

Inhalation exposure model - covers use in room size of:

- CS2-CS8: 20 m3.
- CS10: 2,5 m3.
- CS18: 4 m3.

Inhalation exposure model - Release area:

- CS10: 0,075 m2.
- CS18: 1,7 m2.

Skin contact area:

- CS2-CS8: up to 857,5 cm2
- CS18: up to 215 cm2.

Conditions and measures related to information and behavioral advice to consumers:

Assessment tool used: ECETOC TRA v3.1 (R15) model (consumer module) in which: Fragrance concentration in fragranced end-product from the IFRA guidance (2012) is used at Tier 1.5 level consumer risk assessment; further parameters are refined if necessary (Refined Tier 1.5) using the table of habits and practices for consumer products in western Europe from AISE (2009). CS2, CS4, CS6, CS9, CS15: Tier 2 AISE REACT 1.0 Consumer Tool used for inhalation and dermal exposures.

Conditions and measures related to personal protection and hygiene:

General ventilation:

- CS10: Ventilation rate: 2.0 air changes/ hour.
- CS18: Ventilation rate: 2.5 air changes/ hour.

2.2 Control of environmental exposure

General:

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

Product characteristics:

Physical state: liquid.

Amounts used:

Daily wide dispersive use: 0.0000021 tons/day.

Fraction of the main local source: 0.00075.

Percentage of tonnage used at regional scale: 4 %.

Frequency and duration of use:

Emission days: <=365 days/year.

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): 1.0; (final release): 1.0. Local release rate: 0,00214 kg/day.

Release fraction to soil from process (final release): 0,20.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Effectiveness Water: 9,457%).

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

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

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

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: PC35 (CS3, CS5, CS7, CS8, CS10-CS14, CS16-CS18): TRA Consumer v3.1 (R15). PC35 (CS2, CS4, CS6, CS9, CS15): AISE REACT 1.0 Consumer Tool. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment Exposure estimate/PEC RCR Notes

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Consumer, long-term, systemic, Dermal	0,143 mg/kg bw/day	0,176	PC35 (CS8-CS10, CS12, CS15-CS17)
Consumer, long-term, systemic, Inhalation	0,522 mg/m3	0,435	PC35 (CS11)
Consumer, long-term, systemic, Oral	0,0000025 mg/kg bw/day	<0,01	PC35 (CS6)
Consumer, long-term, systemic, Combined routes	N/A	0,497	PC35 (CS10)
Environment			
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Freshwater	0,000144 mg/L	<0,01	
Freshwater sediment	0,00289 mg/kg dw	<0,01	
Marine water	0,0000156 mg/L	<0,01	
Marine water sediment	0,000313 mg/kg dw	<0,01	
Soil	0,000117 mg/kg dw	<0,01	
STP	0,000969 mg/L	<0,01	
Human via environment, Inhalation	0,00000484 mg/m3	<0,01	
Human via environment, Oral	0,00000897 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 (8): Consumer use - GES7 Consumer end-use of air care products

1. Exposure scenario (8)

Short title of the exposure scenario:

Consumer use - GES7 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:

CS1: ERC8a

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

Further explanations:

PC3 Air care products:

- CS2: AISE C17 Air fresheners aerosol (aqueous, non-aqueous, concentrated (mini-aerosol, timed release aerosol)).
- CS3: AISE C18 Air fresheners non aerosol (perfume in/on solid substrate (gel), diffusers (heated), candles).

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). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see http://www.cefic.org/Industry-support/Implementing-reach/Libraries/.

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in mixture:

- CS2: <= 0,25%.
- CS3: <= 5,0%

Physical state: liquid.

Vapour pressure: 631 Pa at 25 °C Exposure via inhalation route: Yes.

Exposure via dermal route: CS2: Dermal exposure assumed to be negligible. CS3: Yes.

Oral contact foreseen: No.

Spray: CS2: Yes. CS3: No.

Amounts used:

Applied amounts for each use event:

- CS2: 8,4 g.
- CS3: 0,42 g.

Frequency and duration of use/exposure:

Duration covers exposure up to:

- CS2: 0.25 hours/event.
- CS3: 8 hours/event.

Frequency - covers use frequency: up to 1 time/day; frequent use per year.

Human factors not influenced by risk management:

Body parts potentially exposed: CS3: fingertips.

Inhalation factor = 1.

Dermal transfer factor=1

Other given operational conditions affecting consumers exposure:

Location: Indoor use. Body weight: 60 kg.

Conditions and measures related to information and behavioral advice to consumers:

Assessment tool used: ECETOC TRA v3.1 (R15) model (consumer module) in which: Fragrance concentration in fragranced end-product from the IFRA guidance (2012) is used at Tier 1.5 level consumer risk assessment; further parameters are refined if necessary (Refined Tier 1.5) using the table of habits and practices for consumer products in western Europe from AISE (2009). CS3: Tier 2 AISE REACT 1.0 Consumer Tool used for inhalation and dermal exposures.

2.2 Control of environmental exposure

General:

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

Product characteristics:

Physical state: liquid.

Amounts used:

Daily wide dispersive use: 0.0000021 tons/day. Fraction of the main local source: 0.00075. Percentage of tonnage used at regional scale: 4 %.

Frequency and duration of use:

Emission days: <=365 days/year.

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 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): 1.0; (final release): 1.0. Local release rate: 0,00214 kg/day.

Release fraction to soil from process (final release): 0,0.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Effectiveness Water: 9,457%).

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

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

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

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: PC3 (CS2): TRA Consumer v3.1 (R15). PC3 (CS3): AISE REACT 1.0 Consumer Tool. 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>	
Consumer, long-term, systemic, Dermal	0 mg/kg bw/day	<0,01	PC3	
Consumer, long-term, systemic, Inhalation	0,347 mg/m3	0,289	PC3 (CS2)	
Consumer, long-term, systemic, Oral	0 mg/kg bw/day	<0,01	PC3	
Consumer, long-term, systemic, Combined routes	N/A	0,289	PC3 (CS2)	
Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,000144 mg/L	<0,01		
Freshwater sediment	0,00289 mg/kg dw	<0,01		
Marine water	0,0000156 mg/L	<0,01		
Marine water sediment	0,000313 mg/kg dw	<0,01		
Soil	0,000117 mg/kg dw	<0,01		
STP	0,000969 mg/L	<0,01		
Human via environment, Inhalation	0,00000484 mg/m3	<0,01		
Human via environment, Oral	0,00000897 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 (9): Consumer use - GES8 Consumer end-use of biocides

1. Exposure scenario (9)

Short title of the exposure scenario:

Consumer use - GES8 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:

CS1: ERC8a, ERC8d.

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:

- CS2: AISE C19 Insecticides (spray neat).
- CS3: AISE C19 Insecticides (liquid electric).
- CS4: AISE C19 Repellents.

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). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see http://www.cefic.org/Industry-support/Implementing-reach/Libraries/.

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in mixture:

- CS2, CS3: <=1%.
- CS4: <= 0,25%.

Physical state: liquid.

Vapour pressure: 631 Pa at 25 °C

Exposure via inhalation route: CS2, CS3: Yes. CS4: Not relevant.

Exposure via dermal route: CS2: Dermal exposure assumed to be negligible. CS3, CS4: Yes.

Oral contact foreseen: CS2, CS3: No. CS4: Yes.

Spray: CS2: Yes. CS3, CS4: No.

Amounts used:

Applied amounts for each use event:

- CS2: 10.1 g. Inhalation mass generation rate 0,8 g/sec for spray duration <= 10 minutes; Dermal contact rate 46 mg/min for 10 minutes.
- CS3: 50 g. Inhalation mass generation rate 0,000022 g/sec for spray duration <= 480 minutes.
- CS4: 6 g. Ingestion rate 0,00133 g/min for 180 minutes.

Frequency and duration of use/exposure:

Duration covers exposure up to:

- CS2: <=10 minutes/event (dermal); <=240 minutes/event (inhalation).
- CS3: <=8 hours/event.
- CS4: <=180 minutes/event.

Frequency - covers use frequency: up to 1 time/day; frequent use per year.

Human factors not influenced by risk management:

Body parts potentially exposed:

- CS2: dermal exposure negligible compared to inhalation.
- CS3: fingertips.
- CS4: skin contact area up to 1124 cm2.

Inhalation factor = 1.

Dermal transfer factor=1.

Oral transfer factor = 1.

Other given operational conditions affecting consumers exposure:

Location: Indoor/outdoor use.

Body weight: 60 kg.

Inhalation exposure model: CS2 - Covers use in room size of 58 m3; CS3 - Covers use in room size of 16 m3.

Conditions and measures related to information and behavioral advice to consumers:

Assessment tool used: ECETOC TRA v3.1 (R15) model (consumer module) in which: Fragrance concentration in fragranced end-product from the IFRA guidance (2012) is used at Tier 1.5 level consumer risk assessment; further parameters are refined if necessary (Refined Tier 1.5) using the table of habits and practices for consumer products in western Europe from AISE (2009). Tier 2 ConsExpo v5.0 b01 according to the product sub category specific fact sheet for PC8.

Conditions and measures related to personal protection and hygiene:

General ventilation: ventilation rate:

- CS2: 0,5 air changes/ hour.
- CS3: 1 air changes/ hour.

2.2 Control of environmental exposure

Product characteristics:

Physical state: liquid.

Amounts used:

Daily wide dispersive use: 0.0000021 tons/day. Fraction of the main local source: 0.00075. Percentage of tonnage used at regional scale: 4 %.

Frequency and duration of use:

Emission days: <=365 days/year.

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): 1.0; (final release): 1.0. Local release rate: 0,00214 kg/day.

Release fraction to soil from process (final release): 0,20.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Effectiveness Water: 9,457%).

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

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

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

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); ConsExpo v5.0 b01. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	<u>Notes</u>	
Consumer, long-term, systemic, Dermal	0,25 mg/kg bw/day	0,307	PC8 (CS4)	
Consumer, long-term, systemic, Inhalation	0,076 mg/m3	0,063	PC8 (CS2)	
Consumer, long-term, systemic, Oral	0,01 mg/kg bw/day	0,012	PC8 (CS4)	
Consumer, long-term, systemic, Combined routes	N/A	0,32	PC8 (CS4)	

Environment				
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,000144 mg/L	<0,01		
Freshwater sediment	0,00289 mg/kg dw	<0,01		
Marine water	0,0000156 mg/L	<0,01		
Marine water sediment	0,000313 mg/kg dw	<0,01		
Soil	0,000117 mg/kg dw	<0,01		
STP	0,000969 mg/L	<0,01		
Human via environment, Inhalation	0,00000484 mg/m3	<0,01		
Human via environment, Oral	0,00000897 mg/kg bw/day	<0,01	·	

<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

N/A

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 (10): Consumer use - GES9 Consumer end-use of polishes and wax blends

1. Exposure scenario (10)

Short title of the exposure scenario:

Human via environment, Combined routes

Consumer use - GES9 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:

CS1: ERC8a.

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

Further explanations:

PC31 Polishes and wax blends.

- CS2: AISE C20 Furniture floor and leather care: waxes and creams (floor, furniture, shoes).
- CS3: AISE C20 Furniture floor and leather care: spray (furniture, shoes).

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). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see http://www.cefic.org/Industry-support/Implementing-reach/Libraries/.

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in mixture:

- CS2: <= 0.05%.
- CS3: <= 0,1%.

Physical state: liquid.

Vapour pressure: 631 Pa at 25 °C

Exposure via inhalation route: Yes.

Exposure via dermal route: Yes.

Oral contact foreseen: No.

Spray: CS2: No. CS3: Yes.

Average molecular weight of the matrix (product minus the compound of interest):

- CS2 (floor polish): 22 g/mol.
- CS2 (shoe cream): 18 g/mol.
- CS2 (furniture polish): 272 g/mol.

Mass transfer coefficient: 10 m/hour.

Amounts used:

Applied amounts for each use event:

- CS2: 550 g
- CS3: 135 g

Frequency and duration of use/exposure:

Duration covers exposure up to:

- CS2: <= 90 minutes/event.
- CS3: <=0,33 hours/event.

Frequency: covers use frequency:

- CS2 (floor polish), CS3: up to 1 time/day; frequent use per year.
- CS2 (shoe cream): up to 1 time/day; 12 times/year.
- CS2 (furniture polish): up to 1 time/day; 2 times/year

Human factors not influenced by risk management:

Exposed skin surface: Hands.

Inhalation factor = 1.

Dermal transfer factor = 1.

Other given operational conditions affecting consumers exposure:

Location: Indoor use. Body weight: 60 kg.

Inhalation exposure model: CS2 - Covers use in room size of 58 m3.

Inhalation exposure model - Release area: CS2: 22 m2.

Skin contact area: CS2: up to 225 cm2.

Conditions and measures related to information and behavioral advice to consumers:

Assessment tool used: ECETOC TRA v3.1 (R15) model (consumer module) in which: Fragrance concentration in fragranced end-product from the IFRA guidance (2012) is used at Tier 1.5 level consumer risk assessment; further parameters are refined if necessary (Refined Tier 1.5) using the table of habits and practices for consumer products in western Europe from AISE (2009).

- CS2: Tier 2 ConsExpo v5.0 b01 according to the Cleaning products sub category specific fact sheet.
- CS3: Tier 2 AISE REACT 1.0 Consumer Tool used for inhalation and dermal exposures

Conditions and measures related to personal protection and hygiene:

General ventilation: ventilation rate: CS2: 0,5 air changes/ hour.

2.2 Control of environmental exposure

General:

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

Product characteristics:

Physical state: liquid.

Amounts used:

Daily wide dispersive use: 0.0000021 tons/day.

Fraction of the main local source: 0.00075.

Percentage of tonnage used at regional scale: 4 %.

Frequency and duration of use:

Emission days: <=365 days/year.

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 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): 1.0; (final release): 1.0. Local release rate: 0,00214 kg/day.

Release fraction to soil from process (final release): 0,0.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Effectiveness Water: 9,457%).

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

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

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

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: PC31 (CS2): TRA Consumer v3.1 (R15); ConsExpo v5.0 b01. PC31 (CS3): AISE REACT 1.0 Consumer Tool. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	<u>Notes</u>
Consumer, long-term, systemic, Dermal	0,062 mg/kg bw/day	0,076	PC31 (CS3)
Consumer, long-term, systemic, Inhalation	0,375 mg/m3	0,312	PC31 (CS2 (floor polish))
Consumer, long-term, systemic, Oral	0 mg/kg bw/day	<0,01	
Consumer, long-term, systemic, Combined routes	N/A	0,313	PC31 (CS2 (floor polish))
Environment			
Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>
Freshwater	0,000144 mg/L	<0,01	
Freshwater sediment	0,00289 mg/kg dw	<0,01	
Marine water	0,0000156 mg/L	<0,01	
Marine water sediment	0,000313 mg/kg dw	<0,01	
Soil	0,000117 mg/kg dw	<0,01	
STP	0,000969 mg/L	<0,01	
Human via environment, Inhalation	0,00000484 mg/m3	<0,01	
Human via environment, Oral	0,00000897 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 (11): Consumer use - GES10 Consumer end-use of cosmetics

1. Exposure scenario (11)

Short title of the exposure scenario:

Consumer use - GES10 Consumer end-use of cosmetics

List of use descriptors:

Product category (PC): PC39

Environmental release category (ERC): ERC8a

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). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see http://www.cefic.org/Industry-support/Implementing-reach/Libraries/.

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

General:

For cosmetic and personal care products, risk assessment only required for the environment under REACH as human health is covered by alternative legislation.

2.2 Control of environmental exposure

General:

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

Product characteristics:

Physical state: liquid.

Amounts used:

Daily wide dispersive use: 0.0000028 tons/day.

Fraction of the main local source: 0.00075.

Percentage of tonnage used at regional scale: 5,3 %.

Frequency and duration of use:

Emission days: <=365 days/year.

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): 1.0; (final release): 1.0. Local release rate: 0,00283 kg/day.

Release fraction to soil from process (final release): 0,0.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Effectiveness Water: 9,457%).

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

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

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

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-Environment: EUSES 2.1.2.

Environment

Effect/Compartment	Exposure estimate/PEC	<u>RCR</u>	<u>Notes</u>	
Freshwater	0,000175 mg/L	<0,01		
Freshwater sediment	0,00352 mg/kg dw	<0,01		
Marine water	0,0000188 mg/L	<0,01		
Marine water sediment	0,000376 mg/kg dw	<0,01		
Soil	0,000152 mg/kg dw	<0,01		
STP	0,00128 mg/L	<0,01		
Human via environment, Inhalation	0,00000485 mg/m3	<0,01		
Human via environment, Oral	0,0000109 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

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.