

0000 8096 Orange Terpenes (d-limonene)

 Version number: V 10.0
 Replaces version of: 04.12.2024 (V 9)

Revision: 04.12.2024

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

1.1 Product identifier

Identification of the substance	Orange Terpenes (d-limonene)
Registration number (REACH)	01-2119493353-35-0024
EC number	232-433-8
CAS number	8028-48-6, 8008-57-9
Article number	0000 8096

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

Relevant identified uses	Professional use
Uses advised against	The product is not intended for consumer use.

1.3 Details of the supplier of the safety data sheet

 Johann Voegele KG
 Bahnhofstraße 143
 D-74348 Lauffen a.N.
 Germany

 Telephone: +49 7133 9802 - 0
 Telefax: +49 7133 9802 - 60
 e-mail: info@voegele-ingredients.de
 Website: www.voegele-ingredients.de
 e-mail (competent person)

 MSDS@voegele-ingredients.de
 (Regulatory Affairs)

1.4 Emergency telephone number

Emergency information service	+49 (0) 700 24 112 112 (JVC)
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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification acc. to GHS

Section	Hazard class	Hazard class and category	Hazard statement
2.6	flammable liquid	Flam. Liq. 3	H226
3.2	skin corrosion/irritation	Skin Irrit. 2	H315
3.4S	skin sensitisation	Skin Sens. 1	H317
3.10	aspiration hazard	Asp. Tox. 1	H304
4.1C	hazardous to the aquatic environment - chronic hazard	Aquatic Chronic 2	H411

For full text of abbreviations: see SECTION 16.

2.2 Label elements

Labelling

- Signal word danger

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- Pictograms

GHS02, GHS07,
GHS08, GHS09



- Hazard statements

H226 Flammable liquid and vapour.
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H411 Toxic to aquatic life with long lasting effects.

- Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/....
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P331 Do NOT induce vomiting.
P370+P378 In case of fire: Use sand, carbon dioxide or powder extinguisher to extinguish.
P403+P235 Store in a well-ventilated place. Keep cool.

2.3 Other hazards

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance Orange Terpenes (d-limonene)
Identifiers
CAS No 8028-48-6, 8008-57-9

Impurities and additives, classification acc. to GHS		
Name of substance	Identifier	Wt%
d-Limonene	CAS No 5989-27-5 68606-81-5	≥ 90
Myrcene	CAS No 123-35-3	1 – < 3
Eukalyptol (1.8-Cineol)	CAS No 470-82-6	< 1
beta-Pinene	CAS No 127-91-3	< 1
Linalool	CAS No 78-70-6	< 1
alpha-Phellandrene	CAS No 99-83-2	< 1

Remarks

For full text of abbreviations: see SECTION 16

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SECTION 4: First aid measures**4.1 Description of first aid measures****General notes**

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician. Provide fresh air.

Following skin contact

Wash with plenty of soap and water.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media**

Water spray, BC-powder, Carbon dioxide (CO₂)

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture. Solvent vapours are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures.

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures****For non-emergency personnel**

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

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6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Avoidance of ignition sources. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge. Use only in well-ventilated areas. Due to danger of explosion, prevent leakage of vapours into cellars, flues and ditches. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools.

- Specific notes/details

Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures. Vapours are heavier than air, spread along floors and form explosive mixtures with air. Vapours may form explosive mixtures with air.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- Explosive atmospheres

Keep container tightly closed and in a well-ventilated place. Use local and general ventilation. Keep cool. Protect from sunlight.

- Flammability hazards

Keep away from sources of ignition - No smoking. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge. Protect from sunlight.

- Ventilation requirements

Use local and general ventilation. Ground/bond container and receiving equipment.

- Packaging compatibilities

Only packagings which are approved (e.g. acc. to the Dangerous Goods Regulations) may be used.

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters**

Occupational exposure limit values (Workplace Exposure Limits)
this information is not available

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Human health values

Relevant DNELs and other threshold levels				
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
DNEL	31.1 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
DNEL	8.89 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
DNEL	185.8 µg/cm ²	human, dermal	worker (industry)	acute - local effects

Relevant DNELs of components						
Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
d-Limonene	5989-27-5 68606-81-5	DNEL	66.7 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
d-Limonene	5989-27-5 68606-81-5	DNEL	9.5 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Eukalyptol (1.8-Cineol)	470-82-6	DNEL	7.05 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
Eukalyptol (1.8-Cineol)	470-82-6	DNEL	2 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
beta-Pinene	127-91-3	DNEL	5.69 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
beta-Pinene	127-91-3	DNEL	0.8 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
beta-Pinene	127-91-3	DNEL	54 µg/cm ²	human, dermal	worker (industry)	chronic - local effects
Linalool	78-70-6	DNEL	16.5 mg/m ³	human, inhalatory	worker (industry)	acute - systemic effects
Linalool	78-70-6	DNEL	5 mg/kg bw/day	human, dermal	worker (industry)	acute - systemic effects
Linalool	78-70-6	DNEL	24.58 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
Linalool	78-70-6	DNEL	3.5 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

Environmental values

Relevant PNECs and other threshold levels				
End-point	Threshold level	Organism	Environmental compartment	Exposure time
PNEC	5.4 µg/l	aquatic organisms	freshwater	short-term (single instance)
PNEC	0.54 µg/l	aquatic organisms	marine water	short-term (single instance)
PNEC	2.1 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
PNEC	1.3 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
PNEC	0.13 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
PNEC	0.261 mg/kg	terrestrial organisms	soil	short-term (single instance)

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Relevant PNECs of components						
Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
d-Limonene	5989-27-5 68606-81-5	PNEC	14 µg/l	aquatic organ- isms	freshwater	short-term (single instance)
d-Limonene	5989-27-5 68606-81-5	PNEC	1.4 µg/l	aquatic organ- isms	marine water	short-term (single instance)
d-Limonene	5989-27-5 68606-81-5	PNEC	1.8 mg/l	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
d-Limonene	5989-27-5 68606-81-5	PNEC	3.85 mg/kg	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
d-Limonene	5989-27-5 68606-81-5	PNEC	0.385 mg/ kg	aquatic organ- isms	marine sediment	short-term (single instance)
d-Limonene	5989-27-5 68606-81-5	PNEC	0.763 mg/ kg	terrestrial organ- isms	soil	short-term (single instance)
Eukalyptol (1.8-Cin- eol)	470-82-6	PNEC	57 µg/l	aquatic organ- isms	freshwater	short-term (single instance)
Eukalyptol (1.8-Cin- eol)	470-82-6	PNEC	5.7 µg/l	aquatic organ- isms	marine water	short-term (single instance)
Eukalyptol (1.8-Cin- eol)	470-82-6	PNEC	10 mg/l	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Eukalyptol (1.8-Cin- eol)	470-82-6	PNEC	1.425 mg/ kg	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Eukalyptol (1.8-Cin- eol)	470-82-6	PNEC	0.142 mg/ kg	aquatic organ- isms	marine sediment	short-term (single instance)
Eukalyptol (1.8-Cin- eol)	470-82-6	PNEC	0.25 mg/kg	terrestrial organ- isms	soil	short-term (single instance)
beta-Pinene	127-91-3	PNEC	1.004 µg/l	aquatic organ- isms	freshwater	short-term (single instance)
beta-Pinene	127-91-3	PNEC	0.1 µg/l	aquatic organ- isms	marine water	short-term (single instance)
beta-Pinene	127-91-3	PNEC	3.26 mg/l	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
beta-Pinene	127-91-3	PNEC	0.337 mg/ kg	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
beta-Pinene	127-91-3	PNEC	0.034 mg/ kg	aquatic organ- isms	marine sediment	short-term (single instance)
beta-Pinene	127-91-3	PNEC	0.067 mg/ kg	terrestrial organ- isms	soil	short-term (single instance)
Linalool	78-70-6	PNEC	0.2 mg/l	aquatic organ- isms	freshwater	short-term (single instance)
Linalool	78-70-6	PNEC	0.02 mg/l	aquatic organ- isms	marine water	short-term (single instance)
Linalool	78-70-6	PNEC	10 mg/l	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Linalool	78-70-6	PNEC	2.22 mg/kg	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Linalool	78-70-6	PNEC	0.222 mg/ kg	aquatic organ- isms	marine sediment	short-term (single instance)
Linalool	78-70-6	PNEC	0.327 mg/ kg	terrestrial organ- isms	soil	short-term (single instance)

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8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

- Type of material

NBR: acrylonitrile-butadiene rubber

- Material thickness

> 0.7 mm

- Breakthrough times of the glove material

>10 minutes (permeation: level 1)

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Filtering half mask (EN 149). Type: A (against organic gases and vapours with a boiling point of > 65 °C, colour code: Brown).

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	orange
Odour	characteristic
Melting point/freezing point	<-25 °C
Boiling point or initial boiling point and boiling range	not determined
Flammability	flammable liquid in accordance with GHS criteria
Lower and upper explosion limit	not determined
Flash point	53.4 °C
Auto-ignition temperature	235 °C at 1,016 hPa (ECHA)
Decomposition temperature	not relevant
pH (value)	not determined

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Kinematic viscosity	1.17 mm ² /s at 20 °C
Solubility(ies)	not determined

Partition coefficient

Partition coefficient n-octanol/water (log value)	2.78 – 4.88 (ECHA)
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Vapour pressure	186.4 Pa at 25 °C
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Density and/or relative density

Density	0.846 g/cm ³ at 20 °C
Relative vapour density	information on this property is not available

Particle characteristics	not relevant (liquid)
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9.2 Other information

Information with regard to physical hazard classes	there is no additional information
Other safety characteristics	there is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials". It's a reactive substance. The mixture contains reactive substance(s). Risk of ignition.

If heated:

Risk of ignition

10.2 Chemical stability

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hints to prevent fire or explosion

Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools. Take precautionary measures against static discharge.

10.5 Incompatible materials

Oxidisers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Classification acc. to GHS

Acute toxicity

The classification criteria for these hazard classes are not met.
GHS of the United Nations, annex 4: May be harmful if swallowed.

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

May be fatal if swallowed and enters airways.

11.2 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Toxic to aquatic life with long lasting effects.

Aquatic toxicity (acute)			
Endpoint	Value	Species	Exposure time
LL50	5.65 mg/l	fish	96 h
EL50	1.4 mg/l	aquatic invertebrates	24 h

12.2 Persistence and degradability

Biodegradation

The substance is readily biodegradable.

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Degradability of components

Name of sub-stance	CAS No	Process	Degradation rate	Time	Method	Source
d-Limonene	5989-27-5 68606-81-5	carbon dioxide generation	58.8 %	14 d		ECHA
d-Limonene	5989-27-5 68606-81-5	oxygen depletion	80 %	28 d		ECHA
Myrcene	123-35-3	oxygen depletion	76 %	28 d		ECHA
Eukalyptol (1.8-Cineol)	470-82-6	carbon dioxide generation	82 %	28 d		ECHA
Linalool	78-70-6	oxygen depletion	40.9 %	5 d		ECHA

12.3 Bioaccumulative potential

Data are not available.

n-octanol/water (log KOW)	2.78 – 4.88 (ECHA)
BCF	32 – 156 (ECHA)

Bioaccumulative potential of components

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
d-Limonene	5989-27-5 68606-81-5		4.38 (pH value: 7.2, 37 °C)	
Myrcene	123-35-3		4.82 (pH value: ~6.5, 30 °C)	
Eukalyptol (1.8-Cineol)	470-82-6		3.4	
beta-Pinene	127-91-3		4.425 (25 °C)	
Linalool	78-70-6		2.9 (pH value: 7, 20 °C)	

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste treatment-relevant information

Solvent reclamation/regeneration.

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packageings

Only packageings which are approved (e.g. acc. to the Dangerous Goods Regulations) may be used. Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

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Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

14.1 UN number or ID number

UN RTDG	UN 1197
IMDG-Code	UN 1197
ICAO-TI	UN 1197

14.2 UN proper shipping name

UN RTDG	EXTRACTS, LIQUID
IMDG-Code	EXTRACTS, LIQUID
ICAO-TI	Extracts, liquid

14.3 Transport hazard class(es)

UN RTDG	3
IMDG-Code	3
ICAO-TI	3

14.4 Packing group

UN RTDG	III
IMDG-Code	III
ICAO-TI	III

14.5 Environmental hazards

hazardous to the aquatic environment

14.6 Special precautions for user

There is no additional information.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

Information for each of the UN Model Regulations

Transport information - National regulations - Additional information (UN RTDG)

UN number	1197
Class	3
Environmental hazards	yes (hazardous to the aquatic environment)
Packing group	III
Danger label(s)	3, fish and tree



Special provisions (SP)	223 (UN RTDG)
Excepted quantities (EQ)	E1 (UN RTDG)
Limited quantities (LQ)	5 L (UN RTDG)

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International Maritime Dangerous Goods Code (IMDG) - Additional information

Particulars in the shipper's declaration UN1197, EXTRACTS, LIQUID, (d-Limonene), 3, III, 53.4°C c.c., MARINE POLLUTANT

Marine pollutant yes (hazardous to the aquatic environment)

Danger label(s) 3, fish and tree



Special provisions (SP) 223, 955

Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

EmS F-E, S-D

Stowage category A

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Particulars in the shipper's declaration UN1197, Extracts, liquid, 3, III

Environmental hazards yes (hazardous to the aquatic environment)

Danger label(s) 3



Special provisions (SP) A3

Excepted quantities (EQ) E1

Limited quantities (LQ) 10 L

SECTION 15: Regulatory information

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

There is no additional information.

National inventories

Country	Inventory	Status
CA	DSL	substance is listed
EU	REACH Reg.	substance is listed
US	TSCA	substance is listed (ACTIVE)
AU	AIIC	substance is listed
CN	IECSC	substance is listed
KR	KECI	substance is listed
MX	INSQ	substance is listed
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TR	CICR	substance is listed
TW	TCSI	substance is listed
EU	ECSI	substance is listed

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Country	Inventory	Status
VN	NCI	substance is listed

Legend

AIIC	Australian Inventory of Industrial Chemicals
CICR	Chemical Inventory and Control Regulation
DSL	Domestic Substances List (DSL)
ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
INSQ	National Inventory of Chemical Substances
KECI	Korea Existing Chemicals Inventory
NCI	National Chemical Inventory
NZIoC	New Zealand Inventory of Chemicals
PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg.	REACH registered substances
TCSI	Taiwan Chemical Substance Inventory
TSCA	Toxic Substance Control Act

15.2 Chemical safety assessment

For this substance a chemical safety assessment has been carried out.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
EL50	Effective Loading 50 %: the EL50 corresponds to the loading rate required to produce a response in 50% of the test organisms
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
LL50	Lethal Loading 50 %: the LL50 corresponds to the loading rate causing 50 % lethality
log KOW	n-Octanol/water

0000 8096 Orange Terpenes (d-limonene)

Version number: V 10.0
Replaces version of: 04.12.2024 (V 9)

Revision: 04.12.2024

Abbr.	Descriptions of used abbreviations
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
UN RTDG	UN Recommendations on the Transport of Dangerous Good
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

UN Recommendations on the Transport of Dangerous Good. International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H226	Flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H411	Toxic to aquatic life with long lasting effects.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

ES FOR COMMUNICATION

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Substance Name: Orange oil

EC Number: 232-433-8

CAS Number: 8028-48-6

Registration Number:

Date of Generation/Revision: 2012-04-23

Author: Royal Haskoning

Reader guide to the appendix

The appendix to the exposure scenario describes how Orange oil can be extracted from the fruit/plant material, processed and used in an industrial, professional or consumer setting.

The table of contents will help you to find your particular type of use of the substance Orange oil. The name of each exposure scenario describes both the covered activity and information on the type of facility and type of product covered. You only need to concern yourself with the scenarios describing uses applicable to your own use and those of your users.

In the sections relating to each use, you will find which uses are covered and what operational conditions and risk management measures are needed to use the substance safely. Each exposure scenario is built up as follows:

Section 1: Title of the exposure scenario. Provides the relevant Environmental Release Categories (ERCs) and Process Categories (PROCs) for contributing scenarios, together with a description of the activities covered.

Section 2: Conditions of use affecting exposure. Provides an overview of the operational conditions and risk management measures used for the risk characterization for each of the contributing scenarios covered.

For the environmental assessment the following information is present:

- Maximum amount per site (both daily and yearly)
- Maximum number of emission days
- Minimum flow of a river onto which the STP discharges its effluent
- Information regarding the treatment of waste water (including the minimum STP discharge rate)

For the worker exposure the following information is present:

- % of Orange oil in any mixtures used
- The form of the mixture in which Orange oil is used

Most items listed in the subsection "Other operational conditions" are a refined description of the process category covered. NB: if a use differs from the description, it should be verified using the information in section 4 if the use is actually covered. The following information can be found here (among others):

- Maximum duration of use per shift
- Indoor or outdoor use
- Assumed process temperature

In the subsection "Technical and operational conditions and measures" an overview of the risk management measures that need to be in place is given.

Section 3: Exposure estimation and reference to its source. This section contains information on the exposure estimation methods, the calculated exposure values and risk characterization ratios (RCR). This section can be used in the generation of a mixture (extended) Safety Data Sheet, when scaling is used to determine if a use is covered, or when a downstream user performs his own Chemical Safety Assessment. When making a downstream user assessment or when applying scaling, the RCR listed in Section 3 may not be exceeded.

Section 4: Guidance to DU to evaluate whether he works inside the boundaries set by the ES. This section provides guidance to the downstream user to determine if he works within the boundaries set in the exposure scenario. It provides information which can be used in scaling operations, e.g. the assumed effectiveness of risk management measures.

0. Good practices applicable to all worker ES

Generic organisational measures

- Minimise number of staff exposed;
- Minimisation of manual phases;
- 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 followed;
- Training for staff on good practice;
- Good standard of personal hygiene.

Generic personal protective equipment

PPE for sensitizers (98% effective dermal)

- Substance/task appropriate gloves [PPE18];
- Skin coverage with appropriate barrier material based on potential for contact with the chemicals;
- Substance/task appropriate respirator;
- Optional face shield;
- Eye protection.

1. ES 1: Manufacturing stage; Manufacturing of Orange oil

1. Title of Exposure scenario	
Environment: * ENV1a Extraction of fruits/plant material and processing of oil/water emulsion * ENV1b Extraction of fruits/plant material and processing of oil/water emulsion * ENV2 Further refinement of essential oils	ERC 1
Worker	
Manufacture in closed process, no likelihood of exposure	PROC 1
Manufacture in closed, continuous process with occasional controlled exposure	PROC 2
Manufacture in closed batch process (synthesis or formulation)	PROC 3
Manufacture in batch and other process (synthesis) where opportunity for exposure arises	PROC 4
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	PROC 8b
Use as laboratory reagent	PROC 15
2. Conditions of use affecting exposure	
2.1 Control of environmental exposure: ENV1a Extraction of fruits/plant material and processing of oil/water emulsion (ERC 1) ENV1b Extraction of fruits/plant material and processing of oil/water emulsion (ERC 1) ENV2 Further refinement of essential oils (ERC 1)	
2.1.1 Control of environmental exposure: ENV1a Extraction of fruits/plant material and processing of oil/water emulsion (ERC 1)	
Amounts used	
Daily amount per site <= 17.5 tonnes/day	
Annual amount per site <= 3.5E3 tonnes/year	
Frequency and duration of use	
Emission days / year = 200 days/year	
Other given operational conditions affecting environmental exposure	
Receiving river flow rate >= 1.8E4 m3/d	
Conditions and measures related to municipal sewage treatment plant	
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).	
Municipal STP discharge rate >= 2E3 m3/d	
STP sludge is applied on agricultural soil	
2.1.2 Control of environmental exposure: ENV1b Extraction of fruits/plant material and processing of oil/water emulsion (ERC 1)	
Amounts used	
Daily amount per site <= 0.632 tonnes/day	
Annual amount per site <= 126.4 tonnes/year	
Frequency and duration of use	

Emission days / year = 200 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.3 Control of environmental exposure: ENV2 Further refinement of essential oils (ERC 1)
Amounts used
Daily amount per site ≤ 0.632 tonnes/day
Annual amount per site ≤ 230.7 tonnes/year
Frequency and duration of use
Emission days / year = 365 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.2 Control of workers exposure for Manufacture in closed process, no likelihood of exposure (PROC 1)
Product characteristics
Covers percentage substance in the product up to 100 % (unless stated differently)
Liquid
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use
Assumes activities are at room temperature.
Exposed skin surface assumed: One hand face only (240 cm ²)
Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. * Open surface 1-3 m ² .
Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).
Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.3 Control of workers exposure for Manufacture in closed, continuous process with occasional controlled exposure (PROC 2)

Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm²)

Assumes activities are at room temperature.

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of liquid products - falling liquids

* Splash loading

* Avoid carrying out operation for more than 0.5 hour

* For each use event, covers use amounts up to 0.1-1 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.4 Control of workers exposure for Manufacture in closed batch process (synthesis or formulation) (PROC 3)

Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm²)

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Undertake operation under enclosed conditions.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.5 Control of workers exposure for Manufacture in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)

Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently).

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Use in batch and other process (synthesis) where opportunity for exposure arises.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.6 Control of workers exposure for Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Transfer of liquid products - falling liquids

*Submerged loading

*For each use event, covers use amounts up to 100-1000 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.7 Control of workers exposure for Use as laboratory reagent (PROC 15)

Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: One hand face only (240 cm²)

Assumes activities are at room temperature.

Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation).

*Open surface < 0.1 m².

Transfer of liquid products - falling liquids

*Splash loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 0.1-1 l/minute.

*Submerged loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to <0.1 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

3. Exposure estimation and reference to its source

The environmental exposure estimates were calculated according to EUSES version 2.1.2.

Degradation in the STP was calculated according to first-order kinetics.

Environment

ENV1a Extraction of fruits/plant material and processing of oil/water emulsion

Release route	Release rate (kg/day)	Release estimation method
Water	0	Site-specific information
Air	210	Site-specific information
Soil	1.75	ERC 1

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11
Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	0.003 mg/kg dw	0.011

Environment

ENV1b Extraction of fruits/plant material and processing of oil/water emulsion

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	Site-specific information
Air	7.584	Site-specific information
Soil	0.063	ERC 1

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013

Agricultural soil	0.261 mg/kg dw	1
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Environment

ENV2 Further refinement of essential oils

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	Site-specific information
Air	7.584	Site-specific information
Soil	0.063	ERC 1

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Risk characterisation for man via the environment

ENV1a Extraction of fruits/plant material and processing of oil/water emulsion

Inhalation: RCR = 0.004

Oral: RCR = 2.154E-4

Risk characterisation for man via the environment

ENV1b Extraction of fruits/plant material and processing of oil/water emulsion

Inhalation: RCR = 2.041E-4

Oral: RCR = 8.114E-4

Risk characterisation for man via the environment

ENV2 Further refinement of essential oils

Inhalation: RCR = 3.181E-4

Oral: RCR = 0.001

Worker exposure**Long-term, systemic**

Contributing scenario	Inhalation	Dermal	Combined routes	Exposure estimation Method
Manufacture in closed process, no likelihood of exposure (PROC 1)	Exposure: 1.5 mg/m ³ RCR: 0.048	Exposure: 0.007 mg/kg bw/day RCR: 7.713E-4	RCR: 0.049	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: High level containment) Derm: Extended TRA workers

Manufacture in closed, continuous process with occasional controlled exposure (PROC 2)	Exposure: 1.6 mg/m ³ RCR: 0.051	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.055	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: High level containment) Derm: Extended TRA workers
Manufacture in closed batch process (synthesis or formulation) (PROC 3)	Exposure: 15 mg/m ³ RCR: 0.482	Exposure: 0.007 mg/kg bw/day RCR: 7.713E-4	RCR: 0.483	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Medium level containment) Derm: Extended TRA workers
Manufacture in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)	Exposure: 6.1 mg/m ³ RCR: 0.196	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.212	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Low level containment, general ventilation) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)	Exposure: 18 mg/m ³ RCR: 0.579	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.594	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: General ventilation) Derm: Extended TRA workers
Use as laboratory reagent (PROC 15)	Exposure: 14 mg/m ³ RCR: 0.45	Exposure: 0.007 mg/kg bw/day RCR: 7.713E-4	RCR: 0.451	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. No RMM) Derm: Extended TRA workers

Acute systemic

Not required as no hazard identified

Local effects via inhalation route

Not required as no hazard identified

Local effects via dermal route

A qualitative approach was used to assess the risk of sensitization in accordance with REACH Guidance R.8 (moderate hazard level). The use of gloves and generic organisational measures were proposed as Risk Management Measures to control the risk. Residual exposure was quantitatively estimated and assessed.			
Contributing scenario	Acute	Long term	Exposure estimation Method
Manufacture in closed process, no likelihood of exposure (PROC 1)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Manufacture in closed, continuous process with occasional controlled exposure (PROC 2)	Exposure: 0.008 mg/cm ² RCR: 0.043	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Manufacture in closed batch process (synthesis or formulation) (PROC 3)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Manufacture in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)	Exposure: 0.04 mg/cm ² RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)	Exposure: 0.04 mg/cm ² RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use as laboratory reagent (PROC 15)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)

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

Environment

The daily amount per site as mentioned in section 2.1 is the maximum amount (kg/day) that may be safely used, taking into account the default operational conditions as specified in section 2.1 and the release fractions as specified in section 3. This amount is defined as M_{Safe} .

To evaluate the compliance of specific compounding sites, the site-specific substance use rate (M_{Site}) and days emitting ($T_{Emission, Site}$), onsite and offsite emission controls and subsequent total substance emission Reduction Efficiency ($RE_{Total, Site} = 1 - [(1 - RE_{Onsite, Site}) \times (1 - RE_{Offsite, Site})]$), sewage treatment plant effluent flow rate ($G_{Effluent, Site}$) and receiving water dilution factor (q_{Site}) need to be known.

It is simpler and thus may be preferable to some users to compare M_{Site} with M_{Safe} . Adequate control of risk exists if the following conditions are met: $[RE_{Total, Site} \geq RE_{Total, SpERC}, G_{Effluent, Site} \geq G_{Effluent, SpERC}, \text{ and } q_{Site} \geq q_{SpERC}]$ and $M_{Safe} \geq M_{Site}$.

In case the above comparison does not show safe use, the following scaling possibilities are advised:

- The risk is driven by soil. As a default it is assumed that STP sludge is applied on agricultural soil. However this may not always be the case. If the STP sludge is not applied to soil, the RCR for agricultural soil will decrease significantly and therefore the amount that may be used will increase.
- When STP sludge is not applied to soil, the risk will be driven by surface water and sediment. The RCR for these protection targets is lower and therefore the volume can be increased with a factor of approximately 1.7 assuming all other conditions stay equal. If the volume is then not yet high enough, scaling based on municipal STP discharge rate and receiving river flow rate is advised.
- As mentioned in section 3, degradation in the STP has been calculated according to first-order kinetics in the model EUSES. This implies that the concentration in the effluent is proportional to the concentration in the influent and so the predicted concentration in effluent depends on the use volume. An alternative approach is to use Monod kinetics in EUSES. This can be applied for readily biodegradable substances in case: a) the release to the WWTP/STP is more or less continuous so the specific bacteria responsible for biodegradation will be able to maintain themselves in the system and b) the total COD load remains within the specifications of the WWTP/STP. When this approach is applied, the substance concentration in the STP effluent is independent of the concentration in the influent and therefore the use volume, and will remain below 50 µg/l. This implies that under these circumstances M_{safe} is theoretically unlimited.

Human health

A DU works within the boundaries of this ES if he fulfills the conditions of use set in section 2. Table 4.1 provides an overview of the assumed effectiveness for the different RMM. The DU can use this effectiveness estimation in order to assess if any deviating RMM will also provide safe use. This is done by multiplying the relevant RCR with the effectiveness of the RMM implemented at the workplace and dividing it by the effectiveness of the RMM listed in section 2. If the shift duration is greater than 8 hours per day, the long term systemic DNELs have to be adapted with the using the following equation, derived from the Brief and Scala model: DNEL Reduction Factor = $(8 \times \text{hours worked in shift}) \times ((24 - \text{hours worked in shift}) / 16)$. This equation can not be used to adapt a DNEL for a shift duration shorter than 8 hours. With the adapted DNEL, the DU can recalculate the RCR by dividing the exposure estimation in section 3 with the adapted DNEL. If the RCR is smaller than 0.725 (1 - 0.275 or 1 - (Sum of all man through environment and generic consumer exposure)), the downstream user works within the boundaries set by the ES.

Table 4.1 Effectiveness of risk management measures (RMM).

Risk management measure	Assumed effectiveness ¹		Source of effectiveness
	Inhalatory	Dermal	
High level containment - Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).	99.9%	99.9%	Advanced REACH tool (www.advancedreachtool.com).
Medium level containment - Undertake operation under enclosed conditions.	99%	33%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Low level containment - Put lids on containers immediately after use.	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.

¹ All effectiveness's listed are only valid if the RMM is properly designed, installed (if applicable), used and maintained.

Working outdoor / natural ventilation	30%	-	Advanced REACH tool (www.advancedreachtool.com)
General ventilation (mechanical)	50%	-	Advanced REACH tool (www.advancedreachtool.com).
Local exhaust ventilation, fixed capturing hood	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Local exhaust ventilation, other system	50%	17%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Laminar flow booth	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Respirator (Wear a full face respirator conforming to EN140 with Type A / P2 filter or better. APF >20))	95%	Not applicable	Advanced REACH tool (www.advancedreachtool.com).
Respirator (Wear a respirator (half face mask) conforming to EN140 with Type A filter / P2 filter or better. APF >10)	90%	Not applicable	Advanced REACH tool (www.advancedreachtool.com).
Reduction of duration of exposure			ECETOC TRA (http://www.ecetoc.org/tra) for the inhalatory effectiveness, expert judgment for dermal effectiveness.
> 60 and <= 240 minutes per shift	40%	40%	
> 15 and <= 60 minutes per shift	80%	80%	
<= 15 minutes per shift	90%	80%	
Concentration of substance in mixture			ECETOC TRA (http://www.ecetoc.org/tra) for the inhalatory effectiveness, expert judgment for dermal effectiveness.
> 5% and <= 25%	40%	75%	
> 1% and <= 5%	80%	95%	
<= 1%	90%	99%	

2. ES 2: Formulation (SU 3); Blending / Compounding

1. Title of Exposure scenario	
Environment: * Blending of mixtures and distribution * Compounding of fragrance oils (generic large/medium sites) * Compounding of fragrance oils (generic small sites)	ERC 2
Worker	
Formulation and distribution / compounding in closed system, no likelihood of exposure	PROC 1
Formulation and distribution / compounding in closed, continuous process with occasional controlled exposure	PROC 2
Formulation and distribution / compounding in closed batch process (synthesis or formulation)	PROC 3
Formulation and distribution / compounding in batch and other process (synthesis) where opportunity for exposure arises	PROC 4
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	PROC 5
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	PROC 8a
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	PROC 8b
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC 9
Use as laboratory reagent	PROC 15
2. Conditions of use affecting exposure	
2.1 Control of environmental exposure: Blending of mixtures and distribution (ERC 2) Compounding of fragrance oils (generic large/medium sites) (ERC 2) Compounding of fragrance oils (generic small sites) (ERC 2)	
2.1.1 Control of environmental exposure: Blending of mixtures and distribution (ERC 2)	
Amounts used	
Daily amount per site ≤ 0.063 tonnes/day	
Annual amount per site ≤ 6.32 tonnes/year	
Frequency and duration of use	
Emission days / year = 100 days/year	
Other given operational conditions affecting environmental exposure	
Receiving river flow rate $\geq 1.8E4$ m ³ /d	
Conditions and measures related to municipal sewage treatment plant	
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).	
Municipal STP discharge rate $\geq 2E3$ m ³ /d	
STP sludge is applied on agricultural soil	

2.1.2 Control of environmental exposure: Compounding of fragrance oils (generic large/medium sites) (ERC 2)
Amounts used
Daily amount per site ≤ 0.632 tonnes/day
Annual amount per site ≤ 158 tonnes/year
Frequency and duration of use
Emission days / year = 250 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.3 Control of environmental exposure: Compounding of fragrance oils (generic small sites) (ERC 2)
Amounts used
Daily amount per site ≤ 0.253 tonnes/day
Annual amount per site ≤ 63.2 tonnes/year
Frequency and duration of use
Emission days / year = 250 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.2 Control of workers exposure for Formulation and distribution / compounding in closed system, no likelihood of exposure (PROC 1)
Product characteristics
Covers percentage substance in the product up to 100 % (unless stated differently).
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.3 Control of workers exposure for Formulation and distribution / compounding in closed, continuous process with occasional controlled exposure (PROC 2)

Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently).

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of liquid products - falling liquids.

*Splash loading.

*Avoid carrying out operation for more than 0.5 hour.

*For each use event, covers use amounts up to 0.1-1 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.4 Control of workers exposure for Formulation and distribution / compounding in closed batch process (synthesis or formulation) (PROC 3)
Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently).

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Undertake operation under enclosed conditions.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.5 Control of workers exposure for Formulation and distribution / compounding in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)
Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently).

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.6 Control of workers exposure for Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) **(PROC 5)**

Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently).

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Transfer of liquid products - falling liquids.

*Submerged loading.

*Avoid carrying out operation for more than 1 hour.

*For each use event, covers use amounts up to 100-1000 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Activity with agitated surfaces: Put lids on containers immediately after use.

Transfer of liquid products: Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.7 Control of workers exposure for Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities **(PROC 8a)**

Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid.

Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Assumes activities are at room temperature. Exposed skin surface assumed: Two hands (960 cm²). Transfer of liquid products - falling liquids. *Splash loading. *For each use event, covers use amounts up to 100-1000 l/minute. <i>Handling that reduces contact between product and adjacent air.</i>
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place. Put lids on containers immediately after use. Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour). Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection. Wear suitable coveralls to prevent exposure to the skin.
2.8 Control of workers exposure for Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)
Product characteristics
Covers percentage substance in the product up to 100 % (unless stated differently) Liquid
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Assumes activities are at room temperature. Exposed skin surface assumed: Two hands face (480 cm²). Transfer of liquid products - falling liquids. *Submerged loading. *For each use event, covers use amounts up to 100-1000 l/minute. <i>Handling that reduces contact between product and adjacent air.</i>
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place. Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.9 Control of workers exposure for Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

Product characteristics

Covers concentrations up to: 50%

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Transfer of liquid products - falling liquids.

*Splash loading.

*For each use event, covers use amounts up to 10-100 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.10 Control of workers exposure for Use as laboratory reagent (PROC 15)

Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm²).

Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation)

*Open surface < 0.1 m²

Transfer of liquid products - falling liquids.

*Splash loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 0.1-1 l/minute.

*Submerged loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to <0.1 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

3. Exposure estimation and reference to its source

The environmental exposure estimates were calculated according to EUSES version 2.1.2.

Degradation in the STP was calculated according to first-order kinetics.

Environment

Blending of mixtures and distribution

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	ERC - ERC 2
Air	1.58	ERC - ERC 2
Soil	0.006	ERC - ERC 2

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment

Compounding of fragrance oils (generic large/medium sites)

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (Compounding of fragrance oils - Compounding of fragrance oils medium/large compounder)
Air	15.8	SPERC (Compounding of fragrance oils - Compounding of fragrance oils medium/large compounder)
Soil	0.063	SPERC

	(Compounding of fragrance oils - Compounding of fragrance oils medium/large compounder)
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Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment Compounding of fragrance oils (generic small sites)		
Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (Compounding of fragrance oils - Compounding of fragrance oils small compounder)
Air	6.32	SPERC (Compounding of fragrance oils - Compounding of fragrance oils small compounder)
Soil	0.025	SPERC (Compounding of fragrance oils - Compounding of fragrance oils small compounder)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Risk characterisation for man via the environment Blending of mixtures and distribution	
Inhalation: RCR = 7.983E-5 Oral: RCR = 6.351E-4	
Risk characterisation for man via the environment Compounding of fragrance oils (generic large/medium sites)	
Inhalation: RCR = 4.262E-4 Oral: RCR = 9.009E-4	
Risk characterisation for man via the environment Compounding of fragrance oils (generic small sites)	
Inhalation: RCR = 2.101E-4	

Oral: RCR = 8.976E-4

Worker exposure

Long-term, systemic

Contributing scenario	Inhalation	Dermal	Combined routes	Exposure estimation Method
Formulation and distribution / compounding in closed system, no likelihood of exposure (PROC 1)	Exposure: 1.5 mg/m ³ RCR: 0.048	Exposure: 0.007 mg/kg bw/day RCR: 7.713E-4	RCR: 0.049	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: High level containment) Derm: Extended TRA workers
Formulation and distribution / compounding in closed, continuous process with occasional controlled exposure (PROC 2)	Exposure: 1.6 mg/m ³ RCR: 0.051	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.055	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: High level containment) Derm: Extended TRA workers
Formulation and distribution / compounding in closed batch process (synthesis or formulation) (PROC 3)	Exposure: 15 mg/m ³ RCR: 0.482	Exposure: 0.007 mg/kg bw/day RCR: 7.713E-4	RCR: 0.483	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Medium level containment) Derm: Extended TRA workers
Formulation and distribution / compounding in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)	Exposure: 6.1 mg/m ³ RCR: 0.196	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.212	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Low level containment, general ventilation) Derm: Extended TRA workers
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)	Exposure: 16 mg/m ³ RCR: 0.515	Exposure: 0.274 mg/kg bw/day RCR: 0.031	RCR: 0.545	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Low level containment, general ventilation) Derm: Extended TRA workers

				workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)	Exposure: 18 mg/m ³ RCR: 0.579	Exposure: 0.274 mg/kg bw/day RCR: 0.031	RCR: 0.61	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Low level containment, general ventilation) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)	Exposure: 18 mg/m ³ RCR: 0.579	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.594	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: General ventilation) Derm: Extended TRA workers
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)	Exposure: 13 mg/m ³ RCR: 0.418	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.426	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Use as laboratory reagent (PROC 15)	Exposure: 14 mg/m ³ RCR: 0.45	Exposure: 0.007 mg/kg bw/day RCR: 7.713E-4	RCR: 0.451	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. No RMM) Derm: Extended TRA workers

Acute systemic

Not required as no hazard identified

Local effects via inhalation route

Not required as no hazard identified

Local effects via dermal route

A qualitative approach was used to assess the risk of sensitization in accordance with REACH Guidance R.8 (moderate hazard level). The use of gloves and generic organisational measures were proposed as Risk Management Measures to control the risk. Residual exposure was quantitatively estimated and assessed.

Contributing scenario	Acute	Long term	Exposure estimation Method
Formulation and distribution / compounding in closed system, no likelihood of exposure (PROC 1)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)

Formulation and distribution / compounding in closed, continuous process with occasional controlled exposure (PROC 2)	Exposure: 0.008 mg/cm ² RCR: 0.043	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation and distribution / compounding in closed batch process (synthesis or formulation) (PROC 3)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation and distribution / compounding in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)	Exposure: 0.04 mg/cm ² RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)	Exposure: 0.08 mg/cm ² RCR: 0.431	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)	Exposure: 0.04 mg/cm ² RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)	Exposure: 0.04 mg/cm ² RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use as laboratory reagent (PROC 15)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)

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

Environment

The daily amount per site as mentioned in section 2.1 is the maximum amount (kg/day) that may be safely used, taking into account the default operational conditions as specified in section 2.1 and the release fractions as specified in section 3. This amount is defined as M_{Safe} .

To evaluate the compliance of specific compounding sites, the site-specific substance use rate (M_{Site}) and days emitting ($T_{Emission, Site}$), onsite and offsite emission controls and subsequent total substance emission Reduction Efficiency ($RE_{Total, Site} = 1 - [(1 - RE_{Onsite, Site}) \times (1 - RE_{Offsite, Site})]$), sewage treatment plant effluent flow rate ($G_{Effluent, Site}$) and receiving water dilution factor (q_{Site}) need to be known.

It is simpler and thus may be preferable to some users to compare M_{Site} with M_{Safe} . Adequate control of risk exists if the following conditions are met: $[RE_{Total, Site} \geq RE_{Total, SpERC}, G_{Effluent, Site} \geq G_{Effluent, SpERC}, \text{ and } q_{Site} \geq q_{SpERC}]$ and $M_{Safe} \geq M_{Site}$.

In case the above comparison does not show safe use, the following scaling possibilities are advised:

- The risk is driven by soil. As a default it is assumed that STP sludge is applied on agricultural soil.

However this may not always be the case. If the STP sludge is not applied to soil, the RCR for agricultural soil will decrease significantly and therefore the amount that may be used will increase.

- When STP sludge is not applied to soil, the risk will be driven by surface water and sediment. The RCR for these protection targets is lower and therefore the volume can be increased with a factor of approximately 1.7 assuming all other conditions stay equal. If the volume is then not yet high enough, scaling based on municipal STP discharge rate and receiving river flow rate is advised.
- As mentioned in section 3, degradation in the STP has been calculated according to first-order kinetics in the model EUSES. This implies that the concentration in the effluent is proportional to the concentration in the influent and so the predicted concentration in effluent depends on the use volume. An alternative approach is to use Monod kinetics in EUSES. This can be applied for readily biodegradable substances in case: a) the release to the WWTP/STP is more or less continuous so the specific bacteria responsible for biodegradation will be able to maintain themselves in the system and b) the total COD load remains within the specifications of the WWTP/STP. When this approach is applied, the substance concentration in the STP effluent is independent of the concentration in the influent and therefore the use volume, and will remain below 50 µg/l. This implies that under these circumstances M_{safe} is theoretically unlimited.

Human health

A DU works within the boundaries of this ES if he fulfills the conditions of use set in section 2. Table 4.1 provides an overview of the assumed effectiveness for the different RMM. The DU can use this effectiveness estimation in order to assess if any deviating RMM will also provide safe use. This is done by multiplying the relevant RCR with the effectiveness of the RMM implemented at the workplace and dividing it by the effectiveness of the RMM listed in section 2. If the shift duration is greater than 8 hours per day, the long term systemic DNELs have to be adapted with the using the following equation, derived from the Brief and Scala model: DNEL Reduction Factor = $(8 \times \text{hours worked in shift}) \times ((24 - \text{hours worked in shift}) / 16)$. This equation can not be used to adapt a DNEL for a shift duration shorter than 8 hours. With the adapted DNEL, the DU can recalculate the RCR by dividing the exposure estimation in section 3 with the adapted DNEL. If the RCR is smaller than 0.725 (1 - 0.275 or 1 - (Sum of all man through environment and generic consumer exposure)), the downstream user works within the boundaries set by the ES.

Table 4.1 Effectiveness of risk management measures (RMM).

Risk management measure	Assumed effectiveness ²		Source of effectiveness
	Inhalatory	Dermal	
High level containment - Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).	99.9%	99.9%	Advanced REACH tool (www.advancedreachtool.com).
Medium level containment - Undertake operation under enclosed conditions.	99%	33%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Low level containment - Put lids on containers immediately after use.	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Working outdoor / natural ventilation	30%	-	Advanced REACH tool (www.advancedreachtool.com)
General ventilation (mechanical)	50%	-	Advanced REACH tool (www.advancedreachtool.com).
Local exhaust ventilation, fixed capturing hood	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Local exhaust ventilation, other system	50%	17%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Laminar flow booth	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Respirator (Wear a full face respirator conforming to EN140 with Type A / P2 filter or better. APF >20))	95%	Not applicable	Advanced REACH tool (www.advancedreachtool.com).
Respirator (Wear a respirator (half face mask) conforming to EN140 with Type A filter / P2 filter or better. APF >10))	90%	Not applicable	Advanced REACH tool (www.advancedreachtool.com).
Reduction of duration of exposure			ECETOC TRA (http://www.ecetoc.org/tra) for the inhalatory effectiveness, expert judgment for dermal effectiveness.
> 60 and ≤ 240 minutes per shift	40%	40%	
> 15 and ≤ 60 minutes per shift	80%	80%	

² All effectiveness's listed are only valid if the RMM is properly designed, installed (if applicable), used and maintained.

<= 15 minutes per shift	90%	80%	
Concentration of substance in mixture			ECETOC TRA (http://www.ecetoc.org/tra) for the
> 5% and <= 25%	40%	75%	inhalatory effectiveness, expert judgment for dermal
> 1% and <= 5%	80%	95%	effectiveness.
<= 1%	90%	99%	

3. ES 3: Formulation (SU 3); Formulation

1. Title of Exposure scenario	
Environment: * Formulation AISE 1, 5 and 7 - Formulation of Detergents/Maintenance Products: Granular Detergent - Regular (large scale), Granular Detergent -Compact (small scale), Low Viscosity Liquids (large scale) * Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (medium scale), Low Viscosity Liquids (medium scale), High Viscosity Liquids (large scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (large scale), body care soap (medium and large scale) * Formulation AISE 3, 9 and 11 and COLIPA 2 and 16 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (small scale), Low Viscosity Liquids (small scale), High Viscosity Liquids (medium scale); Formulation Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (medium scale), body care soap (small scale) * Formulation AISE 12 and COLIPA 3 - Formulation of Detergents/Maintenance Products: High Viscosity Liquids (small scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (small scale) * Formulation COLIPA 6 and 8 - Formulation of Cosmetics: Medium Viscosity Body Care Products (medium scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (large scale) * Formulation AISE 4 - Formulation of Detergents/Maintenance Products: Granular Detergent - Compact (large scale) * Formulation AISE 6 - Formulation of Detergents/Maintenance Products: Granular Detergent - Compact (small scale) * Formulation COLIPA 4, 7 and 9 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (medium scale), Medium Viscosity Body Care Products (small scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (medium scale) * Formulation COLIPA 5 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (small scale) * Formulation COLIPA 10 - Formulation of Cosmetics: Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (small scale) * CEPE 7 - Formulation of Powder Coatings and Inks - Solids * CEPE 8, 9 - Formulation of Liquid Coatings and Inks - Large Scale and Small Scale * ESVOC 4 - Formulation of solvents and solvent based products * FEICA 2,3 - Formulation of Solvent Borne adhesives - Volatiles (Large Scale and Small Scale) * EFCC2 - Formulation of Construction Chemicals - Use of Volatile substances (additives)	ERC 2
Worker	
Formulation in closed process, no likelihood of exposure - liquid	PROC 1
Formulation in closed process, no likelihood of exposure - solid	PROC 1
Formulation in closed, continuous process with occasional controlled exposure - liquid	PROC 2
Formulation in closed, continuous process with occasional controlled exposure - solid	PROC 2
Formulation in closed batch process (synthesis or formulation) - liquid	PROC 3
Formulation in closed batch process (synthesis or formulation) - solid	PROC 3
Formulation in batch and other process (synthesis) where opportunity for exposure arises - liquid	PROC 4
Formulation in batch and other process (synthesis) where opportunity for exposure arises - solid	PROC 4
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid	PROC 5
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid	PROC 5
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-	PROC 8a

dedicated facilities - liquid	
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid	PROC 8a
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid	PROC 8b
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid	PROC 8b
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid	PROC 9
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid	PROC 9
Roller application or brushing - liquid	PROC 10
Treatment of articles by dipping and pouring - liquid	PROC 13
Formulation of preparations or articles by tableting, compression, extrusion, pelletisation - solid	PROC 14
Use as laboratory reagent - liquid	PROC 15
Use as laboratory reagent - solid	PROC 15

2. Conditions of use affecting exposure

2.1 Control of environmental exposure:

Formulation AISE 1, 5 and 7 - Formulation of Detergents/Maintenance Products: Granular Detergent – Regular (large scale), Granular Detergent -Compact (small scale), Low Viscosity Liquids (large scale)

Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (medium scale), Low Viscosity Liquids (medium scale), High Viscosity Liquids (large scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (large scale), body care soap (medium and large scale)

Formulation AISE 3, 9 and 11 and COLIPA 2 and 16 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (small scale), Low Viscosity Liquids (small scale), High Viscosity Liquids (medium scale); Formulation Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (medium scale), body care soap (small scale)

Formulation AISE 12 and COLIPA 3 - Formulation of Detergents/Maintenance Products: High Viscosity Liquids (small scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (small scale)

Formulation COLIPA 6 and 8 - Formulation of Cosmetics: Medium Viscosity Body Care Products (medium scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (large scale)

Formulation AISE 4 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (large scale)

Formulation AISE 6 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (small scale)

Formulation COLIPA 4, 7 and 9 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (medium scale), Medium Viscosity Body Care Products (small scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (medium scale)

Formulation COLIPA 5 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (small scale)

Formulation COLIPA 10 - Formulation of Cosmetics: Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (small scale)

CEPE 7 - Formulation of Powder Coatings and Inks – Solids

CEPE 8, 9 - Formulation of Liquid Coatings and Inks - Large Scale and Small Scale
ESVOC 4 - Formulation of solvents and solvent based products
FEICA 2,3 - Formulation of Solvent Borne adhesives - Volatiles (Large Scale and Small Scale)
EFCC2 - Formulation of Construction Chemicals - Use of Volatile substances (additives)
2.1.1 Control of environmental exposure: Formulation AISE 1, 5 and 7 - Formulation of Detergents/Maintenance Products: Granular Detergent – Regular (large scale), Granular Detergent -Compact (small scale), Low Viscosity Liquids (large scale) (ERC 2)
Amounts used
Daily amount per site ≤ 0.1 tonnes/day
Annual amount per site ≤ 1 tonnes/year
Frequency and duration of use
Emission days / year = not specified
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.2 Control of environmental exposure: Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (medium scale), Low Viscosity Liquids (medium scale), High Viscosity Liquids (large scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (large scale), body care soap (medium and large scale) (ERC 2)
Amounts used
Daily amount per site ≤ 1.264 tonnes/day
Annual amount per site ≤ 278.1 tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.3 Control of environmental exposure: Formulation AISE 3, 9 and 11 and COLIPA 2 and 16 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (small scale), Low Viscosity Liquids (small scale), High Viscosity Liquids (medium scale); Formulation Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam

bath) (medium scale), body care soap (small scale) (ERC 2)
Amounts used
Daily amount per site ≤ 0.632 tonnes/day
Annual amount per site ≤ 139 tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.4 Control of environmental exposure: Formulation AISE 12 and COLIPA 3 - Formulation of Detergents/Maintenance Products: High Viscosity Liquids (small scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (small scale) (ERC 2)
Amounts used
Daily amount per site ≤ 0.316 tonnes/day
Annual amount per site ≤ 69.52 tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.5 Control of environmental exposure: Formulation COLIPA 6 and 8 - Formulation of Cosmetics: Medium Viscosity Body Care Products (medium scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (large scale) (ERC 2)
Amounts used
Daily amount per site ≤ 0.126 tonnes/day
Annual amount per site ≤ 27.8 tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure

Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%). Municipal STP discharge rate $\geq 2E3$ m ³ /d STP sludge is applied on agricultural soil
2.1.6 Control of environmental exposure: Formulation AISE 4 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (large scale) (ERC 2)
Amounts used
Daily amount per site ≤ 126.4 tonnes/day Annual amount per site $\leq 2.781E4$ tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%). Municipal STP discharge rate $\geq 2E3$ m ³ /d STP sludge is applied on agricultural soil
2.1.7 Control of environmental exposure: Formulation AISE 6 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (small scale) (ERC 2)
Amounts used
Daily amount per site ≤ 6.32 tonnes/day Annual amount per site $\leq 1.39E3$ tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%). Municipal STP discharge rate $\geq 2E3$ m ³ /d STP sludge is applied on agricultural soil
2.1.8 Control of environmental exposure: Formulation COLIPA 4, 7 and 9 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (medium scale), Medium Viscosity Body Care Products (small scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (medium scale) (ERC 2)

Amounts used
Daily amount per site ≤ 0.063 tonnes/day
Annual amount per site ≤ 13.9 tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.9 Control of environmental exposure: Formulation COLIPA 5 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (small scale) (ERC 2)
Amounts used
Daily amount per site ≤ 0.042 tonnes/day
Annual amount per site ≤ 9.27 tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.10 Control of environmental exposure: Formulation COLIPA 10 - Formulation of Cosmetics: Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (small scale) (ERC 2)
Amounts used
Daily amount per site ≤ 0.032 tonnes/day
Annual amount per site ≤ 0.695 tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2\text{E}3 \text{ m}^3/\text{d}$
STP sludge is applied on agricultural soil
2.1.11 Control of environmental exposure: CEPE 7 - Formulation of Powder Coatings and Inks – Solids (ERC 2)
Amounts used
Daily amount per site $\leq 0.253 \text{ tonnes/day}$
Annual amount per site $\leq 56.93 \text{ tonnes/year}$
Frequency and duration of use
Emission days / year = 225 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8\text{E}4 \text{ m}^3/\text{d}$
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2\text{E}3 \text{ m}^3/\text{d}$
STP sludge is applied on agricultural soil
2.1.12 Control of environmental exposure: CEPE 8, 9 - Formulation of Liquid Coatings and Inks - Large Scale and Small Scale (ERC 2)
Amounts used
Daily amount per site $\leq 122.2 \text{ tonnes/day}$
Annual amount per site $\leq 2.75\text{E}4 \text{ tonnes/year}$
Frequency and duration of use
Emission days / year = 225 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8\text{E}4 \text{ m}^3/\text{d}$
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2\text{E}3 \text{ m}^3/\text{d}$
STP sludge is applied on agricultural soil
2.1.13 Control of environmental exposure: ESVOC 4 - Formulation of solvents and solvent based products (ERC 2)
Amounts used
Daily amount per site $\leq 6.3 \text{ tonnes/day}$
Annual amount per site $\leq 1.89\text{E}3 \text{ tonnes/year}$
Frequency and duration of use

Emission days / year = 300 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.14 Control of environmental exposure: FEICA 2,3 - Formulation of Solvent Borne adhesives - Volatiles (Large Scale and Small Scale) (ERC 2)
Amounts used
Daily amount per site ≤ 4.55 tonnes/day
Annual amount per site $\leq 1E3$ tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.15 Control of environmental exposure: EFCC2 - Formulation of Construction Chemicals - Use of Volatile substances (additives) (ERC 2)
Amounts used
Daily amount per site ≤ 0.253 tonnes/day
Annual amount per site ≤ 6.32 tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.2 Control of workers exposure for Formulation in closed process, no likelihood of exposure - liquid (PROC 1)

Product characteristics
Covers concentrations up to: 50%
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: One hand face only (240 cm ²).
Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. * Open surface 1-3 m ² .
Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
2.3 Control of workers exposure for Formulation in closed process, no likelihood of exposure - solid (PROC 1)
Product characteristics
Covers concentrations up to: 10%
Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Exposed skin surface assumed: One hand face only (240 cm ²)
<i>Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.</i> *For each use event, covers use amounts up to 100-1000 kg.
Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.4 Control of workers exposure for Formulation in closed, continuous process with occasional controlled exposure - liquid (PROC 2)

Product characteristics

Covers concentrations up to: 50%

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of liquid products - falling liquids

*Splash loading

*Avoid carrying out operation for more than 0.5 hour.

*For each use event, covers use amounts up to 0.1-1 l/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.5 Control of workers exposure for Formulation in closed, continuous process with occasional controlled exposure - solid (PROC 2)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm²)

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

*For each use event, covers use amounts up to 100-1000 kg.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of solid products - falling powders.

*Avoid carrying out operation for more than 0.5 hour.

*For each use event, covers use amounts up to 0.1-1 kg/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.6 Control of workers exposure for Formulation in closed batch process (synthesis or formulation) - liquid (PROC 3)

Product characteristics

Covers concentrations up to: 50%

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Use in closed batch process (synthesis or formulation).

*Undertake operation under enclosed conditions.

Transfer of liquid products - falling liquids.

*Splash loading.

*Avoid carrying out operation for more than 0.5 hour.

*For each use event, covers use amounts up to 0.1-1 l/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.7 Control of workers exposure for Formulation in closed batch process (synthesis or formulation) - solid (PROC 3)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: One hand face only (240 cm²).

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

*For each use event, covers use amounts up to 100-1000 kg.

*Undertake operation under enclosed conditions.

Transfer of solid products - falling powders.

*Avoid carrying out operation for more than 0.5 hour.

*For each use event, covers use amounts up to 0.1-1 kg/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.8 Control of workers exposure for Formulation in batch and other process (synthesis) where opportunity for exposure arises - liquid (PROC 4)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

*Open surface 1-3 m².

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.9 Control of workers exposure for Formulation in batch and other process (synthesis) where opportunity for exposure arises - solid (PROC 4)

Product characteristics

Covers concentrations up to: 10%.

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm²).

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

*For each use event, covers use amounts up to 100-1000 kg.

Transfer of solid products - falling powders.

*Avoid carrying out operation for more than 0.5 hour.

*For each use event, covers use amounts up to 10-100 g/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.10 Control of workers exposure for Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid (PROC 5)

Product characteristics

Covers concentrations up to: 50%.

Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Assumes activities are at room temperature. Exposed skin surface assumed: Two hands face (480 cm ²). Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. * Open surface 1-3 m ² .
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place. Put lids on containers immediately after use. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection. Wear suitable coveralls to prevent exposure to the skin.
2.11 Control of workers exposure for Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid (PROC 5)
Product characteristics
Covers concentrations up to: 10% Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Exposed skin surface assumed: Two hands face (480 cm ²). <i>Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.</i> *For each use event, covers use amounts up to 100-1000 kg. Transfer of solid products - falling powders. *Avoid carrying out operation for more than 0.5 hour. *For each use event, covers use amounts up to 10-100 g/minute.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place. Put lids on containers immediately after use. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision

controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.12 Control of workers exposure for Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid (**PROC 8a**)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands (960 cm²).

Transfer of liquid products - falling liquids.

*Submerged loading.

*For each use event, covers use amounts up to 100-1000 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.13 Control of workers exposure for Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid (**PROC 8a**)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands (960 cm²).

Transfer of solid products - falling powders.

*For each use event, covers use amounts up to 100-1000 kg/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.14 Control of workers exposure for Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid (**PROC 8b**)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Transfer of liquid products - falling liquids.

*Submerged loading.

*For each use event, covers use amounts up to 100-1000 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.15 Control of workers exposure for Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid (**PROC 8b**)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm²).

Transfer of solid products - falling powders.

*For each use event, covers use amounts up to 100-1000 kg/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.16 Control of workers exposure for Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (**PROC 9**)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Transfer of liquid products - falling liquids.

*Splash loading.

*For each use event, covers use amounts up to 10-100 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.17 Control of workers exposure for Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid (**PROC 9**)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Exposed skin surface assumed: Two hands face (480 cm ²). <i>Transfer of solid products - falling powders.</i> *For each use event, covers use amounts up to 10-100 kg/minute. <i>Handling that reduces contact between product and adjacent air.</i>
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection. Wear suitable coveralls to prevent exposure to the skin.
2.18 Control of workers exposure for Roller application or brushing - liquid (PROC 10)
Product characteristics
Covers concentrations up to: 50%. Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Assumes activities are at room temperature. Exposed skin surface assumed: Two hands (960 cm ²). <i>Spreading of liquid products (0.3-1.0 m²/hour).</i> *Avoid carrying out operation for more than 4 hours. <i>Handling of contaminated objects (0.3-1.0 m²) - Contamination > 90 % of surface.</i> *Avoid carrying out operation for more than 4 hours.
Technical and organisational conditions and measures
<u>General measures applicable to all activities:</u> Demonstrable and effective housekeeping practices are in place. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

Use above 5% concentration:

*Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

2.19 Control of workers exposure for Treatment of articles by dipping and pouring - liquid (PROC 13)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation).

*Use above 25% concentration: Open surface 1-3 m²

*Open surface 0.3-1 m²

*Avoid carrying out operation for more than 4 hours.

Handling of contaminated objects (0.3-1.0 m²) - Contamination > 90 % of surface.

*Avoid carrying out operation for more than 4 hours.

Technical and organisational conditions and measures

General measures applicable to all activities:

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

Use between 5- 25% concentration:

*Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Use above 25% concentration:

*Local exhaust ventilation - efficiency of at least [%]: 50.

*Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

2.20 Control of workers exposure for Formulation of preparations or articles by tableting, compression,

extrusion, pelletisation - solid (PROC 14)
Product characteristics
Covers concentrations up to: 10%
Solid, low dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Exposed skin surface assumed: Two hands face (480 cm ²).
Tabletting, compression, extrusion or pelletisation.
*For each use event, covers use amounts up to 100-1000 kg/minute.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
2.21 Control of workers exposure for Use as laboratory reagent - liquid (PROC 15)
Product characteristics
Covers concentrations up to: 50%.
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: One hand face only (240 cm ²).
Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation).
*Open surface < 0.1 m ²
Transfer of liquid products - falling liquids.
*Splash loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 0.1-1 l/minute.
*Submerged loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to <0.1 l/minute. Handling that reduces contact between product and adjacent air.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.22 Control of workers exposure for Use as laboratory reagent - solid (PROC 15)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: One hand face only (240 cm²).

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

*For each use event, covers use amounts up to <10 gram/minute.

Transfer of solid products - falling powders.

*Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 10-100 gram/minute.

*Carefully handle the substance to minimise releases. Ensure operatives are trained to minimise exposures. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to <10 gram/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

3. Exposure estimation and reference to its source

The environmental exposure estimates were calculated according to EUSES version 2.1.2.

Degradation in the STP was calculated according to first-order kinetics.

Environment

Formulation AISE 1, 5 and 7 - Formulation of Detergents/Maintenance Products: Granular Detergent – Regular (large scale), Granular Detergent -Compact (small scale), Low Viscosity Liquids (large scale).

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 1, 5 and 7)
Air	2.528	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 1, 5 and 7)

Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 1, 5 and 7)
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Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment

Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (medium scale), Low Viscosity Liquids (medium scale), High Viscosity Liquids (large scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (large scale), body care soap (medium and large scale).

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15)
Air	0.253	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment

Formulation AISE 3, 9 and 11 and COLIPA 2 and 16 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (small scale), Low Viscosity Liquids (small scale), High Viscosity Liquids (medium scale); Formulation Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (medium scale), body care soap (small scale)

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 3, 9 and 11 and COLIPA 2 and 16)

Air	0.126	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 3, 9 and 11 and COLIPA 2 and 16)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 3, 9 and 11 and COLIPA 2 and 16)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment Formulation AISE 12 and COLIPA 3 - Formulation of Detergents/Maintenance Products: High Viscosity Liquids (small scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (small scale)		
Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 12 and COLIPA 3)
Air	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 12 and COLIPA 3)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 12 and COLIPA 3)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment Formulation COLIPA 6 and 8 - Formulation of Cosmetics: Medium Viscosity Body Care Products (medium scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (large scale)		
Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 6 and 8)
Air	0	SPERC (AISE and COLIPA SpERCs for formulation -

		Formulation COLIPA 6 and 8)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 6 and 8)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment Formulation AISE 4 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (large scale).		
Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 4)
Air	25.28	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 4)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 4)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment Formulation AISE 6 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (small scale)		
Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 6)
Air	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 6)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 6)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment

Formulation COLIPA 4, 7 and 9 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (medium scale), Medium Viscosity Body Care Products (small scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (medium scale)

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 4, 7 and 9)
Air	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 4, 7 and 9)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 4, 7 and 9)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment

Formulation COLIPA 5 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (small scale)

Release route	Release rate (kg/day)	Release estimation method
Water	1.263	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 5)
Air	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 5)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 5)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618

Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment

Formulation COLIPA 10 - Formulation of Cosmetics: Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (small scale)

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 10)
Air	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 10)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 10)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment

CEPE 7 - Formulation of Powder Coatings and Inks – Solids

Release route	Release rate (kg/day)	Release estimation method
Water	1.265	SPERC (CEPE 7)
Air	0.025	SPERC (CEPE 7)
Soil	0	SPERC (CEPE 7)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.609
Freshwater (sediment)	0.805 mg/kg dw	0.619
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.599
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment

CEPE 8, 9 - Formulation of Liquid Coatings and Inks - Large Scale and Small Scale

Release route	Release rate (kg/day)	Release estimation method
Water	0	SPERC (CEPE 8, 9)
Air	7.333	SPERC (CEPE 8, 9)
Soil	0	SPERC (CEPE 8, 9)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11
Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	1.6E-4 mg/kg dw	6.13E-4

Environment ESVOC 4 - Formulation of solvents and solvent based products		
Release route	Release rate (kg/day)	Release estimation method
Water	1.26	SPERC (ESVOC 4)
Air	63	SPERC (ESVOC 4)
Soil	0	SPERC (ESVOC 4)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.606
Freshwater (sediment)	0.802 mg/kg dw	0.617
Marine water (pelagic)	3.17E-4 mg/L	0.587
Marine water (sediment)	0.078 mg/kg dw	0.597
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment FEICA 2, 3 - Formulation of Solvent Borne adhesives - Volatiles (Large Scale and Small Scale)		
Release route	Release rate (kg/day)	Release estimation method
Water	0	SPERC (FEICA 2, 3)
Air	227.5	SPERC (FEICA 2, 3)
Soil	0	SPERC (FEICA 2, 3)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11

Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	0.004 mg/kg dw	0.014

Environment

EFCC2 - Formulation of Construction Chemicals - Use of Volatile substances (additives)

Release route	Release rate (kg/day)	Release estimation method
Water	1.265	SPERC (EFCC 2)
Air	2.53	SPERC (EFCC 2)
Soil	0	SPERC (EFCC 2)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.609
Freshwater (sediment)	0.805 mg/kg dw	0.619
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.599
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Risk characterisation for man via the environment

Formulation AISE 1, 5 and 7 - Formulation of Detergents/Maintenance Products: Granular Detergent – Regular (large scale), Granular Detergent -Compact (small scale), Low Viscosity Liquids (large scale)

Inhalation: RCR = 1.162E-4

Oral: RCR = 8.437E-4

Risk characterisation for man via the environment

Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (medium scale), Low Viscosity Liquids (medium scale), High Viscosity Liquids (large scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (large scale), body care soap (medium and large scale)

Inhalation: RCR = 7.695E-5

Oral: RCR = 8.431E-4

Risk characterisation for man via the environment

Formulation AISE 3, 9 and 11 and COLIPA 2 and 16 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (small scale), Low Viscosity Liquids (small scale), High Viscosity Liquids (medium scale); Formulation Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (medium scale), body care soap (small scale)

Inhalation: RCR = 7.695E-5

Oral: RCR = 8.431E-4

Risk characterisation for man via the environment

Formulation AISE 12 and COLIPA 3 - Formulation of Detergents/Maintenance Products: High Viscosity

Liquids (small scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (small scale)
Inhalation: RCR = 7.695E-5 Oral: RCR = 8.431E-4
Risk characterisation for man via the environment Formulation COLIPA 6 and 8 - Formulation of Cosmetics: Medium Viscosity Body Care Products (medium scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (large scale)
Inhalation: RCR = 7.695E-5 Oral: RCR = 8.431E-4
Risk characterisation for man via the environment Formulation AISE 4 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (large scale)
Inhalation: RCR = 5.738E-4 Oral: RCR = 8.528E-4
Risk characterisation for man via the environment Formulation AISE 6 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (small scale)
Inhalation: RCR = 9.076E-5 Oral: RCR = 8.433E-4
Risk characterisation for man via the environment Formulation COLIPA 4, 7 and 9 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (medium scale), Medium Viscosity Body Care Products (small scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (medium scale)
Inhalation: RCR = 7.695E-5 Oral: RCR = 8.431E-4
Risk characterisation for man via the environment Formulation COLIPA 5 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (small scale)
Inhalation: RCR = 7.695E-5 Oral: RCR = 8.431E-4
Risk characterisation for man via the environment Formulation COLIPA 10 - Formulation of Cosmetics: Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (small scale)
Inhalation: RCR = 6.651E-5 Oral: RCR = 4.986E-4
Risk characterisation for man via the environment CEPE 7 - Formulation of Powder Coatings and Inks – Solids
Inhalation: RCR = 7.719E-5 Oral: RCR = 8.515E-4
Risk characterisation for man via the environment CEPE 8, 9 - Formulation of Liquid Coatings and Inks - Large Scale and Small Scale

Inhalation: RCR = 2.161E-4

Oral: RCR = 1.455E-4

Risk characterisation for man via the environment

ESVOC 4 - Formulation of solvents and solvent based products

Inhalation: RCR = 0.002

Oral: RCR = 0.001

Risk characterisation for man via the environment

FEICA 2, 3 - Formulation of Solvent Borne adhesives - Volatiles (Large Scale and Small Scale)

Inhalation: RCR = 0.005

Oral: RCR = 2.293E-4

Risk characterisation for man via the environment

EFCC2 - Formulation of Construction Chemicals - Use of Volatile substances (additives)

Inhalation: RCR = 1.162E-4

Oral: RCR = 8.437E-4

Worker exposure

Long-term, systemic

Contributing scenario	Inhalation	Dermal	Combined routes	Exposure estimation Method
Formulation in closed process, no likelihood of exposure - liquid (PROC 1)	Exposure: 0.44 mg/m ³ RCR: 0.014	Exposure: 0.003 mg/kg bw/day RCR: 3.857E-4	RCR: 0.015	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: High level containment) Derm: Extended TRA workers
Formulation in closed process, no likelihood of exposure - solid (PROC 1)	Exposure: 0.032 mg/m ³ RCR: 0.001	Exposure: 6.857E-4 mg/kg bw/day RCR: 7.713E-5	RCR: 0.001	Inhal: External exposure estimation tool (Advanced REACH Tool. Concentration up to 10%. RMM: High level containment) Derm: Extended TRA workers
Formulation in closed, continuous process with occasional controlled exposure - liquid (PROC 2)	Exposure: 0.69 mg/m ³ RCR: 0.022	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.024	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: High level containment) Derm: Extended TRA workers

Formulation in closed, continuous process with occasional controlled exposure - solid (PROC 2)	Exposure: 0.036 mg/m ³ RCR: 0.001	Exposure: 0.003 mg/kg bw/day RCR: 3.085E-4	RCR: 0.001	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: High level containment) Derm: Extended TRA workers
Formulation in closed batch process (synthesis or formulation) - liquid (PROC 3)	Exposure: 4.3 mg/m ³ RCR: 0.138	Exposure: 0.003 mg/kg bw/day RCR: 3.857E-4	RCR: 0.139	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: Medium level containment) Derm: Extended TRA workers
Formulation in closed batch process (synthesis or formulation) - solid (PROC 3)	Exposure: 0.32 mg/m ³ RCR: 0.01	Exposure: 6.857E-4 mg/kg bw/day RCR: 7.713E-5	RCR: 0.01	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: Medium level containment) Derm: Extended TRA workers
Formulation in batch and other process (synthesis) where opportunity for exposure arises - liquid (PROC 4)	Exposure: 4.4 mg/m ³ RCR: 0.142	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.149	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: Low level containment) Derm: Extended TRA workers
Formulation in batch and other process (synthesis) where opportunity for exposure arises - solid (PROC 4)	Exposure: 3 mg/m ³ RCR: 0.096	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.098	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid (PROC 5)	Exposure: 4.4 mg/m ³ RCR: 0.142	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.157	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: Low level containment) Derm: Extended TRA workers

Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid (PROC 5)	Exposure: 3 mg/m ³ RCR: 0.096	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.1	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: Low level containment) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid (PROC 8a)	Exposure: 13 mg/m ³ RCR: 0.418	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.433	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid (PROC 8a)	Exposure: 3.2 mg/m ³ RCR: 0.103	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.106	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid (PROC 8b)	Exposure: 13 mg/m ³ RCR: 0.418	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.426	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid (PROC 8b)	Exposure: 3.2 mg/m ³ RCR: 0.103	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.104	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (PROC 9)	Exposure: 13 mg/m ³ RCR: 0.418	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.426	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid (PROC 9)	Exposure: 0.96 mg/m ³ RCR: 0.031	Exposure: 0.014 mg/kg bw/day	RCR: 0.032	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers

weighing) - solid (PROC 9)		RCR: 0.002		Concentration up to 10%. No RMM) Derm: Extended TRA workers
Roller application or brushing - liquid (PROC 10)	Exposure: 16 mg/m ³ RCR: 0.515	Exposure: 0.137 mg/kg bw/day RCR: 0.031	RCR: 0.546	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: General ventilation) Derm: Extended TRA workers
Roller application or brushing - liquid (PROC 10)	Exposure: 4 mg/m ³ RCR: 0.129	Exposure: 0.137 mg/kg bw/day RCR: 0.031	RCR: 0.16	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 5%. No RMM) Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 12 mg/m ³ RCR: 0.386	Exposure: 0.069 mg/kg bw/day RCR: 0.015	RCR: 0.401	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: LEV, general ventilation) Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 15 mg/m ³ RCR: 0.482	Exposure: 0.069 mg/kg bw/day RCR: 0.015	RCR: 0.497	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 25%. RMM: General ventilation) Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 2.2 mg/m ³ RCR: 0.071	Exposure: 0.069 mg/kg bw/day RCR: 0.015	RCR: 0.086	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 5%. No RMM) Derm: Extended TRA workers
Formulation of preparations or articles by tableting, compression, extrusion, pelletisation - solid (PROC 14)	Exposure: 0.32 mg/m ³ RCR: 0.01	Exposure: 0.007 mg/kg bw/day RCR: 7.713E-4	RCR: 0.011	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA

				workers
Use as laboratory reagent - liquid (PROC 15)	Exposure: 4.2 mg/m ³ RCR: 0.135	Exposure: 0.003 mg/kg bw/day RCR: 3.857E-4	RCR: 0.135	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Use as laboratory reagent - solid (PROC 15)	Exposure: 0.092 mg/m ³ RCR: 0.003	Exposure: 6.857E-4 mg/kg bw/day RCR: 7.713E-5	RCR: 0.003	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers

Acute systemic

Not required as no hazard identified

Local effects via inhalation route

Not required as no hazard identified

Local effects via dermal route

A qualitative approach was used to assess the risk of sensitization in accordance with REACH Guidance R.8 (moderate hazard level). The use of gloves and generic organisational measures were proposed as Risk Management Measures to control the risk. Residual exposure was quantitatively estimated and assessed.

Contributing scenario	Acute	Long term	Exposure estimation Method
Formulation in closed process, no likelihood of exposure - liquid (PROC 1)	Exposure: 0.002 mg/cm ² RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation in closed process, no likelihood of exposure - solid (PROC 1)	Exposure: 3.99E-4 mg/cm ² RCR: 0.002	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation in closed, continuous process with occasional controlled exposure - liquid (PROC 2)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation in closed, continuous process with occasional controlled exposure - solid (PROC 2)	Exposure: 8.75E-4 mg/cm ² RCR: 0.005	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation in closed batch process (synthesis or formulation) - liquid (PROC 3)	Exposure: 0.002 mg/cm ²	N/A	Acute: External exposure estimation tool (Quantitative

	RCR: 0.011		assessment of residual exposure)
Formulation in closed batch process (synthesis or formulation) - solid (PROC 3)	Exposure: 3.99E-4 mg/cm ² RCR: 0.002	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation in batch and other process (synthesis) where opportunity for exposure arises - liquid (PROC 4)	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation in batch and other process (synthesis) where opportunity for exposure arises - solid (PROC 4)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid (PROC 5)	Exposure: 0.04 mg/cm ² RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid (PROC 5)	Exposure: 0.008 mg/cm ² RCR: 0.043	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid (PROC 8a)	Exposure: 0.01 mg/cm ² RCR: 0.054	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid (PROC 8a)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid (PROC 8b)	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid (PROC 8b)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (PROC 9)	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative exposure of residual exposure)
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid (PROC 9)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative exposure of residual exposure)

Roller application or brushing - liquid (PROC 10)*	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Treatment of articles by dipping and pouring - liquid (PROC 13)*	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation of preparations or articles by tableting, compression, extrusion, pelletisation - solid (PROC 14)	Exposure: 0.002 mg/cm ² RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use as laboratory reagent - liquid (PROC 15)	Exposure: 0.002 mg/cm ² RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use as laboratory reagent - solid (PROC 15)	Exposure: 3.99E-4 mg/cm ² RCR: 0.002	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
*Exposure estimation and risk characterisation was based on long term systemic dermal exposure value and therefore this value is identical for all concentrations.			

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

Environment

The daily amount per site as mentioned in section 2.1 is the maximum amount (kg/day) that may be safely used, taking into account the default operational conditions as specified in section 2.1 and the release fractions as specified in section 3. This amount is defined as M_{Safe} .

To evaluate the compliance of specific formulation, the site-specific substance use rate (M_{Site}) and days emitting ($T_{Emission, Site}$), onsite and offsite emission controls and subsequent total substance emission Reduction Efficiency ($RE_{Total, Site} = 1 - [(1 - RE_{Onsite, Site}) \times (1 - RE_{Offsite, Site})]$), sewage treatment plant effluent flow rate ($G_{Effluent, Site}$) and receiving water dilution factor (q_{Site}) need to be known.

It is simpler and thus may be preferable to some users to compare M_{Site} with M_{Safe} . Adequate control of risk exists if the following conditions are met: $[RE_{Total, Site} \geq RE_{Total, SpERC}, G_{Effluent, Site} \geq G_{Effluent, SpERC}, \text{ and } q_{Site} \geq q_{SpERC}]$ and $M_{Safe} \geq M_{Site}$.

In case the above comparison does not show safe use, the following scaling possibilities are advised:

- The risk is driven by soil for nearly all formulation contributing scenarios. As a default it is assumed that STP sludge is applied on agricultural soil. However this may not always be the case. If the STP sludge is not applied to soil, the RCR for agricultural soil will decrease significantly and therefore the amount that may be used will increase.
- When STP sludge is not applied to soil, the risk will be driven by surface water and sediment. The RCR for these protection targets is lower and therefore the volume can be increased with a factor of approximately 1.7 assuming all other conditions stay equal. If the volume is then not yet high enough, scaling based on municipal STP discharge rate and receiving river flow rate is advised.
- As mentioned in section 3, degradation in the STP has been calculated according to first-order kinetics in the model EUSES. This implies that the concentration in the effluent is proportional to the concentration in the influent and so the predicted concentration in effluent depends on the use volume. An alternative approach is to use Monod kinetics in EUSES. This can be applied for readily

biodegradable substances in case: a) the release to the WWTP/STP is more or less continuous so the specific bacteria responsible for biodegradation will be able to maintain themselves in the system and b) the total COD load remains within the specifications of the WWTP/STP. When this approach is applied, the substance concentration in the STP effluent is independent of the concentration in the influent and therefore the use volume, and will remain below 50 µg/l. This implies that under these circumstances M_{safe} is theoretically unlimited.

Human health

A DU works within the boundaries of this ES if he fulfills the conditions of use set in section 2. Table 4.1 provides an overview of the assumed effectiveness for the different RMM. The DU can use this effectiveness estimation in order to assess if any deviating RMM will also provide safe use. This is done by multiplying the relevant RCR with the effectiveness of the RMM implemented at the workplace and dividing it by the effectiveness of the RMM listed in section 2. If the shift duration is greater than 8 hours per day, the long term systemic DNELs have to be adapted with the using the following equation, derived from the Brief and Scala model: DNEL Reduction Factor = $(8 \times \text{hours worked in shift}) \times ((24 - \text{hours worked in shift}) / 16)$. This equation can not be used to adapt a DNEL for a shift duration shorter than 8 hours. With the adapted DNEL, the DU can recalculate the RCR by dividing the exposure estimation in section 3 with the adapted DNEL. If the RCR is smaller than 0.725 (1 - 0.275 or 1 - (Sum of all man through environment and generic consumer exposure)), the downstream user works within the boundaries set by the ES.

Table 4.1 Effectiveness of risk management measures (RMM).

Risk management measure	Assumed effectiveness ³		Source of effectiveness
	Inhalatory	Dermal	
High level containment - Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).	99.9%	99.9%	Advanced REACH tool (www.advancedreachtool.com).
Medium level containment - Undertake operation under enclosed conditions.	99%	33%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Low level containment - Put lids on containers immediately after use.	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Working outdoor / natural ventilation	30%	-	Advanced REACH tool (www.advancedreachtool.com)
General ventilation (mechanical)	50%	-	Advanced REACH tool (www.advancedreachtool.com).
Local exhaust ventilation, fixed capturing hood	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Local exhaust ventilation, other system	50%	17%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Laminar flow booth	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Respirator (Wear a full face respirator conforming to EN140 with Type A / P2 filter or better. APF >20))	95%	Not applicable	Advanced REACH tool (www.advancedreachtool.com).
Respirator (Wear a respirator (half face mask) conforming to EN140 with Type A filter / P2 filter or better. APF >10)	90%	Not applicable	Advanced REACH tool (www.advancedreachtool.com).
Reduction of duration of exposure			ECETOC TRA (http://www.ecetoc.org/tra) for the inhalatory effectiveness, expert judgment for dermal effectiveness.
> 60 and ≤ 240 minutes per shift	40%	40%	
> 15 and ≤ 60 minutes per shift	80%	80%	
≤ 15 minutes per shift	90%	80%	
Concentration of substance in mixture			ECETOC TRA (http://www.ecetoc.org/tra) for the inhalatory effectiveness, expert judgment for dermal effectiveness.
> 5% and ≤ 25%	40%	75%	
> 1% and ≤ 5%	80%	95%	
≤ 1%	90%	99%	

³ All effectiveness's listed are only valid if the RMM is properly designed, installed (if applicable), used and maintained.

4. ES 4: Industrial end-use (SU 3); Industrial use

1. Title of Exposure scenario	
Environment: * Industrial use of fragranced products * CEPE 15, 16a - Other spray coating - Volatiles / Abatement including indoor point sources * CEPE 17a - Other spray coating, indoor use - point sources – Solids * ESVOC 11 - Industrial use of solvents in oil field drilling and production operations * ESVOC 13 - Industrial use of formulated lubricants * ESVOC 38 - Use of the substance within laboratory setting, including pilot plants * FEICA 6,7 - Industrial Use of Substances other than Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others * FEICA 8,9 - Industrial Use of Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others adhesives	ERC 4, 5
Worker	
Use in closed process, no likelihood of exposure - liquid	PROC 1
Use in closed process, no likelihood of exposure - solid	PROC 1
Use in closed, continuous process with occasional controlled exposure - liquid	PROC 2
Use in closed, continuous process with occasional controlled exposure - solid	PROC 2
Use in closed batch process - liquid	PROC 3
Use in closed batch process - solid	PROC 3
Use in batch and other process where opportunity for exposure arises - liquid	PROC 4
Use in batch and other process where opportunity for exposure arises - solid	PROC 4
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid	PROC 5
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid	PROC 5
Industrial and non-industrial spraying - liquid	PROC 7 PROC 11
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid	PROC 8a
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid	PROC 8a
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid	PROC 8b
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid	PROC 8b
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid	PROC 9
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid	PROC 9
Roller application or brushing - liquid	PROC 10
Treatment of articles by dipping and pouring - liquid	PROC 13
Production of preparations or articles by tableting, compression, extrusion, pelletisation - solid	PROC 14
Use as laboratory reagent - liquid	PROC 15
Use as laboratory reagent - solid	PROC 15

Hand-mixing with intimate contact and only PPE available - liquid

PROC 19

2. Conditions of use affecting exposure

Control of environmental exposure for Industrial use of fragranced products is included under Chapter 6.

2.1 Control of environmental exposure:

CEPE 15, 16a - Other spray coating - Volatiles / Abatement including indoor point sources

CEPE 17a - Other spray coating, indoor use - point sources – Solids

ESVOC 11 - Industrial use of solvents in oil field drilling and production operations

ESVOC 13 - Industrial use of formulated lubricants

ESVOC 38 - Use of the substance within laboratory setting, including pilot plants

FEICA 6,7 - Industrial Use of Substances other than Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others

FEICA 8,9 - Industrial Use of Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others adhesives

2.1.1 Control of environmental exposure: CEPE 15, 16a - Other spray coating - Volatiles / Abatement including indoor point sources (ERC 4)**Amounts used**Daily amount per site ≤ 0.063 tonnes/dayAnnual amount per site ≤ 13.86 tonnes/year**Frequency and duration of use**

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposureReceiving river flow rate $\geq 1.8E4$ m³/d**Conditions and measures related to municipal sewage treatment plant**

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate $\geq 2E3$ m³/d

STP sludge is applied on agricultural soil

2.1.2 Control of environmental exposure: CEPE 17a - Other spray coating, indoor use - point sources – Solids (ERC 5)**Amounts used**Daily amount per site ≤ 9.1 tonnes/dayAnnual amount per site $\leq 2E3$ tonnes/year**Frequency and duration of use**

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposureReceiving river flow rate $\geq 1.8E4$ m³/d

Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%). Municipal STP discharge rate $\geq 2 \text{E}3 \text{ m}^3/\text{d}$ STP sludge is applied on agricultural soil
2.1.3 Control of environmental exposure: ESVOC 11 - Industrial use of solvents in oil field drilling and production operations (ERC 4)
Amounts used
Daily amount per site $\leq 0.018 \text{ tonnes/day}$ Annual amount per site $\leq 0.543 \text{ tonnes/year}$
Frequency and duration of use
Emission days / year = 30 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8 \text{E}4 \text{ m}^3/\text{d}$
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%). Municipal STP discharge rate $\geq 2 \text{E}3 \text{ m}^3/\text{d}$ STP sludge is applied on agricultural soil
2.1.4 Control of environmental exposure: ESVOC 13 - Industrial use of formulated lubricants (ERC 4)
Amounts used
Daily amount per site $\leq 42.2 \text{ tonnes/day}$ Annual amount per site $\leq 844 \text{ tonnes/year}$
Frequency and duration of use
Emission days / year = 20 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8 \text{E}4 \text{ m}^3/\text{d}$
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%). Municipal STP discharge rate $\geq 2 \text{E}3 \text{ m}^3/\text{d}$ STP sludge is applied on agricultural soil
2.1.5 Control of environmental exposure: ESVOC 38 - Use of the substance within laboratory setting, including pilot plants (ERC 4)
Amounts used
Daily amount per site $\leq 0.063 \text{ tonnes/day}$ Annual amount per site $\leq 1.264 \text{ tonnes/year}$
Frequency and duration of use

Emission days / year = 20 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.6 Control of environmental exposure: FEICA 6, 7 - Industrial Use of Substances other than Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others (ERC 5)
Amounts used
Daily amount per site ≤ 12.5 tonnes/day
Annual amount per site $\leq 2.75E3$ tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.1.7 Control of environmental exposure: FEICA 8, 9 - Industrial Use of Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others adhesives (ERC 5)
Amounts used
Daily amount per site ≤ 1.25 tonnes/day
Annual amount per site ≤ 275 tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil

2.2 Control of workers exposure for Use in closed process, no likelihood of exposure - liquid (PROC 1)**Product characteristics**

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

*Open surface 1-3 m².

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.3 Control of workers exposure for Use in closed process, no likelihood of exposure - solid (PROC 1)**Product characteristics**

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: One hand face only (240 cm²)

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

*For each use event, covers use amounts up to 100-1000 kg.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.4 Control of workers exposure for Use in closed, continuous process with occasional controlled exposure - liquid (PROC 2)

Product characteristics

Covers concentrations up to: 50%

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

*Open surface 1-3 m².

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of liquid products - falling liquids

*Splash loading.

*Avoid carrying out operation for more than 0.5 hour.

*For each use event, covers use amounts up to 0.1-1 l/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.5 Control of workers exposure for Use in closed, continuous process with occasional controlled exposure - solid (PROC 2)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm²)

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

*For each use event, covers use amounts up to 100-1000 kg.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of solid products - falling powders.

*Avoid carrying out operation for more than 0.5 hour.

*For each use event, covers use amounts up to 0.1-1 kg/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.6 Control of workers exposure for Use in closed batch process - liquid (PROC 3)

Product characteristics

Covers concentrations up to: 50%

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Use in closed batch process (synthesis or formulation).

Transfer of liquid products - falling liquids.

*Splash loading.

*Avoid carrying out operation for more than 0.5 hour.

*For each use event, covers use amounts up to 0.1-1 l/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision

controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.7 Control of workers exposure for Use in closed batch process - solid (PROC 3)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: One hand face only (240 cm²).

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

*For each use event, covers use amounts up to 100-1000 kg.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of solid products - falling powders.

*Avoid carrying out operation for more than 0.5 hour.

*For each use event, covers use amounts up to 0.1-1 kg/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.8 Control of workers exposure for Use in batch and other process where opportunity for exposure arises - liquid (PROC 4)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces.

* Open surface 1-3 m².

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.9 Control of workers exposure for Use in batch and other process where opportunity for exposure arises - solid (PROC 4)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm²).

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

*For each use event, covers use amounts up to 100-1000 kg.

Transfer of solid products - falling powders.

*Avoid carrying out operation for more than 0.5 hour.

*For each use event, covers use amounts up to 10-100 g/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.10 Control of workers exposure for Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid (PROC 5)

Product characteristics

Covers concentrations up to: 50%.

Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Assumes activities are at room temperature. Exposed skin surface assumed: Two hands face (480 cm ²). Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. *Open surface 1-3 m ² .
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place. Put lids on containers immediately after use. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection. Wear suitable coveralls to prevent exposure to the skin.
2.11 Control of workers exposure for Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid (PROC 5)
Product characteristics
Covers concentrations up to: 10% Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Exposed skin surface assumed: Two hands face (480 cm ²). <i>Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.</i> *For each use event, covers use amounts up to 100-1000 kg. <i>Transfer of solid products - falling powders.</i> *Avoid carrying out operation for more than 0.5 hour. *For each use event, covers use amounts up to 10-100 g/minute.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place. Put lids on containers immediately after use. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision

controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.12 Control of workers exposure for Industrial and non-industrial spraying - liquid (PROC 7 and 11)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands and upper wrists (1500 cm²).

Handling of contaminated objects (0.3-1 m²) - Contamination > 90 % of surface.

*Avoid carrying out operation for more than 4 hours.

Surface spraying with no or low compressed air use.

*Avoid carrying out operation for more than 4 hours.

Industrial:

*Moderate application rate (0.3 - 3 l/minute)

*Ensure that spray direction is only horizontal or downward.

Professional:

*Low application rate (0.03 - 0.3 l/minute)

*Ensure that spray direction is only downward.

For dissolving solids:

Transfer of solid products - falling powders.

*Avoid carrying out operation for more than 0.5 hour.

Outdoor use.

Assumes activities are at room temperature.

Professional Use of Façade/surface Cleaning Products.

Covers percentage substance in the product up to 25 %.

Surface spraying with no or low compressed air use.

*Low application rate (0.03 - 0.3 l/minute).

*In any direction (including upwards).

*Stay upwind/keep distance from source.

Covers percentage substance in the product up to 5 %.

Spraying with high compressed air use.

*Moderate application rate (0.3 - 3 l/minute).

*In any direction (including upwards).

*Stay upwind/keep distance from source.

Technical and organisational conditions and measures

General measures applicable to all activities:

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

For industrial use concentration >10%:

Spraying:

* Carry out in a vented booth provided with laminar airflow.

* Use in room with a volume of minimum [m3]: 300 m³.

* Mechanical ventilation giving at least [ACH]: 1.

Handling:

* Local exhaust ventilation - efficiency of at least [%]: 90%.

For professional use concentration >10%:

*During spraying: Local exhaust ventilation - efficiency of at least [%]: 50%, or: Wear a half-mask respirator, selected in accordance with EN529 - efficiency of at least [%]: 50%.

*During handling: Local exhaust ventilation - efficiency of at least [%]: 90%, or: Wear a half-mask respirator, selected in accordance with EN529 - efficiency of at least [%]: 90%.

*Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

For professional use concentration <10%:

* Provide a good standard of general ventilation. Natural ventilation is from doors, windows etc. Controlled ventilation means air is supplied or removed by a powered fan.

2.13 Control of workers exposure for Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid (PROC 8a)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands (960 cm²).

Transfer of liquid products - falling liquids.

*Submerged loading.

*For each use event, covers use amounts up to 100-1000 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.14 Control of workers exposure for Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid (PROC 8a)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands (960 cm²).

Transfer of solid products - falling powders.

*For each use event, covers use amounts up to 100-1000 kg/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.15 Control of workers exposure for Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid (PROC 8b)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Transfer of liquid products - falling liquids.

*Submerged loading.

*For each use event, covers use amounts up to 100-1000 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.16 Control of workers exposure for Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid (**PROC 8b**)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm²).

Transfer of solid products - falling powders.

*For each use event, covers use amounts up to 100-1000 kg/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.17 Control of workers exposure for Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (**PROC 9**)

Product characteristics

Covers concentrations up to: 50%.

Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Assumes activities are at room temperature. Exposed skin surface assumed: Two hands face (480 cm ²). Transfer of liquid products - falling liquids. *Splash loading. *For each use event, covers use amounts up to 10-100 l/minute. <i>Handling that reduces contact between product and adjacent air.</i>
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection. Wear suitable coveralls to prevent exposure to the skin.
2.18 Control of workers exposure for Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid (PROC 9)
Product characteristics
Covers concentrations up to: 10% Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Exposed skin surface assumed: Two hands face (480 cm ²). <i>Transfer of solid products - falling powders.</i> *For each use event, covers use amounts up to 10-100 kg/minute. <i>Handling that reduces contact between product and adjacent air.</i>
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.19 Control of workers exposure for Roller application or brushing - liquid (PROC 10)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands (960 cm²).

Spreading of liquid products (0.3-1.0 m²)

*Avoid carrying out operation for more than 4 hours..

Handling of contaminated objects (0.3-1.0 m²) - Contamination > 90 % of surface.

*Avoid carrying out operation for more than 4 hours.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

Use above 5% concentration:

*Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

2.20 Control of workers exposure for Treatment of articles by dipping and pouring - liquid (PROC 13)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm²).

Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation).

**Use above 25% concentration: Open surface 1-3 m²*

**Open surface 0.3-1 m²*

**Avoid carrying out operation for more than 4 hours.*

Handling of contaminated objects (0.3-1.0 m²) - Contamination > 90 % of surface.

**Avoid carrying out operation for more than 4 hours.*

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

Use between 5- 25% concentration:

**Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).*

Use above 25% concentration:

**Local exhaust ventilation - efficiency of at least [%]: 50.*

**Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).*

2.21 Control of workers exposure for Production of preparations or articles by tableting, compression, extrusion, pelletisation - solid (PROC 14)

Product characteristics

Covers concentrations up to: 10%

Solid, low dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm²).

Tableting, compression, extrusion or pelletisation.

*For each use event, covers use amounts up to 100-1000 kg/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.22 Control of workers exposure for Use as laboratory reagent - liquid (PROC 15)

Product characteristics

Covers concentrations up to: 50%.

Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Assumes activities are at room temperature. Exposed skin surface assumed: One hand face only (240 cm²). Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation). *Open surface < 0.1 m² Transfer of liquid products - falling liquids. *Splash loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 0.1-1 l/minute. *Submerged loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to <0.1 l/minute. Handling that reduces contact between product and adjacent air.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection. Wear suitable coveralls to prevent exposure to the skin.
2.23 Control of workers exposure for Use as laboratory reagent - solid (PROC 15)
Product characteristics
Covers concentrations up to: 10% Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use. Exposed skin surface assumed: One hand face only (240 cm²). <i>Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.</i> *For each use event, covers use amounts up to <10 gram/minute. Transfer of solid products - falling powders. *Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 10-100 gram/minute. *Carefully handle the substance to minimise releases. Ensure operatives are trained to minimise exposures. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to <10 gram/minute.

Technical and organisational conditions and measures	
Demonstrable and effective housekeeping practices are in place. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection. Wear suitable coveralls to prevent exposure to the skin.	
2.24 Control of workers exposure for Hand-mixing with intimate contact and only PPE available - liquid (PROC 19)	
Product characteristics	
Covers concentrations up to: 50%. Liquid.	
Amount used, frequency and duration of use/exposure	
Covers daily exposures up to 8 hours (unless stated differently).	
Other operational conditions affecting workers exposure	
Indoor use. Assumes activities are above room temperature. Exposed skin surface assumed: Two hands and forearms (1980 cm²). Hand-mixing with intimate contact and only PPE available. *For concentration >10% and large scale (1-3 m²): Assumes large workrooms. *Small scale (0.3-1 m²).	
Technical and organisational conditions and measures	
Demonstrable and effective housekeeping practices are in place. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection. Wear suitable coveralls to prevent exposure to the skin.	
<i>For concentration >10%:</i> * Local exhaust ventilation - efficiency of at least [%]: 50%. * Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).	

3. Exposure estimation and reference to its source		
The environmental exposure estimates were calculated according to EUSES version 2.1.2. Degradation in the STP was calculated according to first-order kinetics.		
Environment		
CEPE 15, 16a - Other spray coating - Volatiles / Abatement including indoor point sources		
Release route	Release rate (kg/day)	Release estimation method
Water	1.26	SPERC (CEPE 15, 16a)
Air	61.74	SPERC (CEPE 15, 16a)

Soil	0	SPERC (CEPE 15, 16a)
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Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.606
Freshwater (sediment)	0.802 mg/kg dw	0.617
Marine water (pelagic)	3.17E-4 mg/L	0.587
Marine water (sediment)	0.078 mg/kg dw	0.597
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment CEPE 17a - Other spray coating, indoor use - point sources – Solids		
Release route	Release rate (kg/day)	Release estimation method
Water	0	SPERC (CEPE 17a)
Air	200.2	SPERC (CEPE 17a)
Soil	0	SPERC (CEPE 17a)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11
Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	0.003 mg/kg dw	0.012

Environment ESVOC 11 - Industrial use of solvents in oil field drilling and production operations		
Release route	Release rate (kg/day)	Release estimation method
Water	1.267	Other method
Air	0.5	Other method
Soil	0	Other method

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.62
Freshwater (sediment)	0.819 mg/kg dw	0.63
Marine water (pelagic)	3.23E-4 mg/L	0.598
Marine water (sediment)	0.079 mg/kg dw	0.608
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment

ESVOC 13 - Industrial use of formulated lubricants		
Release route	Release rate (kg/day)	Release estimation method
Water	1.266	SPERC (ESVOC 13)
Air	63.3	SPERC (ESVOC 13)
Soil	0	SPERC (ESVOC 13)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.609
Freshwater (sediment)	0.805 mg/kg dw	0.619
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.599
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment ESVOC 38 - Use of the substance within laboratory setting, including pilot plants		
Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (ESVOC 38)
Air	1.58	SPERC (ESVOC 38)
Soil	0	SPERC (ESVOC 38)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment FEICA 6,7 - Industrial Use of Substances other than Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others		
Release route	Release rate (kg/day)	Release estimation method
Water	0	SPERC (FEICA 6, 7)
Air	212.5	SPERC (FEICA 6, 7)
Soil	0	SPERC (FEICA 6, 7)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11
Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	0.003 mg/kg dw	0.013

Environment

FEICA 8, 9 - Industrial Use of Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others adhesives

Release route	Release rate (kg/day)	Release estimation method
Water	0	SPERC (FEICA 8, 9)
Air	250	SPERC (FEICA 8, 9)
Soil	0	SPERC (FEICA 8, 9)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11
Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	0.004 mg/kg dw	0.015

Risk characterisation for man via the environment

CEPE 15, 16a - Other spray coating - Volatiles / Abatement including indoor point sources

Inhalation: RCR = 0.001

Oral: RCR = 8.639E-4

Risk characterisation for man via the environment

CEPE 17a - Other spray coating, indoor use - point sources – Solids

Inhalation: RCR = 0.004

Oral: RCR = 2.19E-4

Risk characterisation for man via the environment

ESVOC 11 - Industrial use of solvents in oil field drilling and production operations

Inhalation: RCR = 6.723E-5

Oral: RCR = 5.278E-4

Risk characterisation for man via the environment

ESVOC 13 - Industrial use of formulated lubricants

Inhalation: RCR = 1.813E-4

Oral: RCR = 4.989E-4

Risk characterisation for man via the environment

ESVOC 38 - Use of the substance within laboratory setting, including pilot plants

Inhalation: RCR = 6.819E-5

Oral: RCR = 4.95E-4

Risk characterisation for man via the environment

FEICA 6,7 - Industrial Use of Substances other than Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others

Inhalation: RCR = 0.004

Oral: RCR = 2.236E-4

Risk characterisation for man via the environment

FEICA 8,9 - Industrial Use of Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others adhesives

Inhalation: RCR = 0.005

Oral: RCR = 2.38E-4

Worker exposure

Long-term, systemic

Contributing scenario	Inhalation	Dermal	Combined routes	Exposure estimation Method
Use in closed process, no likelihood of exposure - liquid (PROC 1)	Exposure: 0.44 mg/m ³ RCR: 0.014	Exposure: 0.003 mg/kg bw/day RCR: 3.857E-4	RCR: 0.015	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: High level containment) Derm: Extended TRA workers
Use in closed process, no likelihood of exposure - solid (PROC 1)	Exposure: 0.032 mg/m ³ RCR: 0.001	Exposure: 6.857E-4 mg/kg bw/day RCR: 7.713E-5	RCR: 0.001	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: High level containment) Derm: Extended TRA workers
Use in closed, continuous process with occasional controlled exposure - liquid (PROC 2)	Exposure: 0.69 mg/m ³ RCR: 0.022	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.024	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: High level

				containment) Derm: Extended TRA workers
Use in closed, continuous process with occasional controlled exposure - solid (PROC 2)	Exposure: 0.036 mg/m ³ RCR: 0.001	Exposure: 0.003 mg/kg bw/day RCR: 3.085E-4	RCR: 0.001	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: High level containment) Derm: Extended TRA workers
Use in closed batch process - liquid (PROC 3)	Exposure: 4.3 mg/m ³ RCR: 0.138	Exposure: 0.003 mg/kg bw/day RCR: 3.857E-4	RCR: 0.139	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: Medium level containment) Derm: Extended TRA workers
Use in closed batch process - solid (PROC 3)	Exposure: 0.32 mg/m ³ RCR: 0.01	Exposure: 6.857E-4 mg/kg bw/day RCR: 7.713E-5	RCR: 0.01	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: Medium level containment) Derm: Extended TRA workers
Use in batch and other process where opportunity for exposure arises - liquid (PROC 4)	Exposure: 4.4 mg/m ³ RCR: 0.142	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.149	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: Low level containment) Derm: Extended TRA workers
Use in batch and other process where opportunity for exposure arises - solid (PROC 4)	Exposure: 3 mg/m ³ RCR: 0.096	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.098	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: Low level containment) Derm: Extended TRA workers
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant	Exposure: 4.4 mg/m ³ RCR: 0.142	Exposure: 0.137 mg/kg bw/day	RCR: 0.157	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%.

contact) - liquid (PROC 5)		RCR: 0.015		RMM: Low level containment) Derm: Extended TRA workers
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid (PROC 5)	Exposure: 3 mg/m ³ RCR: 0.096	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.1	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: Low level containment) Derm: Extended TRA workers
Industrial and non-industrial spraying - liquid (PROC 7 and 11)	Exposure: 1.5 mg/m ³ RCR: 0.048	Exposure: 0.214 mg/kg bw/day RCR: 0.024	RCR: 0.072	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 5%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid (PROC 8a)	Exposure: 13 mg/m ³ RCR: 0.418	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.433	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid (PROC 8a)	Exposure: 3.2 mg/m ³ RCR: 0.103	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.106	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid (PROC 8b)	Exposure: 13 mg/m ³ RCR: 0.418	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.426	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid (PROC 8b)	Exposure: 3.2 mg/m ³ RCR: 0.103	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.104	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA

				workers
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (PROC 9)	Exposure: 13 mg/m ³ RCR: 0.418	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.426	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid (PROC 9)	Exposure: 0.96 mg/m ³ RCR: 0.031	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.032	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Roller application or brushing - liquid (PROC 10)	Exposure: 16 mg/m ³ RCR: 0.515	Exposure: 0.137 mg/kg bw/day RCR: 0.031	RCR: 0.546	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 5%. No RMM) Derm: Extended TRA workers
Roller application or brushing - liquid (PROC 10)	Exposure: 4 mg/m ³ RCR: 0.129	Exposure: 0.137 mg/kg bw/day RCR: 0.031	RCR: 0.16	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 5%. No RMM) Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 12 mg/m ³ RCR: 0.386	Exposure: 0.069 mg/kg bw/day RCR: 0.015	RCR: 0.401	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: LEV, general ventilation) Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 15 mg/m ³ RCR: 0.482	Exposure: 0.069 mg/kg bw/day RCR: 0.015	RCR: 0.497	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 25%. RMM: General ventilation) Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 2.2 mg/m ³	Exposure: 0.069 mg/kg	RCR: 0.086	Inhal: External exposure estimation tool (Advanced

	RCR: 0.071	bw/day RCR: 0.015		REACH Tool. OC: Concentration up to 5%. No RMM) Derm: Extended TRA workers
Production of preparations or articles by tableting, compression, extrusion, pelletisation - solid (PROC 14)	Exposure: 0.32 mg/m ³ RCR: 0.01	Exposure: 0.007 mg/kg bw/day RCR: 7.713E-4	RCR: 0.011	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Use as laboratory reagent - liquid (PROC 15)	Exposure: 4.2 mg/m ³ RCR: 0.135	Exposure: 0.003 mg/kg bw/day RCR: 3.857E-4	RCR: 0.135	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Use as laboratory reagent - solid (PROC 15)	Exposure: 0.092 mg/m ³ RCR: 0.003	Exposure: 6.857E-4 mg/kg bw/day RCR: 7.713E-5	RCR: 0.003	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Hand-mixing with intimate contact and only PPE available - liquid (PROC 19)	Exposure: 14 mg/m ³ RCR: 0.45	Exposure: 1.414 mg/kg bw/day RCR: 0.159	RCR: 0.609	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Hand-mixing with intimate contact and only PPE available - liquid (PROC 19)	Exposure: 9.1 mg/m ³ RCR: 0.293	Exposure: 1.414 mg/kg bw/day RCR: 0.159	RCR: 0.452	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Hand-mixing with intimate contact and only PPE available - liquid (PROC 19)	Exposure: 3.6 mg/m ³ RCR: 0.116	Exposure: 1.414 mg/kg bw/day RCR: 0.159	RCR: 0.275	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA

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Acute systemic

Not required as no hazard identified

Local effects via inhalation route

Not required as no hazard identified

Local effects via dermal route

A qualitative approach was used to assess the risk of sensitization in accordance with REACH Guidance R.8 (moderate hazard level). The use of gloves and generic organisational measures were proposed as Risk Management Measures to control the risk. Residual exposure was quantitatively estimated and assessed.

Contributing scenario	Acute	Long term	Exposure estimation Method
Use in closed process, no likelihood of exposure - liquid (PROC 1)	Exposure: 0.002 mg/cm ² RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in closed process, no likelihood of exposure - solid (PROC 1)	Exposure: 1.99E-4 mg/cm ² RCR: 0.001	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in closed, continuous process with occasional controlled exposure - liquid (PROC 2)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in closed, continuous process with occasional controlled exposure - solid (PROC 2)	Exposure: 8.75E-4 mg/cm ² RCR: 0.005	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in closed batch process - liquid (PROC 3)	Exposure: 0.002 mg/cm ² RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in closed batch process - solid (PROC 3)	Exposure: 3.99E-4 mg/cm ² RCR: 0.002	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in batch and other process where opportunity for exposure arises - liquid (PROC 4)	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in batch and other process where opportunity for exposure arises - solid (PROC 4)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)

Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid (PROC 5)	Exposure: 0.04 mg/cm ² RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid (PROC 5)	Exposure: 0.008 mg/cm ² RCR: 0.043	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Industrial and non-industrial spraying - liquid (PROC 7 and 11)	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid (PROC 8a)	Exposure: 0.002 mg/cm ² RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid (PROC 8a)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid (PROC 8b)	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid (PROC 8b)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (PROC 9)	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid (PROC 9)	Exposure: 0.004 mg/cm ² RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Roller application or brushing - liquid (PROC 10)*	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Treatment of articles by dipping and pouring - liquid (PROC 13)*	Exposure: 0.02 mg/cm ² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Production of preparations or articles by tableting, compression, extrusion,	Exposure: 0.002 mg/cm ²	N/A	Acute: External exposure estimation tool (Quantitative

pelletisation - solid (PROC 14)	RCR: 0.011		assessment of residual exposure)
Use as laboratory reagent - liquid (PROC 15)	Exposure: 0.002 mg/cm ² RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use as laboratory reagent - solid (PROC 15)	Exposure: 3.99E-4 mg/cm ² RCR: 0.002	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Hand-mixing with intimate contact and only PPE available - liquid (PROC 19)*	Exposure: 0.05 mg/cm ² RCR: 0.269	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
*Exposure estimation and risk characterisation was based on long term systemic dermal exposure value and therefore this value is identical for all estimated concentrations/scenarios.			

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

Environment

The daily amount per site as mentioned in section 2.1 is the maximum amount (kg/day) that may be safely used, taking into account the default operational conditions as specified in section 2.1 and the release fractions as specified in section 3. This amount is defined as M_{Safe} .

To evaluate the compliance of specific formulation, the site-specific substance use rate (M_{Site}) and days emitting ($T_{Emission, Site}$), onsite and offsite emission controls and subsequent total substance emission Reduction Efficiency ($RE_{Total, Site} = 1 - [(1 - RE_{Onsite, Site}) \times (1 - RE_{Offsite, Site})]$), sewage treatment plant effluent flow rate ($G_{Effluent, Site}$) and receiving water dilution factor (q_{Site}) need to be known.

It is simpler and thus may be preferable to some users to compare M_{Site} with M_{Safe} . Adequate control of risk exists if the following conditions are met: $[RE_{Total, Site} \geq RE_{Total, SpERC}, G_{Effluent, Site} \geq G_{Effluent, SpERC}, \text{ and } q_{Site} \geq q_{SpERC}]$ and $M_{Safe} \geq M_{Site}$.

In case the above comparison does not show safe use, the following scaling possibilities are advised:

- The risk is driven by soil for a number of industrial use contributing scenarios. As a default it is assumed that STP sludge is applied on agricultural soil. However this may not always be the case. If the STP sludge is not applied to soil, the RCR for agricultural soil will decrease significantly and therefore the amount that may be used will increase.
- When STP sludge is not applied to soil, the risk will be driven by surface water and sediment. The RCR for these protection targets is lower and therefore the volume can be increased with a factor of approximately 1.7 assuming all other conditions stay equal. If the volume is then not yet high enough, scaling based on municipal STP discharge rate and receiving river flow rate is advised.
- As mentioned in section 3, degradation in the STP has been calculated according to first-order kinetics in the model EUSES. This implies that the concentration in the effluent is proportional to the concentration in the influent and so the predicted concentration in effluent depends on the use volume. An alternative approach is to use Monod kinetics in EUSES. This can be applied for readily biodegradable substances in case: a) the release to the WWTP/STP is more or less continuous so the specific bacteria responsible for biodegradation will be able to maintain themselves in the system and b) the total COD load remains within the specifications of the WWTP/STP. When this approach is applied, the substance concentration in the STP effluent is independent of the concentration in the influent and therefore the use volume, and will remain below 50 µg/l. This implies that under these circumstances M_{safe} is theoretically unlimited.

Human health

A DU works within the boundaries of this ES if he fulfills the conditions of use set in section 2. Table 4.1 provides an overview of the assumed effectiveness for the different RMM. The DU can use this effectiveness estimation in order to assess if any deviating RMM will also provide safe use. This is done by multiplying the relevant RCR with the effectiveness of the RMM implemented at the workplace and dividing it by the effectiveness of the RMM listed in section 2. If the shift duration is greater than 8 hours per day, the long term systemic DNELs have to be adapted with the using the following equation, derived from the Brief and Scala model: DNEL Reduction Factor = $(8 \times \text{hours worked in shift}) \times ((24 - \text{hours worked in shift}) / 16)$. This equation can not be used to adapt a DNEL for a shift duration shorter than 8 hours. With the adapted DNEL, the DU can recalculate the RCR by dividing the exposure estimation in section 3 with the adapted DNEL. If the RCR is smaller than 0.725 (1 - 0.275 or 1 - (Sum of all man through environment and generic consumer exposure)), the downstream user works within the boundaries set by the ES.

Table 4.1 Effectiveness of risk management measures (RMM).

Risk management measure	Assumed effectiveness ⁴		Source of effectiveness
	Inhalatory	Dermal	
High level containment - Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).	99.9%	99.9%	Advanced REACH tool (www.advancedreachtool.com).
Medium level containment - Undertake operation under enclosed conditions.	99%	33%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Low level containment - Put lids on containers immediately after use.	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Working outdoor / natural ventilation	30%	-	Advanced REACH tool (www.advancedreachtool.com)
General ventilation (mechanical)	50%	-	Advanced REACH tool (www.advancedreachtool.com).
Local exhaust ventilation, fixed capturing hood	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Local exhaust ventilation, other system	50%	17%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Laminar flow booth	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.
Respirator (Wear a full face respirator conforming to EN140 with Type A / P2 filter or better. APF >20)	95%	Not applicable	Advanced REACH tool (www.advancedreachtool.com).
Respirator (Wear a respirator (half face mask) conforming to EN140 with Type A filter / P2 filter or better. APF >10)	90%	Not applicable	Advanced REACH tool (www.advancedreachtool.com).
Reduction of duration of exposure			ECETOC TRA (http://www.ecetoc.org/tra) for the inhalatory effectiveness, expert judgment for dermal effectiveness.
> 60 and ≤ 240 minutes per shift	40%	40%	
> 15 and ≤ 60 minutes per shift	80%	80%	
≤ 15 minutes per shift	90%	80%	
Concentration of substance in mixture			ECETOC TRA (http://www.ecetoc.org/tra) for the inhalatory effectiveness, expert judgment for dermal effectiveness.
> 5% and ≤ 25%	40%	75%	
> 1% and ≤ 5%	80%	95%	
≤ 1%	90%	99%	

⁴ All effectiveness's listed are only valid if the RMM is properly designed, installed (if applicable), used and maintained.

5. ES 5: Professional end-use (SU 22); Professional use

1. Title of Exposure scenario
Environment
Environmental assessment see Consumer use.
Worker
Worker assessment see Industrial use.
2. Conditions of use affecting exposure
2.1 Control of environmental exposure
Environmental assessment see Consumer use.
2.2 Control of workers exposure
Worker assessment see Industrial use.
3. Exposure estimation and reference to its source
Environment
Environmental assessment see Consumer use.
Risk characterisation for man via the environment
Man through environment assessment see Consumer use.
Worker exposure
Worker assessment see Industrial use.
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES
<u>Environment</u> See Consumer use.
<u>Human health</u> See Industrial use.

6. ES 6: Consumer end-use (SU 21); Consumer use

1. Title of Exposure scenario	
Environment: * Professional and consumer use of fragrances, cosmetics, detergents/maintenance products and laboratory agents * Professional and consumer use of coatings/inks, lubricants and construction chemicals * Professional and consumer use resulting in and after inclusion into / onto a matrix	ERC 8a, 8c, 8d, 8f, 9a, 9b, 10a, 11a
Consumer	
GES4_C Covers general exposures to consumers arising from the use of household products sold as washing and cleaning products, aerosols, coatings, de-icers, lubricants and air care products	
2. Conditions of use affecting exposure	
2.1 Control of environmental exposure: Professional and consumer use of fragrances, cosmetics, detergents/maintenance products and laboratory agents Professional and consumer use of coatings/inks, lubricants and construction chemicals Professional and consumer use resulting in and after inclusion into / onto a matrix	
2.1.1 Control of environmental exposure: Professional and consumer use of fragrances, cosmetics, detergents/maintenance products and laboratory agents	
Amounts used	
Daily wide dispersive use = 0.001 tonnes/day	
Other given operational conditions affecting environmental exposure	
Receiving river flow rate $\geq 1.8E4$ m ³ /d	
Conditions and measures related to municipal sewage treatment plant	
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%). Municipal STP discharge rate $\geq 2E3$ m ³ /d STP sludge is applied on agricultural soil	
2.1.2 Control of environmental exposure: Professional and consumer use of coatings/inks, lubricants and construction chemicals	
Amounts used	
Daily wide dispersive use = 0.003 tonnes/day	
Other given operational conditions affecting environmental exposure	
Receiving river flow rate $\geq 1.8E4$ m ³ /d	
Conditions and measures related to municipal sewage treatment plant	
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%). Municipal STP discharge rate $\geq 2E3$ m ³ /d STP sludge is applied on agricultural soil	
2.1.3 Control of environmental exposure: Professional and consumer use resulting in and after inclusion into	

/ onto a matrix
Amounts used
Daily wide dispersive use = 0.003 tonnes/day
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4$ m ³ /d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3$ m ³ /d
STP sludge is applied on agricultural soil
2.2 Control of consumers exposure for GES4_C Covers general exposures to consumers arising from the use of household products sold as washing and cleaning products, aerosols, coatings, de-icers, lubricants and air care products

3. Exposure estimation and reference to its source		
The environmental exposure estimates were calculated according to EUSES version 2.1.2. Degradation in the STP was calculated according to first-order kinetics.		
Environment Professional and consumer use of fragrances, cosmetics, detergents/maintenance products and laboratory agents		
Release route	Release rate (kg/day)	Release estimation method
Water	1	ERC (ERC 8d)
Air	0	ERC (ERC 8d)
Soil	0.2	ERC (ERC 8d)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.504
Freshwater (sediment)	0.667 mg/kg dw	0.513
Marine water (pelagic)	2.62E-4 mg/L	0.485
Marine water (sediment)	0.064 mg/kg dw	0.493
Effluent	0.021 mg/L	0.01
Agricultural soil	0.206 mg/kg dw	0.789

Environment Professional and consumer use of coatings/inks, lubricants and construction chemicals		
Release route	Release rate (kg/day)	Release estimation method
Water	0.138	SPERC (Wide dispersive use coatings/inks, lubricants, construction chemicals)
Air	0.003	SPERC (Wide dispersive use coatings/inks, lubricants, construction chemicals)
Soil		SPERC

0.15	(Wide dispersive use coatings/inks, lubricants, construction chemicals)
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Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	8.88E-4 mg/L	0.164
Freshwater (sediment)	0.218 mg/kg dw	0.168
Marine water (pelagic)	7.84E-5 mg/L	0.145
Marine water (sediment)	0.019 mg/kg dw	0.148
Effluent	0.003 mg/L	0.001
Agricultural soil	0.028 mg/kg dw	0.109

Environment Professional and consumer use resulting in and after inclusion into / onto a matrix		
Release route	Release rate (kg/day)	Release estimation method
Water	0.088	SPERC (Wide dispersive use inclusion into/onto matrix)
Air	0.003	SPERC (Wide dispersive use inclusion into/onto matrix)
Soil	0	SPERC (Wide dispersive use inclusion into/onto matrix)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	7.83E-4 mg/L	0.145
Freshwater (sediment)	0.192 mg/kg dw	0.148
Marine water (pelagic)	6.78E-5 mg/L	0.126
Marine water (sediment)	0.017 mg/kg dw	0.128
Effluent	0.002 mg/L	8.952E-4
Agricultural soil	0.018 mg/kg dw	0.07

Risk characterisation for man via the environment	
Inhalation: RCR = 8.055E-5	
Oral: RCR = 8.94E-4	
Risk characterisation for man via the environment	
Inhalation: RCR = 6.747E-5	
Oral: RCR = 2.459E-4	
Risk characterisation for man via the environment	
Inhalation: RCR = 6.663E-5	
Oral: RCR = 2.087E-4	

Consumer exposure	
Type of product	Maximum concentration of Orange oil allowed in consumer products (% w/w)

Laundry & aerosol cleaning spray	2%
Dishwashing product	5%
Aerosol air fresheners	15%
Biocidal products	6%
Fuels (not as main component)	5%
Paints	6%
Paint removers	50%
Coatings and paints, thinners	10%
Non-metal-surface treatment products	0.5%
Polishes	13%

Long-term, systemic

Contributing scenario	Inhalation	Dermal	Oral	Combined routes	Exposure estimation Method
GES4_C Covers general exposures to consumers arising from the use of household products sold as washing and cleaning products, aerosols, coatings, de-icers, lubricants and air care products	Exposure: 1.94 mg/m ³ RCR: 0.249	Exposure: 0.024 mg/kg bw/day RCR: 0.005	Exposure: 0.02 mg/kg bw/day RCR: 0.005	RCR: 0.259	Values derived from IFRA's final report on "REACH Exposure Scenario's for fragrance substances (03/02/2010, page 19 and 20)".

Risk characterisation for acute systemic

Not required as no hazard identified

Local effects via inhalation route

Not required as no hazard identified

Local effects via dermal route

A qualitative approach was used to assess the risk of sensitization in accordance with REACH Guidance R.8 (moderate hazard level). The maximum final concentration in the product is 1% (IFRA's final report on "REACH Exposure Scenario's for fragrance substances, 03/02/2010) and the product should be labelled according to the Detergents Regulation to inform consumers on the intrinsic properties. Sensitizing substances in detergents exceeding 0.01% by weight must be listed using the INCI nomenclature according to the regulation.

Contributing scenario	Acute	Long term	Exposure estimation Method
GES4_C Covers general exposures to consumers arising from the use of household products sold as washing and cleaning products, aerosols, coatings, de-icers, lubricants and air care products	Exposure: 9.6E-4 mg/cm ² RCR: 0.01	N/A	Acute: IFRA report.

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ESEnvironment

Not applicable for consumer uses.

Human health

Not applicable for consumer uses.