

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

1.1 Product identifier

Trade name : dl- α -Tocopherol
REACH Registration Number : 01-2120086658-39-0001
Substance name : 2H-1-Benzopyran-6-ol, 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-
CAS-No. : 10191-41-0

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

Use of the Substance/Mixture : Additive for the stabilisation of foods, Ingredient for pharmaceutical products, Ingredient for personal care products

1.3 Details of the supplier of the safety data sheet

Company : DSM Nutritional Products Europe Ltd
PO Box 2676
CH-4002 Basel
Telephone : +41618157777
Telefax : +41618157770
E-mail address of person responsible for the SDS : sds.nutritionalproducts@dsm.com

1.4 Emergency telephone number

+41 848 00 11 77 (Carechem 24 International)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin sensitisation, Sub-category 1B H317: May cause an allergic skin reaction.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements : **Prevention:**
P261 Avoid breathing mist or vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
Response:
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
Disposal:

P501

Dispose of contents/ container to an approved waste disposal plant.

2.3 Other hazards

The substance does not fulfill the PBT criteria.
The substance does not fulfill the vPvB criteria.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

Synonyms : Vitamin E
Brief description of the product : Substance
Molecular formula : C₂₉ H₅₀ O₂

3.1 Substances

Hazardous components

Chemical name	CAS-No. EC-No.	Concentration (% w/w)
3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	10191-41-0 233-466-0	>= 90 - <= 100

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.

If inhaled : Move to fresh air.
Consult a physician after significant exposure.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and plenty of water.
If symptoms persist, call a physician.

In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Rinse mouth with water.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
Obtain medical attention.

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4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Nausea, Vomiting, Diarrhoea, Fatigue, Weakness

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures**5.1 Extinguishing media**Suitable extinguishing media : Alcohol-resistant foam
Dry chemical
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : None known.

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Standard procedure for chemical fires.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**Personal precautions : Use personal protective equipment.
Ensure adequate ventilation.**6.2 Environmental precautions**

Environmental precautions : Try to prevent the material from entering drains or water courses.

6.3 Methods and material for containment and cleaning upMethods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.**6.4 Reference to other sections**

For personal protection see section 8., For disposal considerations see section 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**Advice on safe handling : Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.

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Advice on protection against fire and explosion : Take necessary action to avoid static electricity discharge. Product will burn under fire conditions.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of work-day.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : To maintain product quality, do not store in heat or direct sunlight. Keep under inert gas.

Keep container tightly closed and dry.

7.3 Specific end use(s)

Specific use(s) : Not applicable

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	10191-41-0	TWA	7.3 mg/m ³	DSM Internal Limit

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Vitamin E	Workers	Inhalation	Long-term systemic effects	44 mg/m ³
	Workers	Skin contact	Long-term systemic effects	125 mg/kg bw/d
	Workers	Skin contact	Long-term local effects	0.185 mg/cm ²
	Consumers	Skin contact	Long-term systemic effects	62.5 mg/kg bw/d
	Consumers	Inhalation	Long-term systemic effects	10.8 mg/m ³
	Consumers	Ingestion	Long-term systemic effects	6.25 mg/kg bw/d
	Consumers	Skin contact	Long-term local effects	0.185 mg/cm ²

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Vitamin E	Intermittent use/release	0.516 mg/l
	Fresh water sediment	735000 mg/kg dry weight (d.w.)
	Marine water	0.052 mg/l
	Marine sediment	73500 mg/kg dry weight (d.w.)
	Soil	259000 mg/kg dry weight (d.w.)

8.2 Exposure controls

Personal protective equipment

Eye protection : Safety glasses with side-shields

Hand protection	: Consider the hazard characteristics of this product and any special workplace conditions when selecting the appropriate type of protective gloves. Glove material: for example nitrile rubber
Skin and body protection	: Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Respiratory protection	: In the case of vapour formation use a respirator with an approved filter.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: viscous, oily liquid
Colour	: colourless - yellowish brown
Odour	: odourless
Odour Threshold	: No information available.
pH	: No data available
Melting point/range	: 2.5 - 3.5 °C
Boiling point/boiling range	: ca. 393 °C (1,013 hPa) 265 °C (3.75 hPa)
Flash point	: 301 °C (ISO 2719)
Evaporation rate	: not determined
Lower explosion limit	: not determined
Upper explosion limit	: not determined
Vapour pressure	: < 0.001 hPa (20 °C)
Relative vapour density	: not determined
Density	: 0.95 g/cm ³ (25 °C)
Water solubility	: < 1 mg/l (20 °C) practically insoluble
Solubility in other solvents	: Ethanol: soluble Chloroform: soluble Acetone: soluble Ether: soluble Oils and fats: soluble
Partition coefficient: n-octanol/water	: log Pow 12.2 (calculated value)
Ignition temperature	: 403 °C (984 hPa, DIN 51794)
Thermal decomposition	: Decomposes on heating in the presence of air.
Viscosity, dynamic	: 5,174 mPa.s (20 °C)
Explosive properties	: Not explosive
Oxidizing properties	: Not oxidizing

9.2 Other information

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Refractive index	: 1.503 - 1.507 (589 nm)
Molecular weight	: 430.71 g/mol
Surface tension	: 8.1 mN/m (430 °C)

SECTION 10: Stability and reactivity**10.1 Reactivity**

No hazards to be specially mentioned.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Possible incompatibility with materials listed under section 10.5.

10.4 Conditions to avoid

Exposure to light.

Heat

10.5 Incompatible materials

Oxygen
Oxidizing agents
Ferric salts
Silver salts

Strong acids and strong bases

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide and unburned hydrocarbons (smoke).

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

Acute oral toxicity	: LD50 (Rat): > 4,000 mg/kg
	: LD50 (Mouse): > 4,000 mg/kg
Acute dermal toxicity	: LD50 (Rat): > 3,000 mg/kg
Skin irritation	: Mild skin irritation (Rabbit)
	: no phototoxic skin reaction (Guinea pig, OECD Test Guideline 432)
Eye irritation	: slight irritation (Rabbit, Draize Test) temporary redness
Sensitisation	: Causes sensitisation. (Guinea pig, Maximisation Test, OECD Test Guideline 406)

	: no photoallergenic skin reaction (Guinea pig, OECD Test Guideline 432)
Genotoxicity in vitro	: not mutagenic (Various test systems)
Carcinogenicity	: Did not show carcinogenic effects in animal experiments.
Teratogenicity	: not teratogenic not embryotoxic
STOT - single exposure (Acute exposure)	: The substance or mixture is not classified as specific target organ toxicant, single exposure.
STOT - repeated exposure	: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.
Aspiration toxicity	: No aspiration toxicity classification

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment	: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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Experience with human exposure

Product:

	: RDA (Recommended Daily Allowance) 8 - 10 mg
	: Therapeutic dosage 100 - 300 mg/day
Skin contact	: Skin sensitisation Remarks: (Cases have been reported rarely.)
Ingestion	: Acute overdose produces the following symptoms: Nausea, Vomiting, Diarrhoea, Fatigue, Weakness

Further information

Product:

Remarks	: The product passes into and partly through the skin of rats and pigs.
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SECTION 12: Ecological information**12.1 Toxicity**

- Toxicity to fish : Salmo gairdneri (rainbow trout)
LC0 (96 h) \geq 10 mg/l
- Toxicity to daphnia and other aquatic invertebrates : Daphnia magna (Water flea)
EC50 (48 h) $>$ 100 mg/l
(OECD Test Guideline 202)
- Toxicity to algae : Pseudokirchneriella subcapitata (microalgae)
ErC50 (72 h) $>$ 25.8 mg/l
No toxicity at the limit of solubility
(OECD Test Guideline 201)
: NOEC 25.8 mg/l
- Toxicity to bacteria : activated sludge
Concentration of the substance 100 mg/l
No inhibition was observed under the biodegradation test conditions.
(OECD Test Guideline 301F)

12.2 Persistence and degradability

- Biodegradability : Not readily biodegradable.
8 % (28 d)
(OECD Test Guideline 301F)
- : Inherently biodegradable.
70 - 80 % (63 d)
(OECD Test Guideline 301F)
publicly available data

12.3 Bioaccumulative potential

- Partition coefficient: n-octanol/water : log Pow 12.2 (calculated value)

12.4 Mobility in soil

- Distribution among environmental compartments : No data available
- Surface tension : 8.1 mN/m (430 °C)

12.5 Results of PBT and vPvB assessment

- Assessment : The substance does not fulfill the PBT criteria.
: The substance does not fulfill the vPvB criteria.

12.6 Endocrine disrupting properties

- Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Product:

Additional ecological information : There is no data available for this product.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.
Do not dispose of waste into sewer.
Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging : Dispose of as unused product.
Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number or ID number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial

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emissions (integrated pollution prevention and control)
Not applicable

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

15.2 Chemical safety assessment

A Chemical Safety Assessment has been carried out for this substance.

SECTION 16: Other information

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

DNEL - Derived No-Effect Level; NFPA - National Fire Protection Association (USA); PNEC - Predicted No-Effect Concentration; STEL - Short term exposure limit; TLV-C - Ceiling Limit Value; TWA - Time Weighted Average; WEL - Workplace Exposure Limit.

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific

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material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

IE / EN

Annex

	Title of Exposure Scenario
ES 1:	Formulation
ES 2:	Use at industrial sites - Manufacture of food packaging material
ES 3:	Professional use - Hairdressing services
ES 4:	Consumer use of cosmetics

Abbreviations

ART = Advanced REACH Tool

ECETOC TRA = European Centre for Ecotoxicology and Toxicology Of Chemicals - Targeted Risk Assessment

ES = Exposure scenario

EUSES = European Union System for the Evaluation of Substances

PEC = Predicted exposure concentration

RCR = Risk characterisation ratio: "Level of Exposure/DNEL" or "PEC/PNEC"

ES 1: Formulation

1. Scenario description

Main User Groups	: SU 3: Industrial uses: Uses of substances as such or in preparations at industrial sites
Process categories	: PROC1: Use in closed process, no likelihood of exposure PROC2: Use in closed, continuous process with occasional controlled exposure PROC3: Use in closed batch process (synthesis or formulation) PROC4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact) PROC8a: Transfer of substance or preparation (charging/discharging) from/ to vessels/ large containers at non-dedicated facilities PROC8b: Transfer of substance or preparation (charging/discharging) from/ to vessels/ large containers at dedicated facilities PROC9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC14: Production of preparations or articles by tableting, compression, extrusion, pelletisation PROC15: Use as laboratory reagent
Environmental Release Categories	: ERC2: Formulation of preparations

2.1 Contributing scenario controlling environmental exposure for: ERC2

Amount used

Daily amount per site	: <= 9.9 t
Annual amount per site	: <= 99.0 t

Environment factors not influenced by risk management

Flow rate of receiving surface water	: 18,000 m ³ /d
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Other given operational conditions affecting environmental exposure

Emission or Release Factor: Air	: 2.5 %
Emission or Release Factor: Water	: 2 %
Emission or Release Factor: Soil	: 0.01 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant	: Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent	: 2,000 m ³ /d
Effectiveness (of a measure)	: 91.97 %

Conditions and measures related to external treatment of waste for disposal

Disposal methods	: Dispose of contents/container in accordance with local regulation.
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2.2 Contributing scenario controlling worker exposure for: PROC1, PROC3

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Product characteristics

Concentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) : Liquid substance

Frequency and duration of use

Frequency of use : <= 8 hours/day

Human factors not influenced by risk management

Dermal exposure : Hand

Other operational conditions affecting workers exposure

Outdoor / Indoor : Indoor use

Technical conditions and measures

Handle substance within a closed system. 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.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

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

Wear suitable gloves tested to EN374. (Effectiveness (of a measure): 80 %)

2.3 Contributing scenario controlling worker exposure for: PROC2

Product characteristics

Concentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) : Liquid substance

Frequency and duration of use

Frequency of use : <= 8 hours/day

Human factors not influenced by risk management

Dermal exposure : Both hands

Other operational conditions affecting workers exposure

Outdoor / Indoor : Indoor use

Technical conditions and measures

Handle substance within a closed system. 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.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

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

Wear suitable gloves tested to EN374. (Effectiveness (of a measure): 80 %)

2.4 Contributing scenario controlling worker exposure for: PROC4, PROC5

Product characteristics

Concentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 100 % (unless stated differently).

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Physical Form (at time of use) : Liquid substance

Frequency and duration of use

Frequency of use : <= 8 hours/day

Human factors not influenced by risk managementDermal exposure : Palms of both hands (480 cm²)**Other operational conditions affecting workers exposure**

Outdoor / Indoor : Indoor use

Technical conditions and measures

Use only in area provided with appropriate exhaust ventilation.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

Conditions and measures related to personal protection, hygiene and health evaluationWear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.
(Effectiveness (of a measure): 90 %)

2.5 Contributing scenario controlling worker exposure for: PROC8a, PROC8b

Product characteristicsConcentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) : Liquid substance**Frequency and duration of use**

Frequency of use : <= 8 hours/day

Human factors not influenced by risk management

Dermal exposure : Both hands

Other operational conditions affecting workers exposure

Outdoor / Indoor : Indoor use

Technical conditions and measures

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.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

Conditions and measures related to personal protection, hygiene and health evaluationWear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.
(Effectiveness (of a measure): 90 %)

2.6 Contributing scenario controlling worker exposure for: PROC14

Product characteristicsConcentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) : Liquid substance**Frequency and duration of use**

Frequency of use : <= 8 hours/day

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Human factors not influenced by risk managementDermal exposure : Palms of both hands (480 cm²)**Other operational conditions affecting workers exposure**

Outdoor / Indoor : Indoor use

Technical conditions and measures

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.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

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

Wear suitable gloves tested to EN374. (Effectiveness (of a measure): 80 %)

2.7 Contributing scenario controlling worker exposure for: PROC15

Product characteristicsConcentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) : Liquid substance**Frequency and duration of use**

Frequency of use : <= 8 hours/day

Human factors not influenced by risk management

Dermal exposure : Palm of one hand

Other operational conditions affecting workers exposure

Outdoor / Indoor : Indoor use

Technical conditions and measures

Use only in area provided with appropriate exhaust ventilation.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

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

Wear suitable gloves tested to EN374. (Effectiveness (of a measure): 80 %)

3. Exposure estimation and reference to its source

Environment

Contributing Scenario	Exposure Assessment Method	Specific conditions	Compartment	Value	Level of Exposure (PEC)	RCR
ERC2	EUSES		Fresh water		0.022 mg/l	0.043
			Fresh water sediment		0.0005 mg/kg dry weight	0.70
			Marine water		0.0022 mg/l	0.043
			Marine sediment		0.0052 mg/kg dry weight	0.70
			Soil		0.0039 mg/kg dry weight	0.15

Workers

Contributing Scenario	Exposure Assessment Method	Specific conditions	Value	Level of Exposure	RCR
PROC1, PROC3	ECETOC TRA	Worker (Industrial)	Inhalation: long-term, systemic	1.795 mg/m ³	0.041
PROC1, PROC3	ECETOC TRA		Dermal: long-term, systemic	0.138 mg/kg bw/d	< 0.01
PROC1, PROC3	ECETOC TRA		Chronic dermal local exposure	0.04 mg/cm ²	0.216
PROC2	ECETOC TRA	Worker (Industrial)	Inhalation: long-term, systemic	1.795 mg/m ³	0.041
PROC2	ECETOC TRA		Dermal: long-term, systemic	0.274 mg/kg bw/d	< 0.01
PROC2	ECETOC TRA		Chronic dermal local exposure	0.04 mg/cm ²	0.216
PROC4, PROC5	ECETOC TRA	Worker (Industrial)	Inhalation: long-term, systemic	<= 1.795 mg/m ³	<= 0.041
PROC4, PROC5			Dermal: long-term, systemic	<= 1.371 mg/kg bw/d	< 0.011
PROC4, PROC5	RISKOFDERM v2.1		Chronic dermal local exposure	<= 0.11 mg/cm ²	<= 0.595
PROC8a, PROC8b	ECETOC TRA	Worker (Industrial)	Inhalation: long-term, systemic	1.795 mg/m ³	0.041
PROC8a, PROC8b	ECETOC TRA		Dermal: long-term, systemic	1.371 mg/kg bw/d	0.011
PROC8a, PROC8b	ECETOC TRA		Chronic dermal local exposure	0.1 mg/cm ²	0.54
PROC14	ECETOC TRA	Worker (Industrial)	Inhalation: long-term, systemic	1.795 mg/m ³	0.041
PROC14	ECETOC TRA		Dermal: long-term, systemic	0.686 mg/kg bw/d	< 0.01
PROC14	ECETOC TRA		Chronic dermal local exposure	0.1 mg/cm ²	0.541
PROC15	ECETOC TRA	Worker (Industrial)	Inhalation: long-term, systemic	1.795 mg/m ³	0.041
PROC15	ECETOC TRA		Dermal: long-term, systemic	0.068 mg/kg bw/d	< 0.01
PROC15	ECETOC TRA		Chronic dermal local exposure	0.02 mg/cm ²	0.107

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

EUSES = EUSES version 2.1.2

ES 2: Use at industrial sites - Manufacture of food packaging material

1. Scenario description

Main User Groups	: SU 3: Industrial uses: Uses of substances as such or in preparations at industrial sites
Sectors of end-use	: SU12: Manufacture of plastics products, including compounding and conversion
Process categories	: PROC4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact) PROC6: Calendering operations PROC8a: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities PROC8b: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities PROC13: Treatment of articles by dipping and pouring PROC15: Use as laboratory reagent

Environmental Release Categories : **ERC5:** Industrial use resulting in inclusion into or onto a matrix

2.1 Contributing scenario controlling environmental exposure for: ERC5

Amount used

Daily amount per site	: <= 0.45 t
Annual amount per site	: <= 99.0 t

Environment factors not influenced by risk management

Flow rate of receiving surface water	: 18,000 m ³ /d
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Other given operational conditions affecting environmental exposure

Emission or Release Factor: Air	: 50 %
Emission or Release Factor: Water	: 50 %
Emission or Release Factor: Soil	: 1 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant	: Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent	: 2,000 m ³ /d
Effectiveness (of a measure)	: 91.97 %

Conditions and measures related to external treatment of waste for disposal

Disposal methods	: Dispose of contents/container in accordance with local regulation.
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2.9 Contributing scenario controlling worker exposure for: PROC4, PROC5

Product characteristics

Concentration of the Substance in Mixture/Article	: Covers the percentage of the substance in the product up to 100 % (unless stated differently).
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Physical Form (at time of use) : Liquid substance

Frequency and duration of useFrequency of use : \leq 8 hours/day**Human factors not influenced by risk management**Dermal exposure : Palms of both hands (480 cm²)**Other operational conditions affecting workers exposure**

Outdoor / Indoor : Indoor use

Technical conditions and measures

Use only in area provided with appropriate exhaust ventilation.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

Conditions and measures related to personal protection, hygiene and health evaluationWear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.
(Effectiveness (of a measure): 90 %)

2.10 Contributing scenario controlling worker exposure for: PROC6, PROC8a, PROC8b

Product characteristicsConcentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) : Liquid substance**Frequency and duration of use**Frequency of use : \leq 8 hours/day**Human factors not influenced by risk management**

Dermal exposure : Both hands

Other operational conditions affecting workers exposure

Outdoor / Indoor : Indoor use

Technical conditions and measures

Use only in area provided with appropriate exhaust ventilation.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

Conditions and measures related to personal protection, hygiene and health evaluationWear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.
(Effectiveness (of a measure): 90 %)

2.11 Contributing scenario controlling worker exposure for: PROC13

Product characteristicsConcentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) : Liquid substance**Frequency and duration of use**Frequency of use : \leq 8 hours/day**Human factors not influenced by risk management**

SAFETY DATA SHEET

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Dermal exposure : Palms of both hands (480 cm²)

Other operational conditions affecting workers exposure

Outdoor / Indoor : Indoor use

Technical conditions and measures

Use only in area provided with appropriate exhaust ventilation.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

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

Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.
(Effectiveness (of a measure): 90 %)

2.12 Contributing scenario controlling worker exposure for: PROC15

Product characteristics

Concentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) : Liquid substance

Frequency and duration of use

Frequency of use : <= 8 hours/day

Human factors not influenced by risk management

Dermal exposure : Palm of one hand

Other operational conditions affecting workers exposure

Outdoor / Indoor : Indoor use

Technical conditions and measures

Use only in area provided with appropriate exhaust ventilation.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

3. Exposure estimation and reference to its source

Environment

Contributing Scenario	Exposure Assessment Method	Specific conditions	Compartment	Value	Level of Exposure (PEC)	RCR
ERC2	EUSES		Fresh water		0.025 mg/l	0.049
			Fresh water sediment		0.0006 mg/kg dry weight	0.797
			Marine water		0.0025 mg/l	0.049
			Marine sediment		0.0059 mg/kg dry weight	0.797
			Soil		0.0044 mg/kg dry weight	0.169

Workers

Contributing Scenario	Exposure Assessment	Specific condi-	Value	Level of Exposure	RCR
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	Method	tions			
PROC4, PROC5	ECETOC TRA	Worker (Industrial)	Inhalation: long-term, systemic	1.795 mg/m ³	0.041
PROC4, PROC5	ECETOC TRA		Dermal: long-term, systemic	1.371 mg/kg bw/d	0.011
PROC4, PROC5	ECETOC TRA		Chronic dermal local exposure	0.11 mg/cm ²	0.595
PROC6, PROC8a, PROC8b	ECETOC TRA	Worker (Industrial)	Inhalation: long-term, systemic	1.795 mg/m ³	0.041
PROC6, PROC8a, PROC8b	ECETOC TRA		Dermal: long-term, systemic	2.743 mg/kg bw/d	0.022
PROC6, PROC8a, PROC8b	ECETOC TRA		Chronic dermal local exposure	0.1 mg/cm ²	0.54
PROC13	ECETOC TRA	Worker (Industrial)	Inhalation: long-term, systemic	1.795 mg/m ³	0.041
PROC13	ECETOC TRA		Dermal: long-term, systemic	1.371 mg/kg bw/d	0.011
PROC13	ECETOC TRA		Chronic dermal local exposure	0.11 mg/cm ²	0.595
PROC15	ECETOC TRA	Worker (Industrial)	Inhalation: long-term, systemic	1.795 mg/m ³	0.041
PROC15	ECETOC TRA		Dermal: long-term, systemic	0.34 mg/kg bw/d	< 0.01
PROC15	ECETOC TRA		Chronic dermal local exposure	0.099 mg/cm ²	0.536

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

EUSES = EUSES version 2.1.2

ES 3: Professional use - Hairdressing services

1. Scenario description

Main User Groups	: SU 22: Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
Process categories	: PROC5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact) PROC8a: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities
Environmental Release Categories	: ERC8a: Wide dispersive indoor use of processing aids in open systems

2.1 Contributing scenario controlling environmental exposure for: ERC8a

Amount used

Daily amount per site : <= 0.054 kg

Environment factors not influenced by risk management

Flow rate of receiving surface water : 18,000 m³/d

Other given operational conditions affecting environmental exposure

Emission or Release Factor: Air : 100 %
Emission or Release Factor: Water : 100 %
Emission or Release Factor: Soil : 0 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant : Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent : 2,000 m³/d
Effectiveness (of a measure) : 91.97 %

Conditions and measures related to external treatment of waste for disposal

Disposal methods : Dispose of contents/container in accordance with local regulation.

2.2 Contributing scenario controlling worker exposure for: PROC5

Product characteristics

Concentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 5%.
Physical Form (at time of use) : Liquid substance

Frequency and duration of use

Frequency of use : <= 8 hours/day

Human factors not influenced by risk management

Dermal exposure : Palms of both hands (480 cm²)

Other operational conditions affecting workers exposure

Outdoor / Indoor : Indoor use

Technical conditions and measures

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.

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

Wear suitable gloves tested to EN374. (Effectiveness (of a measure): 80 %)

2.3 Contributing scenario controlling worker exposure for: PROC8a

Product characteristics

Concentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 25 %.
Physical Form (at time of use) : Liquid substance

Frequency and duration of use

Frequency of use : <= 8 hours/day

Human factors not influenced by risk management

Dermal exposure : Both hands

Other operational conditions affecting workers exposure

Outdoor / Indoor : Indoor use

Technical conditions and measures

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.

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

Wear suitable gloves tested to EN374. (Effectiveness (of a measure): 80 %)

3. Exposure estimation and reference to its source

Environment

Contributing Scenario	Exposure Assessment Method	Specific conditions	Compartment	Value	Level of Exposure (PEC)	RCR
ERC2	EUSES		Fresh water		0.00002 mg/l	< 0.01
			Fresh water sediment		40.5 mg/kg dry weight	< 0.01
			Marine water		0.000003 mg/l	< 0.01
			Marine sediment		7.85 mg/kg dry weight	< 0.01
			Soil		8.91 mg/kg dry weight	< 0.01

Workers

Contributing Scenario	Exposure Assessment Method	Specific conditions	Value	Level of Exposure	RCR
PROC5	ECETOC TRA	Worker (Professional)	Inhalation: long-term, systemic	0.359 mg/m ³	< 0.01
PROC5	ECETOC TRA		Dermal: long-term, systemic	0.548 mg/kg bw/d	< 0.01
PROC5	ECETOC TRA		Chronic dermal local exposure	0.08 mg/cm ²	0.432

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PROC8a	ECETOC TRA	Worker (Professional)	Inhalation: long-term, systemic	1.077 mg/m ³	0.024
PROC8a	ECETOC TRA		Dermal: long-term, systemic	1.645 mg/kg bw/d	0.013
PROC8a	ECETOC TRA		Chronic dermal local exposure	1.645 mg/cm ²	0.013

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

EUSES = EUSES version 2.1.2

ES 4: Consumer use of cosmetics

1. Scenario description

Main User Groups : **SU 21:** Consumer uses: Private households (= general public = consumers)
 Chemical product category : **PC39:** Cosmetics, personal care products
 Environmental Release Categories : **ERC8a:** Wide dispersive indoor use of processing aids in open systems

2.1 Contributing scenario controlling environmental exposure for: ERC8a

Amount used

Daily amount per site : \leq 0.054 kg

Environment factors not influenced by risk management

Flow rate : 18,000 m³/d

Other given operational conditions affecting environmental exposure

Emission or Release Factor: Air : 100 %
 Emission or Release Factor: Water : 100 %
 Emission or Release Factor: Soil : 0 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant : Municipal sewage treatment plant
 Flow rate of sewage treatment plant effluent : 2,000 m³/d
 Effectiveness (of a measure) : 91.97 %

Conditions and measures related to external treatment of waste for disposal

Disposal methods : Dispose of contents/container in accordance with local regulation.

3. Exposure estimation and reference to its source

Environment

Contributing Scenario	Exposure Assessment Method	Specific conditions	Compartment	Value	Level of Exposure (PEC)	RCR
ERC2	EUSES		Fresh water		0.00002 mg/l	< 0.01
			Fresh water sediment		40.5 mg/kg dry weight	< 0.01
			Marine water		0.000003 mg/l	< 0.01
			Marine sediment		7.85 mg/kg dry weight	< 0.01
			Soil		8.91 mg/kg dry weight	< 0.01

Risk to consumers' health does not need to be assessed as this is already covered by the Cosmetic Directive 76/768/EEC.

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

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