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

#### 1.1 Product identifier

Trade name

**Genamine BTMS** 

Material no.: 237405

UFI: 8XT2-F0M3-C00V-6596

**Chemical nature:** Behenyltrimethylammonium methosulphate (contains ca. 17.5%

isopropanol.)

Behentrimonium Methosulfate INCI designation::

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

#### Corresponding identified use of the substance or mixture

Industry sector: Cosmetics industry Use: Surfactant for cosmetics.

Exposure scenarios: see attachment

#### 1.3 Detailed data on the supplier of the safety data sheet

#### Company name

Ekokoza s.r.o

Fryčovice 297, 73945, Fryčovice ID: 07508247, eshop@ekokoza.cz

#### Information on the substance/mixture

**BU Industrial & Consumer Specialties** 

Product Stewardship Email: eshop@ekokoza.cz

#### 1.4 Telephone number for emergency situations

00800-5121 5121 (24 hours)

**Toxicology Information Center** +420 0 224 919 293 (7/5)

+420 0 224 915 402

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No. 1272/2008)

H315: Irritating to skin. Skin irritation, Category 2

Serious eye damage, Category 1 H318: Causes serious eye damage.

Specific target organ toxicity -H373: May cause damage to organs through

repeated exposure, Category 2 prolonged or repeated exposure.

Short-term (acute) hazard for the aquatic

environment, Category 1

H400: Highly toxic to aquatic life.

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Long-term (chronic) hazard for the aquatic environment, Category 2

H411: Toxic to aquatic life, with long-term

effects.

#### 2.2 Marking elements

#### Labeling (REGULATION (EC) No. 1272/2008)

Hazard warning symbols







With a signal word : Danger

Standard hazard

: H315 Irritating to skin.

statements H318 Causes serious eye damage.

H373 May cause damage to organs through prolonged or repeated exposure.

H410 Highly toxic to aquatic life, with long-term effects.

Instructions for safe handling

#### Prevention:

P260 Do not breathe dust/fume/gas/mist/vapour/aerosols.

P273 Avoid release to the environment. P280 Wear safety glasses/face shield.

P280 Wear protective gloves.

#### Precautions:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if worn and if they can be removed easily. Continue rinsing. Call a TOXICOLOGICAL INFORMATION CENTER/ doctor immediately.

P362 + P364 Take off contaminated clothing and wash before

reuse.

#### Removal:

P501 Dispose of contents/container in an approved waste disposal facility.

#### Hazardous ingredients that must be listed on the label:

Docosyltrimethylammonium methyl sulphate

#### 2.3 Other hazards

The substance/mixture does not contain components considered to be either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at a concentration of 0.1% or higher.

Methanol and methyl acetate vapors may accumulate in the gas atmosphere of closed containers. Therefore, it is necessary to avoid fire and sources of ignition.

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#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

Chemical name	CAS No.	Classification	Concentration
	EC		(% w/w)
	No. Index		
	No. Registration No.		
Docosyltrimethylammonium methyl	81646-13-1	Skin Irritation. 2;	>= 70 - < 90
sulphate	279-791-1	H315 Eye Dam. 1;	
	01-2119949051-44- 0000	H318 STOT RE 2;	
		H373 (Gastrointestinal	
		tract)	
		Aquatic Acute 1; H400	
		Aquatic Chronic 2; H411 Flam.	
Propan-2-ol	67-63-0	Liq. 2; H225 Eye Irrit. 2;	>= 10 - < 20
	200-661-7	H319 STOT SE 3;	
	603-117-00-0	H336 (Central nervous	
	01-2119457558-25	system)	
	01-2119457558-25-		
	0001		
	01-2119457558-25-		
	0002		
	01-2119457558-25-		
	0006		
	01-21 19457558-25-0016		
	01-2119457558-25-		
	0028		
	01-2119457558-25-		
	0083		
	01-2119457558-25-		
	0150		
	01-2119457558-25-		
	0163		
	01-2119457558-25-		
	XXXX		

See section 16 for explanation of abbreviations.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid

General instructions : Seek medical attention/treatment if you feel unwell.

Remove all contaminated clothing immediately.

When inhaled : Remove victim to fresh air.

If symptoms persist, seek medical attention.

In contact with skin : In case of contact, immediately rinse skin with large

amount of water and soap.

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In contact with eyes : In case of eye contact, rinse immediately with plenty of water and consult a

doctor.

: Call a doctor immediately. When ingested

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: irritant effects

Damage

Risks : Irritating to skin.

Causes serious eye irritation.

May cause organ damage through prolonged or repeated exposure.

4.3 Indication of immediate medical attention and special treatment

Treatment : Symptomatic treatment.

#### **SECTION 5: Firefighting measures**

5.1 Fire extinguishers

Suitable extinguishing agents : spraying with a water jet

Alcohol-resistant foam

Unsuitable fire extinguishers : Carbon dioxide (CO2)

Dry powder

Full stream of water

5.2 Special hazards arising from the substance or mixture

Specific firefighting hazards : In the event of a fire, the smoke gases that determine the danger are: oxide

> carbonaceous (CO). Nitrogen oxides (NOx)

Sulfur oxide

5.3 Instructions for firefighters

firefighters

Special protective equipment for

: Self-contained breathing apparatus

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal protection measures, protective equipment and emergency procedures

Measures for the protection of persons : Use appropriate protective equipment.

Provide adequate ventilation.

Keep sources of ignition at a sufficient distance.

6.2 Environmental protection measures

Protection measures : The product should not be discharged into drains, waterways

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environment or into the soil.

#### 6.3 Methods and material for containment and cleaning up

Cleaning methods : Capture mechanically. Wash off the residue with warm water.

#### 6.4 Reference to Other Sections

For information on safe handling see chapter 7., Personal protection see section 8., Disposal instructions see point 13.

#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Instructions for safe handling : Ensure good ventilation.

Protect against the formation of electrostatic charges. Handle the package with care and open it carefully.

Instructions for protection against fire and explosion

: not highly flammable Take precautions against electrostatic charging. Do not roll the barrel, do not pull the barrel to prevent electrostatic charging. It is recommended to let the barrels rest for an hour after shipping before opening to allow any charging to settle. Methanol and methyl acetate vapors may accumulate in the gas atmosphere of closed containers. Therefore, it is necessary to avoid

fire and sources of ignition.

Hygiene measures : Wash your hands before a work break and after finishing work.

Use a protective skin cream before handling the product. Remove all contaminated clothing immediately and wash before reuse.

#### 7.2 Conditions for safe storage of substances and mixtures, including incompatible substances and mixtures

Requirements for storage

areas and containers

: No special measures are required.

More information on storage conditions

: Containers must be tightly closed and stored in a dry, cool and well-

ventilated place. Store only in the original packaging at a

temperature not exceeding 40 °C.

hygroscopic substance Protect from direct sunlight.

#### 7.3 Specific end / specific end uses

Specific (specific)

: No other recommendations

use

#### SECTION 8: Exposure controls / personal protective equipment

#### 8.1 Control parameters

#### Exposure limit values for the workplace

Components Value Type	CAS No.		Control parameters	Basis
		(Form of exposure)		

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Propan-2-ol	67-63-0	PEL	500 mg/m3	CZ OEL
	Additional inform	Additional information: irritates mucous membranes (eyes, respiratory tract) and skin		
	NPK-P 1,000 mg/m3 CZ OEL			
	Additional information: irritates mucous membranes (eyes, respiratory tract) and skin			

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

Substance name Area of us	e Exposure routes Pos	sible health effects		Value
Propan-2-ol CAS No.: 67-63-0	Workers	Cutaneous	Long-term - systemic effects	888 mg/kg body weight/day
Comment:	TODAY		aysternic chects	1117 13 1117
	Workers	Inhalation	Long-term -	500 mg/m3
			systemic effects	
Comment:	TODAY			
	Consumers	Cutaneous	Long-term -	319 mg/kg
			systemic effects	body weight/day
Comment:	TODAY	TODAY		
	Consumers	Inhalation	Long-term -	89 mg/m3
			systemic effects	
Comment:	TODAY	3000		·
	Consumers	Orally	Long-term -	26 mg/kg
			systemic effects	body weight/day
Notes:	TODAY			

#### Estimated No-Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance	Environment	Value
name Propan-2-ol CAS No.: 67-63-0	Fresh water	140.9 mg/l
	Sea water	140.9 mg/l
	Freshwater sediment	552 mg/kg dry weight
	Marine sediment	552 mg/kg dry weight
	Soil	28.0 mg/kg dry weight
	Water (intermittent release) Sewage	140.9 mg/l
	treatment plant	2251 mg/l
	Orally	160 mg/kg food

#### 8.2 Limiting Exposure

#### Personal protective equipment

Eye protection: Depending on the risk, use appropriate eye protection

(safety glasses and, if necessary, a protective shield).

Hand protection

Comment : This type of protective gloves is offered by various manufacturers.

Study the manufacturer's detailed statement, especially the information on minimum thickness and minimum penetration time. Also consider the

specific working conditions under which the gloves are used.

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Comment : For short-term exposure (splash protection): Nitrile rubber gloves.

Minimum thickness (glove): not determined

Penetration when handling a dry substance is unlikely, therefore the penetration time for these protective gloves has not been measured.

Comment : Long-term exposure Impermeable butyl rubber gloves Minimum

thickness (glove): not determined Breakthrough when handling dry substance is unlikely, therefore breakthrough time for these

protective gloves has not been measured.

Respiratory protection : Respiratory protection in case of insufficient suction or prolonged

exposure.

Full face mask according to the DIN EN 136 standard Filter A (organic gases and vapors) according to DIN EN 141

The use of filter devices is possible, the surrounding atmosphere of the experiment contains at least 17% by volume of oxygen and the highest permissible concentration of gases, usually 0.5% by volume, is not exceeded. Valid regulatory measures, e.g. EN 136 /

141 / 143 / 371 / 372 as well as other national regulations must be observed.

Protective measures : Do not breathe vapors.

Avoid contact with skin and eyes.

#### **SECTION 9: Physical and chemical properties**

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

Physical condition : pellets

Color : White to light yellow

Odor : after isopropanol

Melting point : 80 - 85 °C

Method: DIN 51004

Boiling point : Decomposes below boiling point.

Upper explosion limit / Upper

flammability limit

: Not applicable

Lower explosive limit / Lower

flammability limit

: Not applicable

Flash-point : Not applicable

Auto-ignition temperature : Not applicable

Decomposition temperature : approx. 288 °C

Method: DTA

pH : 7.0 - 9.0

Concentration: 1%

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Method: DIN EN 1262 Isopropanol/water 1:1

Viscosity

Dynamic viscosity : Not applicable

Kinematic viscosity : Not applicable

Solubility

Solubility in water : 0.05 g/l (70 °C)

turbidly soluble

Partition coefficient: n-

octanol/water

: Not applicable

Steam pressure : 43 hPa

The data refer to the solvent.

Density : 0.9 g/cm3 (20 °C)

Method: DIN 51757

Relative vapor density : 2.7

The data refer to the solvent

Particle size

Particle size : Data not available

9.2 Additional Information

Flammable solids

Burning rate : 265 p

Combustion number : 5

Ignition by flame

Spontaneous ignition : The substance or mixture is not classified as self-heating.

The rate of corrosion of metals : Not applicable

#### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

See section 10.3 "Possibility of hazardous reaction"

#### 10.2 Chemical stability

Stable

The product is sensitive to light.

hygroscopic substance

#### 10.3 Possibility of hazardous reactions

Hazardous reactions: Uncleaned empty containers may contain product gases which form explosive mixtures with air.

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10.4 Conditions to Avoid

Conditions to avoid : Protect from heat. No smoking.

Keep away from open flames and sparks.

10.5 Incompatible Materials

Materials to avoid : Not known

#### 10.6 Hazardous decomposition products

Decomposition does not occur if the specified method of storage and use is followed.

#### **SECTION 11: Toxicological information**

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

#### **Acute toxicity**

Product:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 401

Notes: Information refers to the main folder.

Acute inhalation toxicity : Notes: not determined

Acute dermal toxicity : Notes: not determined

#### Ingredients:

#### Docosyltrimethylammonium methyl sulphate:

Acute oral toxicity : LD50 (Rat, female): 3,190 mg/kg

Method: OECD Test Guideline 401

Assessment: The substance or mixture is not acutely orally toxic

Notes: Analogous to a product of similar composition.

Acute inhalation toxicity : Notes: Data not available

Acute dermal toxicity : LD50: > 2,000 mg/kg

Method: other

Assessment: The substance or mixture is not acutely dermally toxic

Notes: Analogous to a product of similar composition.

Propan-2-ol:

Acute oral toxicity : LD50 (Rat, Data not available): 5,840 mg/kg

Method: OECD Test Guideline 401

SLP: no

Acute inhalation toxicity : LC50 (Rat, male and female): > 25 mg/l, > 10000 ppm

Exposure time: 6 h
Test atmosphere: steam

Method: OECD Test Guideline 403

SLP: yes

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Acute dermal toxicity : LD50 (Rabbit, Data not available): 13,900 mg/kg

Method: OECD Test Guideline 402

SLP: no

#### Skin corrosion/irritation

Product:

Species : Rabbit

Method : OECD Test Guideline 404

Result : irritating

Comment : The information refers to the main folder.

Ingredients:

Docosyltrimethylammonium methyl sulphate:

Species : Rabbit Method : other

Result : Skin irritation

Comment : Analogous to a product of similar composition.

Propan-2-ol:

Species : Rabbit Exposure time : 4 h Method : other

Result : Does not irritate the skin

SLP : no

#### Serious eye damage / eye irritation

Product:

Species : rabbit eye

Method : OECD Test Guideline 405
Result : Risk of serious damage to eyes.
Comment : The information refers to the main folder.

Components:

Docosyltrimethylammonium methyl sulphate:

Species : Rabbit Method : other

Result : Risk of serious damage to eyes.

Comment : Analogous to a product of similar composition.

Propan-2-ol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritating to eyes.

SLP : no

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#### Respiratory sensitization / skin sensitization

Product:

Species : Guinea pig

Method : OECD Test Guideline 406
Result : does not cause sensitization

Ingredients:

Docosyltrimethylammonium methyl sulphate:

Test type: Maximization test

Type : Guinea pig

Method : other

Result : Does not have sensitizing effects on the skin.

Evaluation : Irritating to skin., Causes serious eye damage.

Propan-2-ol:

Test type : Buehler's test
Exposure routes : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : Does not have sensitizing effects on the skin.

SLP : yes

Germ cell mutagenicity

**Product:** 

Mutagenicity in germ cells -

Evaluation

: Not mutagenic according to the Ames test.

Ingredients:

Docosyltrimethylammonium methyl sulphate:

Genotoxicity in vitro : Test type: Ames test

Test system: Salmonella typhimurium

Metabolic activation: with or without metabolic activation

Method: OECD Test Guideline 471

Result: negative

Notes: Analogous to a product of similar composition.

Test type: Mammalian cell genetic mutation test

Test system: Chinese hamster fibroblasts

Metabolic activation: with or without metabolic activation

Method: OECD Test Guideline 476

Result: negative

Notes: Analogous to a product of similar composition.

Test Type: Micronucleus Test

Test system: Chinese hamster fibroblasts

Metabolic activation: with or without metabolic activation

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Method: OECD Test Guideline 487 Result: negative

Remarks: Analogous to

a product of similar composition.

Mutagenicity in germ cells -

Evaluation

: In vitro tests did not show mutagenic effects

Propan-2-ol:

Genotoxicity in vitro : Test Type: In vitro study of genetic mutation in mammalian cells

Test system: Chinese hamster ovary cells

Concentration: 500 - 5000 µg/ml

Metabolic activation: with or without metabolic activation

Method: OECD Test Guideline 476

Result: negative SLP: yes

Test type: Ames test

Test system: Salmonella typhimurium Concentration: 100 - 10000 µg/plate

Metabolic activation: with or without metabolic activation

Method: OECD Test Guideline 471

Result: negative SLP: no

Genotoxicity in vivo : Test Type: Micronucleus Test

Species: Mouse (male and female)

Strain: ICR

Cell Type: Bone Marrow

Method of administration: Intraperitoneal injection

Exposure time: Single exposure Dose: 350-1173-2500-3500 mg/kg Method: OECD Test Guideline 474

Result: negative SLP: yes

Mutagenicity in germ cells -

Evaluation

: In vitro tests did not show mutagenic effects, In vivo tests did not show mutagenic

effects

#### Carcinogenicity

#### Product:

Carcinogenicity - Assessment : No information available.

#### Ingredients:

#### Docosyltrimethylammonium methyl sulphate:

Carcinogenicity - Assessment : No information available.

#### Propan-2-ol:

Species : Rat. male and female

: Inhalation Method of execution

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Exposure time : 104 w

Dose : 200 - 2500 - 5000 ppm

Control group : yes

Frequency of treatment : 6 hours/day, 5 days/week

: approx. 12.29 mg/l

Method : OECD Test Guideline 451

SLP : yes

Carcinogenicity - Assessment: No carcinogenic effects were observed in animal experiments.

#### Reproductive toxicity

Product:

Reproductive toxicity -

Evaluation

: No information available.

No information available.

#### Ingredients:

#### Docosyltrimethylammonium methyl sulphate:

Effects on fertility : Species: Rat, male and female

Strain: Wistar

Method of administration: orally (gastric tube) General parental toxicity: NOAEL: 30 mg/kg body weight

General toxicity F1: NOAEL: 30 mg/kg body weight

Method: OECD Test Guideline 421

Reproductive toxicity -

Evaluation

: Based on animal experiments, there is no evidence of adverse effects

on sexual function, fertility or development.

#### Propan-2-ol:

Effects on fertility : Test Type: Fertility / Early Embryonic Development

Species: Rat, male and female

Strain: Wistar

Method of execution: Drinking water

Dose: 0.5 - 1 - 2%

General parental toxicity: NOAEL: 853 mg/kg body weight

Method: OECD Test Guideline 415

SLP: yes

Test type: two-generation study Species: Rat, male and female

Strain: Sprague-Dawley

Method of administration: orally (gastric tube)

Dose: 100 - 500 - 1000 mg/kg

General parental toxicity: NOAEL: 500 mg/kg body weight

General toxicity F1: NOAEL: 500 mg/kg body weight General toxicity F2: NOAEL: 500 mg/kg body weight

Method: OECD Test Guideline 416

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SLP: yes

Effects on fetal development : Test Type: Prenatal

Species: Rat Strain: Wistar

Method of execution: Drinking water

Dose: 0.5 - 1.25 - 2.5%

Duration of individual treatment: 10 days General maternal toxicity: NOAEL: 596 mg/kg body weight

Developmental toxicity: NOAEL: 596 mg/kg body weight

Method: OECD Test Guideline 414

SLP: yes

Test Type: Prenatal

Species: Rat

Strain: Sprague-Dawley

Method of administration: orally (gastric tube)

Dose: 400 - 800 - 1200 mg/kg

Duration of individual treatment: 9 days

General maternal toxicity: NOAEL: 400 mg/kg body weight

Teratogenicity: NOAEL: 400 mg/kg body weight

Developmental toxicity: NOAEL: 400 mg/kg body weight

Method: OECD Test Guideline 414

SLP: yes

Reproductive toxicity -

Evaluation

: No known toxic effects on reproduction. There are no known teratogenic effects.

#### Specific target organ toxicity - single exposure

Product:

Comment : not specified

Ingredients

Docosyltrimethylammonium methyl sulphate:

Comment : Data not available

Propan-2-ol:

Evaluation : May cause drowsiness or dizziness.

Specific target organ toxicity - repeated exposure

Product:

Comment : not specified

Ingredients:

Docosyltrimethylammonium methyl sulphate:

Exposure routes : Orally

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Target organs : Gastrointestinal tract

Evaluation : The substance or mixture is classified as a specific target organ toxin,

repeated exposure, category 2.

Propan-2-ol:

Evaluation : The substance or mixture is not classified as a specific target

organ toxin, repeated exposure.

Repeated dose toxicity

Product:

Species : A rat

NOAEL : 10 mg/kg

Exposure time : 28 d

Method : OECD Test Guideline 407

Comment : The information refers to the main folder.

Ingredients:

Docosyltrimethylammonium methyl sulphate:

Species : Rat, male and female
NOAEL : 10 mg/kg body weight/day

Method of execution : orally (gastric tube)

Exposure time : 28d

Dose : 10, 50, 150 mg/kg/day

Method : other

Target organs : Gastrointestinal tract

Comment : Analogous to a product of similar composition.

Propan-2-ol:

Species : Rat, male and female

NOAEL : 12.5 mg/l
Method of execution : Inhalation
Experimental atmosphere : steam
Exposure time : 2 a

Number of exposures : 6 hours/day, 5 days/week
Dose : 500 - 2500 - 5000 ppm

Control group : yes
Method : other
SLP : yes

**Aspiration toxicity** 

Ingredients:

Docosyltrimethylammonium methyl sulphate:

Data not available

Propan-2-ol:

No inhalation toxicity classification

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#### 11.2 Information on additional hazards

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

**Product:** 

Toxicity to fish : LC50 (Danio rerio) : 0.5 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other

aquatic invertebrates

: Notes: not determined

Toxicity to algae/aquatic

plants

: Notes: not determined

Toxicity to microorganisms:

Notes: not determined

#### Ingredients:

#### Docosyltrimethylammonium methyl sulphate:

Toxicity to fish : LC50 (Danio rerio) : 3.5 mg/l Exposure time: 96 h

Test type: static test Method: OECD Test

Guideline 203 Remarks: Analogous to a

product of similar composition.

Toxicity to daphnia and other

aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): 1.39 mg/l Exposure

time: 48 h Test type: static test Method:

OECD Test Guideline 202 Remarks:

Analogous to a product of similar composition.

Toxicity to algae/aquatic

plants

: EC50 (Desmodesmus subspicatus (green algae)): 3.48 mg/l

Exposure time: 72 h Test type: static test

Method: OECD Test Guideline 201 Notes: Analogous to a product of similar composition.

Toxicity to microorganisms: EC50 (Activated sewage sludge): 43

mg/

I Exposure time: 3 h Test type: static test

Method: OECD Test Guideline 209 Notes: Analogous to a product of similar composition.

Toxicity to fish (Chronic

toxicity)

: NOEC: 0.24 mg/l Exposure time: 9 d

Species: Danio rerio (striped danio)

Test type: semi-static test

Method: OECD Test Guideline 212 Notes: Analogous to a product of similar composition.

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Toxicity to daphnia and  $$\rm :NOEC:~128~\mu g/I~$ 

other aquatic invertebrates

(Chronic toxicity)

Target indicator: Reproduction rate

Exposure time: 21 d Species: Daphnia magna Test type: semi-static test

Notes: Analogous to a product of similar composition.

Toxicity to soil organisms: Test type: artificial soil 1,000 mg/kg

Exposure time: 14 d Target

indicator: mortality Species: Eisenia fetida (rainbow worms)

Method: OECD Test Guideline 207 Notes: Analogous to a product of similar composition.

Sediment toxicity : NOEC: 62.5 mg/kg dry weight Test type:

static test Species:

Lumbriculus variegatus (worm)

Method: OECD 225

Notes: Analogous to a product of similar composition.

**Ecotoxicological assessment** 

Acute aquatic toxicity : Highly toxic to aquatic organisms.

Chronic aquatic toxicity : Toxic to aquatic organisms, with long-term effects.

Propan-2-ol:

Toxicity to fish : LC50 (Pimephales promelas (guts)): 9,640 mg/l

Target indicator: mortality Exposure time: 96 h Test type: continuous test Analytical monitoring: yes

Method: OECD Test Guideline 203

SLP: no

Toxicity to daphnia and other

aquatic invertebrates

: LC50 (Daphnia magna (Water flea)): > 10,000 mg/l Target indicator:

Immobilization Exposure time: 24 h

Test type: static test Analytical monitoring: no Method: OECD Guideline 202 for

GLP testing: no

Toxicity to algae/aquatic

plants

: EC10 (Scenedesmus quadricauda (green algae)): approx. 1,800

mg/l

Target indicator: Growth rate

Exposure time: 7 d Test type: static test Analytical monitoring: no

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Method: other SLP: no

Toxicity to microorganisms: EC10 (Pseudomonas putida (Bacteria)): approx. 1,050 mg/l Exposure time: 16 h Test

type: static test Analytical monitoring: no Method: DIN

38412 T.8 SLP: no

Toxicity to fish (Chronic toxicity) : Notes: not required

Toxicity to daphnia and other aquatic invertebrates

(Chronic toxicity)

: Notes: not required

Toxicity to plants : IC50: 2.104 mg/l

Exposure time: 3 d Target indicator: Growth Species: Lactuca sativa (lettuce)

Analytical monitoring: no

Method: other SLP: no

Sediment toxicity : Notes: Not applicable

Toxicity to terrestrial organisms : Notes: Not applicable

#### 12.2 Persistence and Deployability

#### Product:

Biodegradability : Biodegradation: 80% Exposure time: 28

d Method: OECD Test

Guideline 301 B Notes: The information refers to the

main component.

Biodegradation: > 80%

Method: OECD Test Guideline 302B

#### Ingredients:

#### Docosyltrimethylammonium methyl sulphate:

Biodegradability : Inoculum: Activated sludge from municipal wastewater.

Result: The substance is easily biodegradable.

Biodegradation: 80% Related to:

Carbon Dioxide (CO2) Exposure time: 28 d Method: other

Notes: Analogous to a product of similar composition.

#### Propan-2-ol:

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Biodegradability : Test type: aerobic

Inoculum: activated sludge

Result: The substance is easily biodegradable.

Biodegradation: 53%

Related to: Biological Oxygen Demand (BOD)

Exposure time: 5 d

Method: Directive 67/548/EEC, Annexes V, C.5.

SLP: no

Stability in water : Notes: Not applicable

12.3 Bioaccumulative potential

Product:

Bioaccumulation : Notes: not determined

Ingredients:

Docosyltrimethylammonium methyl sulphate:

Bioaccumulation : Notes: Due to the distribution coefficient n-

octanol/water is not expected to accumulate in the body.

Partition coefficient: n-octanol/

: log Pow: 3.01 (20 °C)

water

Method: OECD Test Guideline 107

Propan-2-ol:

Bioaccumulation : Notes: Not applicable

Partition coefficient: n-octanol/

water

: log Pow: 0.05 pH: 25

Method: No information available.

12.4 Mobility in soil

Product:

Distribution among : Notes: not determined

environmental components

Ingredients:

Docosyltrimethylammonium methyl sulphate:

Distribution among : Medium: other

environmental components Koc: > 950 - < 516000, log Koc: > 3 - < 5.7

Method: OECD Test Guideline 106

Notes: Analogous to a product of similar composition.

Stability in soil : Test Type: Laboratory

Soil temperature: 20 °C Dispersion time: 23.2 d

Percent Dissipation: 50% (DT50)

Method: other

Notes: Analogous to a product of similar composition.

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Propan-2-ol:

Distribution among : Notes: Not applicable

environmental components

#### 12.5 Results of PBT and vPvB assessment

Product:

Evaluation : The substance/mixture does not contain components considered to be either

persistent, bioaccumulative and toxic (PBT), or highly persistent and highly bioaccumulative (vPvB) at a concentration of 0.1% or higher.

Ingredients:

Docosyltrimethylammonium methyl sulphate:

Evaluation : The substance is not considered a PBT or vPvB-based substance.

Propan-2-ol:

Evaluation : The substance is not considered to be persistent, bioaccumulative or

toxic (PBT).

12.6 Properties causing disruption of the endocrine system

Data not available

12.7 Other Adverse Effects

Product:

Fate and behavior in the : Data not available

environment

Additional ecological : Data not available

information

Ingredients:

Propan-2-ol:

Additional ecological : substance slightly hazardous to water

information Avoid entry into ground water, waterways or waste water.

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste management methods

Product : Burn hazardous waste in compliance with local authorities

regulations.

Contaminated packaging : Packaging that cannot be cleaned must be disposed of in the same way as the fabric.

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#### **SECTION 14: Transport information**

#### Paragraph 14.1. until 14.5.

ADR

UN number: UN 3077

Risk designation: Environmentally hazardous substance, solid, nos
Risk of exposure: Behenyl trimethyl ammonium methosulfate

Class: 9
Primary risk: 9
Packaging group: III
Danger number: 90

Note: Shipment permitted

ADN

UN number : UN 3077

Risk designation: Environmentally hazardous substance, solid, nos
Risk of exposure: Behenyl trimethyl ammonium methosulfate

Class: 9
Primary risk: 9
Packaging group: III

Note: Shipment permitted

RID

UN number: UN 3077

Risk designation: Environmentally hazardous substance, solid, nos
Risk of exposure: Behenyl trimethyl ammonium methosulfate

Class: 9
Primary risk: 9
Packaging group: III
Danger number: 90

Note: Shipment permitted

IATA

UN no. UN 3077

Proper shipping name: Environmentally hazardous substance, solid, nos Hazard inducer(s): Behenyl trimethyl ammonium methosulfate

Primary risk: 9
Packing group: III

Remarks Shipment permitted

**IMDG** 

UN no. UN 3077

Proper shipping name: Environmentally hazardous substance, solid, nos Hazard inducer(s): Behenyl trimethyl ammonium methosulfate

Class: 9
Primary risk: 9
Packing group: III

Remarks Shipment permitted
Marine pollutant: Marine Pollutant

EmS: FA SF

#### 14.6. Special precautions for users

See this safety data sheet, chapter 6 to 8.

according to Regulation (EC) No. 1907/2006

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#### 14.7. Maritime bulk transport according to IMO instruments

It is not bulk transport according to the IBC code.

Additional information

Non-dangerous good of class 9 for packaging <= 5 L / 5 kg

#### **SECTION 15: Regulatory Information**

#### 15.1 Safety, health and environmental regulations/specific legislation relating to the substance or mixture

REACH - Restrictions on the production, placing on the market : Not applicable

and use of certain dangerous substances, preparations and articles

(Annex XVII)

REACH - List of substances of very high concern subject to

authorization (Article 59).

: Not applicable

Council (EC) No. 1005/2009 on substances that damage the ozone

layer

: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants

(recast)

: Not applicable

Council Regulation (EC) No 111/2005 laying down rules for monitoring trade in drug precursors between the Community

and third countries

: Benign and/or limited

Regulation (EC) No. 649/2012 of the European Parliament and

of the Council on the export and import of hazardous chemical substances

: Not applicable

REACH - List of substances subject to authorization (Appendix

XIV)

: Not applicable

#### Other regulations:

With the exception of the data and regulations listed in this chapter, no other information on occupational safety, health and environmental protection is available.

#### 15.2 Chemical safety assessment

Corresponding Hazard Assessments (CSA) are available for one or more components of the listed product

#### **SECTION 16: Further information**

#### Full text of the H-statement

H225

: Highly flammable liquid and vapor.

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H315 : Irritating to skin.

H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H336 : May cause drowsiness or dizziness.
H373 : May cause organ damage with prolonged or

repeated exposure by ingestion.

H400 : Highly toxic to aquatic organisms.H411 : Toxic to aquatic organisms, with long-term effects.

Full text of other abbreviations

Aquatic Acute : Short-term (acute) hazard for the aquatic environment
Aquatic Chronic : Long-term (chronic) hazard for the aquatic environment

Eye Dam. : Serious eye damage

Eye Irritation. : Eye irritation
Flam. Liq. : Flammable liquids
Skin Irritation. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure STOT SE : Specific target organ toxicity - single exposure

CZ OEL : Which at work - Appendix No. 2: Permissible exposure limits

CZ OEL / PEL : Permissible exposure limits

CZ OEL / NPK-P : Maximum permissible concentration

ADN - European Agreement on the International Carriage of Dangerous Goods by River; ADR - European Agreement on the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM -American Society for Testing Materials; bw - Body weight; CLP - Regulation on classification in packaging labelling; Regulation (EC) No. 1272/2008; CMR - Carcinogen, mutagen or reproductively toxic substance; DIN - Standard from the German Institute for Standardization; DSL - National Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - Number of the European Community; ECx - Concentration at response x %; ELx - Load intensity at response x %; EmS - Emergency plan; ENCS - List of Existing and New Chemical Substances (Japan); ErCx -Concentration at response in the form of growth x %; 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 Hazardous Chemicals in Bulk; IC50 - Half maximum inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - List of Existing Chemical Substances in China; IMDG - International Maritime Transport of Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Act (Japan); ISO - International Organization for Standardization; KECI - List of Existing Chemical Substances - Korea; LC50 - Lethal concentration for 50% of the test population; LD50 - Lethal dose for 50% of the population under test (median lethal dose); MARPOL - International Convention for the Prevention of Pollution from Ships; nose - Not otherwise specified; NO(A)EC - No Observed Adverse Effect Concentration; NO(A)EL - No Observed Adverse Effect Dose; NOELR - No Observed Adverse Effect Load Intensity; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Cooperation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, bioaccumulative and toxic substance; PICCS - Philippine List of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure-Activity Relationship; REACH - Regulation of the European Parliament and the Council on the Registration, Evaluation, Authorization and Restriction of Chemical Substances (EC) No. 1907/2006; RID - Regulations on the International Rail Transport of Dangerous Goods; SADT -Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - substance of very high concern; TCSI - Taiwan Chemical Substances List; TECI - List of Existing Chemical Substances - Thailand; TRGS - Technical rules for hazardous substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Highly persistent and highly bioaccumulative

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#### More information

More information : It is necessary to pay attention to the national and local legal regulations.

Mixture classification:		Grading process:
Skin Irritation. 2	H315	Based on test data.
Eye Dam. 1	H318	Based on test data.
STOT RE 2	H373	Calculation method
Aquatic Acute 1	H400	Based on test data.
Aquatic Chronic 2	H411	Calculation method

The information corresponds to our current knowledge and its purpose is to describe the product with regard to safety requirements. These data do not guarantee any specific or general specifications.

The user himself is responsible for the correct selection of the suitability of the product for the intended use and for the selection of the method of use. We do not accept responsibility for any damages arising from the use of this data. In all cases, our general terms and conditions apply.

CZ/CS

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#### **Exposure scenario**

Number	Name
ES 1	Formulation and repackaging; cosmetics, personal care products SU10 - PROC1, PROC2, PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC15 - ERC2
	Docosyltrimethylammonium methyl sulphate
ES 2	Consumer use; cosmetics, personal care products PC39 - ERC8a  Docosyltrimethylammonium methyl sulphate

# 1. ES 1: Formulation and Repackaging; cosmetics, preparations for personal care; SU10

#### 1.1. Name

Formulation [compounding] of preparations and/or new packaging (SU10)	
Environment	
CS1: Formulation and Repackaging (Formulation into Mixture)	ERC2
Workers	
CS2: Formulation and repackaging (Chemical manufacturing or refining v	PROC1
closed process with no probability of exposure or in processes with equivalent control conditions)	
CS3: Formulation and repackaging (Chemical production or refining	PROC2
in a closed manufacturing process with occasional controlled exposure or a process	
with equivalent conditions to prevent leakage)	
CS4: Formulation and Repackaging (Manufacturing or formulation in the chemical	PROC3
industry in closed batch processes with occasionally controlled exposure	
or in processes with equivalent control conditions)	
CS5: Formulation and Repackaging (Mixing or Blending in Batch Manufacturing Processes)	PROC5
	BB000
CS6: Formulation and repackaging (Transportation of substance or preparation	PROC8a
(filling/discharging) in non-specialized facilities)	BB000
CS7: Formulation and repackaging (Transportation of substance or preparation	PROC8a
(filling/discharging) in non-specialized facilities)	BB 0.001
CS8: Formulation and repackaging (Transportation of substance or mixture	PROC8b
(filling/discharging) in specialized facilities)	PPOON
CS9: Formulation and repackaging (Transportation of substance or mixture	PROC8b
(filling/discharging) in specialized facilities)	DDOOO
CS10: Formulation and repackaging (Transportation of substance or mixture into small	PROC9
containers (closed filling line, including weighing))	DDOCO
CS11: Formulation and repackaging (Transportation of substance or mixture into small	PROC9
containers (closed filling line, including weighing))	DDOC15
CS12: Formulation and repackaging (Use as a laboratory reagent)	PROC15

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#### 1.2. ES 1 Conditions of use affecting exposure

### 1.2.1 ES 1 - CS 1: Environmental exposure control: Formulation and repackaging (Formulation into mixture) (ERC2)

Characteristic features of the product

Concentration of the substance in the mixture/article : <= 100%

Molecular weight: 480 g/mol

Physical form (at the time of use): Solid, low dustiness

Comment : Increased temperature

**Quantity used** 

Daily amount on site : 620 kg

Frequency and duration of use

Permanent exposure : 1 use per day

Permanent exposure : 300 times per year

Environmental factors unaffected by risk management

Receiving flow rate: 18,000 m3/d

surface water

Technical conditions and measures / Organizational measures

Comment : Ensure workers are trained to minimize exposure.

Ensure that control measures are regularly reviewed and maintained.

To prevent leakage or spillage during application, provide a suitable

system to catch the liquid.

To avoid exposure, collect samples through a closed loop or other

system.

Comment : Loading

Use in systems with covered handling

Conditions and measures related to the sewage treatment plant

Type of wastewater treatment plant : Local wastewater treatment plant

Flow rate of water from the sewage

: 2,000 m3/d

treatment plant

Effectiveness (Measure) : 80%

Sludge processing : No application of sewage sludge to the soil

Waste management measures

Waste management : Combustion

Disposal methods : (Efficiency (Measure): > 99%)

Comment : No process waste

### 1.2.2 ES 1 - CS 2: Worker exposure control: Formulation and repackaging (Chemical production or refining in a closed process without probability

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#### exposure or in processes with equivalent control conditions) (PROC1)

Characteristic features of the product

Concentration of the substance in the mixture/article : <= 5%

Molecular weight: 480 g/mol

Physical form (at the time of use) : Solid substance, low dustiness Comment : Increased temperature

Frequency and duration of use

Product sampling : < 1 min

Comment : Closed systems, Short-term, Continuous process

Human factors unaffected by risk management

Dermal exposure : Palm of one hand

It includes a skin contact area of up to : 240 cm2

Comment : Product sampling

Other operating conditions affecting worker exposure

Outdoor / Indoor : Indoor and outdoor use

Risk management measures

Application Type (Usage) : Product sampling

Exposure routes : skin

Personal protective equipment : Wear suitable gloves tested according to EN 374.

Use safety glasses.

Use suitable protective clothing.

Application Type (Usage) : Material transfers

Internal use : inhalation

Technical conditions and measures

: Local exhaust system

Effectiveness (measures)

: 80%

Application Type (Usage) : Cleaning and maintenance of equipment

Exposure routes : inhalation

Personal protective equipment : Use appropriate respiratory protection equipment.

Effectiveness (measure) : 90%

Organizational measures

: Ensure workers are trained to minimize exposure.

to prevent/limit releases, dispersion

Ensure that control measures are regularly reviewed and maintained.

and exposures

Exposure routes

Supervision in place to check that the risk management measures in place are being used correctly and that operating conditions are

being followed.

It assumes that a good basic standard of occupational hygiene is in

place

Technical conditions and measures : Handle the substance in a closed system.

To avoid exposure, collect samples through a closed loop or other

system.

Technical conditions and measures : Remote filling / transfer equipment

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Material transfers

Transportation in closed pipelines.

1.2.3 ES 1 - CS 3: Control of worker exposure: Formulation and repackaging (Chemical production or refining in a closed production process with occasional controlled exposure or a process with equivalent conditions to prevent release) (PROC2)

#### Characteristic features of the product

Concentration of the substance in the mixture/article: <= 5%

Physical form (at the time of use): Solid, low dustiness

Comment : Increased temperature

Frequency and duration of use

Product sampling : < 1 min

Comment : Closed systems, Continuous process

Human factors unaffected by risk management

Dermal exposure : Assumes that potential skin contact is limited to internal

side of hand / one hand / palm.

It includes a skin contact area of up to : 480 cm2

Comment : Product sampling

Other operating conditions affecting worker exposure

Outdoor / Indoor : Indoor and outdoor use

Risk management measures

Application Type (Usage) : Product sampling

Exposure routes : skin

Personal protective equipment : Wear suitable gloves tested according to EN 374.

Use safety glasses.

Use suitable protective clothing.

Application Type (Usage) : Material transfers

Internal use : inhalation

Exposure routes

: Local exhaust system

Technical conditions and measures : Loc

Effectiveness (measures) : 80%

Application Type (Usage) : Cleaning and maintenance of equipment

Exposure routes : inhalation

Personal protective equipment : Use appropriate respiratory protection equipment.

Effectiveness (measure) : 90%

Organizational measures

to prevent/limit releases, dispersion

and exposures

: Ensure workers are trained to minimize exposure.

Ensure that control measures are regularly reviewed and maintained.

Supervision in place to check that the risk management measures in place are being used correctly and that operating conditions are

being followed.

It assumes that a good basic standard of hygiene is in place

according to Regulation (EC) No. 1907/2006

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work

Technical conditions and measures : Handle the substance in a closed system.

To avoid exposure, collect samples through a closed loop or other

system.

Technical conditions and measures : Remote filling / transfer equipment

Material transfers

Transportation in closed pipelines.

1.2.4 ES 1 - CS 4: Control of worker exposure: Formulation and repackaging (Manufacturing or formulation in the chemical industry in closed batch processes with occasionally controlled exposure or in processes with equivalent control conditions) (PROC3)

#### Characteristic features of the product

Concentration of the substance in the mixture/article: <= 5%

Physical form (at the time of use): Solid, low dustiness

Comment : Increased temperature

Frequency and duration of use

: < 1 min Product sampling

Comment : Closed systems, Batch processes, Short-term, Continuous

#### Human factors unaffected by risk management

Dermal exposure : Palm of one hand

: 240 cm2 It includes a skin contact area of up to

Comment : Product sampling

Other operating conditions affecting worker exposure

Outdoor / Indoor : Indoor and outdoor use

Risk management measures

Application Type (Usage) : Product sampling

Exposure routes : skin

Personal protective equipment : Wear suitable gloves tested according to EN 374.

Use safety glasses.

Use suitable protective clothing.

Application Type (Usage) : Material transfers

> Internal use : inhalation

Exposure routes Technical conditions and measures

: Local exhaust system

Effectiveness (measures)

: 80%

: Cleaning and maintenance of equipment Application Type (Usage)

: inhalation Exposure routes

Personal protective equipment : Use appropriate respiratory protection equipment.

Effectiveness (measure)

Organizational measures for : Ensure workers are trained to minimize exposure.

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prevention/limitation of releases,

dispersion and exposures

Ensure that control measures are regularly reviewed and maintained.

Supervision in place to check that the risk management measures in place are being used correctly and that operating conditions are

being followed.

It assumes that a good basic standard of occupational hygiene is in

place

Technical conditions and measures : Handle the substance in a closed system.

To avoid exposure, collect samples through a closed loop or other

system.

Technical conditions and measures : Remote filling / transfer equipment

Material transfers

Transportation in closed pipelines.

### 1.2.5 ES 1 - CS 5: Control of worker exposure: Formulation and repackaging (Mixing or blending in batch production processes) (PROC5)

#### Characteristic features of the product

Concentration of the substance in the mixture/article

: <= 5%

Physical form (at the time of use): Solid, low dustiness

Comment : Increased temperature

Frequency and duration of use

Length of exposure : > 4 h

Product sampling : < 1 min

Frequency of use : 1 use per day

Frequency of use : 350 times per year

#### Human factors unaffected by risk management

Dermal exposure : Assumes that potential skin contact is limited to internal

side of hand / one hand / palm.

It includes a skin contact area of up to : 480 cm2

Comment : Product sampling

#### Other operating conditions affecting worker exposure

Outdoor / Indoor : Indoor and outdoor use

Risk management measures

Application Type (Usage) : Product sampling

Exposure routes : skin

Personal protective equipment : Wear suitable gloves tested according to EN 374.

Use safety glasses.

Use suitable protective clothing.

Application Type (Usage) : Material transfers

Internal use

Exposure routes : inhalation

Technical conditions and measures : Local exhaust system

Effectiveness (measures) : 80%

according to Regulation (EC) No. 1907/2006

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Application Type (Usage) : Cleaning and maintenance of equipment

Exposure routes : inhalation

Personal protective equipment : Use appropriate respiratory protection equipment.

Effectiveness (measure) : 90%

Organizational measures : Ensure workers are trained to minimize exposure.

to prevent/limit releases, dispersion

and exposures

Ensure that control measures are regularly reviewed and maintained.

Supervision in place to check that the risk management measures in

place are being used correctly and that operating conditions are being followed.

It assumes that a good basic standard of occupational hygiene is in

place

Technical conditions and measures : Handle the substance in a closed system.

To avoid exposure, collect samples through a closed loop or other

system.

Technical conditions and measures : Remote filling / transfer equipment

Material transfers

Transportation in closed pipelines.

# 1.2.6 ES 1 - CS 6: Control of worker exposure: Formulation and repackaging (Transportation of substance or preparation (filling/discharging) in non-specialized facilities) (PROC8a)

#### Characteristic features of the product

Concentration of the substance in the mixture/article : <= 5%

Physical form (at the time of use): Solid substance, low dustiness Comment: Increased temperature

Frequency and duration of use

Length of exposure : > 4 h

Frequency of use : 1 use per day
Frequency of use : 350 times per year

#### Human factors unaffected by risk management

Dermal exposure : Assumes that potential skin contact is limited to the hands.

It includes a skin contact area of up to : 960 cm2

Comment : Loading and unloading, Loading

Other operating conditions affecting worker exposure

Outdoor / Indoor : Indoor and outdoor use

Comment : Loading and unloading, Loading, Material transfers

Risk management measures

Exposure routes : skin

Personal protective equipment : Wear chemical resistant gloves (tested to EN 374) in combination with 'basic'

employee training.

Use safety glasses.

Use suitable protective clothing.

according to Regulation (EC) No. 1907/2006

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Application Type (Usage) : Material transfers

Internal use

Exposure routes : inhalation

Technical conditions and measures : Local exhaust system

Effectiveness (measures) : 80%

Organizational measures

: Ensure workers are trained to minimize exposure.

to prevent/limit releases, dispersion

and exposures

Ensure that control measures are regularly reviewed and maintained.

Supervision in place to check that the risk management measures in

place are being used correctly and that operating conditions are

being followed.

It assumes that a good basic standard of occupational hygiene is in place

Technical conditions and measures : Handle the substance in a closed system.

To avoid exposure, collect samples through a closed loop or other

svstem.

Technical conditions and measures : Remote filling / transfer equipment

Material transfers

Transportation in closed pipelines.

# 1.2.7 ES 1 - CS 7: Control of worker exposure: Formulation and repackaging (Transportation of substance or preparation (filling/discharging) in non-specialized facilities) (PROC8a)

#### Characteristic features of the product

Concentration of the substance in the mixture/article : <= 100%

Physical form (at the time of use) : Solid substance, low dustiness Comment : Increased temperature

Frequency and duration of use

Length of exposure : <= 4 h

Frequency of use : 1 use per day

Frequency of use : 350 times per year

#### Human factors unaffected by risk management

Dermal exposure : Assumes that potential skin contact is limited to the hands.

It includes a skin contact area of up to : 960 cm2

Comment : Loading and unloading, Loading

Other operating conditions affecting worker exposure

Outdoor / Indoor : Indoor and outdoor use

Comment : Loading and unloading, Loading, Material transfers

Risk management measures

Exposure routes : skin

Personal protective equipment : Wear chemical resistant gloves (tested to EN 374) in combination with 'basic'

employee training.

Use safety glasses.

Use suitable protective clothing.

according to Regulation (EC) No. 1907/2006

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Application Type (Usage) : Material transfers

Internal use : inhalation

Exposure routes

: Local exhaust system

Technical conditions and measures Effectiveness (measures)

: 80%

Organizational measures

: Ensure workers are trained to minimize exposure.

to prevent/limit releases, dispersion

Ensure that control measures are regularly reviewed and maintained.

and exposures

Supervision in place to check that the risk management measures in place are being used correctly and that operating conditions are

being followed.

It assumes that a good basic standard of occupational hygiene is in

place

Technical conditions and measures

: Handle the substance in a closed system.

To avoid exposure, collect samples through a closed loop or other

system.

Technical conditions and measures

: Remote filling / transfer equipment

Material transfers

Transportation in closed pipelines.

# 1.2.8 ES 1 - CS 8: Control of worker exposure: Formulation and repackaging (Transportation of substance or mixture (filling/discharging) in specialized facilities) (PROC8b)

#### Characteristic features of the product

Concentration of the substance in the mixture/article : <= 5%

Physical form (at the time of use) : Solid substance, low dustiness Comment : Increased temperature

Frequency and duration of use

#### Human factors unaffected by risk management

Dermal exposure : Assumes that potential skin contact is limited to the hands.

It includes a skin contact area of up to : 960 cm2

Comment : Loading and unloading, Loading

Other operating conditions affecting worker exposure

Outdoor / Indoor : Indoor and outdoor use

Comment : Loading and unloading, Loading, Material transfers

Risk management measures

Exposure routes : skin

Personal protective equipment : Wear chemical resistant gloves (tested to EN 374) in combination with 'basic'

employee training.

Use safety glasses.

according to Regulation (EC) No. 1907/2006

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Use suitable protective clothing.

Application Type (Usage) : Material transfers

Internal use

Exposure routes : inhalation

Technical conditions and measures : Local exhaust system

Effectiveness (measures) : 80%

Organizational measures : Ensure workers are trained to minimize exposure.

to prevent/limit releases, dispersion

and exposures

Ensure that control measures are regularly reviewed and maintained.

Supervision in place to check that the risk management measures in place are being used correctly and that operating conditions are

being followed.

It assumes that a good basic standard of occupational hygiene is in

olace

Technical conditions and measures : Handle the substance in a closed system.

To avoid exposure, collect samples through a closed loop or other

system.

Technical conditions and measures : Remote filling / transfer equipment

Material transfers

Transportation in closed pipelines.

# 1.2.9 ES 1 - CS 9: Control of worker exposure: Formulation and repackaging (Transportation of substance or mixture (filling/discharging) in specialized facilities) (PROC8b)

#### Characteristic features of the product

Concentration of the substance in the mixture/article: <= 100%

Physical form (at the time of use): Solid substance, low dustiness

Comment: Increased temperature

Frequency and duration of use

Length of exposure : <= 4 h

Frequency of use : 1 use per day

Frequency of use : 350 times per year

Human factors unaffected by risk management

Dermal exposure : Assumes that potential skin contact is limited to the hands.

It includes a skin contact area of up to : 960 cm2

Comment : Loading and unloading, Loading

Other operating conditions affecting worker exposure

Outdoor / Indoor : Indoor and outdoor use

Comment : Loading and unloading, Loading, Material transfers

Risk management measures

Exposure routes : skin

Personal protective equipment : Wear chemical resistant gloves (tested to EN 374) in combination with 'basic'

employee training.

according to Regulation (EC) No. 1907/2006

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Use safety glasses.

Use suitable protective clothing.

Application Type (Usage) : Material transfers

Internal use : inhalation

Exposure routes
Technical conditions and measures

: Local exhaust system

Effectiveness (measures)

: 80%

Organizational measures

to prevent/limit releases, dispersion

and exposures

: Ensure workers are trained to minimize exposure.

Ensure that control measures are regularly reviewed and maintained.

Supervision in place to check that the risk management measures in place are being used correctly and that operating conditions are

being followed.

It assumes that a good basic standard of occupational hygiene is in

place

Technical conditions and measures : Handle the substance in a closed system.

To avoid exposure, collect samples through a closed loop or other

system.

Technical conditions and measures : Remote filling / transfer equipment

Material transfers

Transportation in closed pipelines.

# 1.2.10 ES 1 - CS 10: Control of worker exposure: Formulation and repackaging (Transportation of substance or mixture into small containers (closed filling line, including weighing)) (PROC9)

#### Characteristic features of the product

Concentration of the substance in the mixture/article : <= 5%

Physical form (at the time of use) : Solid substance, low dustiness Comment : Increased temperature

Frequency and duration of use

Length of exposure :> 4 h

Frequency of use : 1 use per day
Frequency of use : 350 times per year

Human factors unaffected by risk management

Dermal exposure : Assumes that potential skin contact is limited to internal

side of hand / one hand / palm.

It includes a skin contact area of up to : 480 cm<sup>2</sup>

Comment : Loading and unloading, Loading

Other operating conditions affecting worker exposure

Outdoor / Indoor : Indoor and outdoor use

Comment : Loading and unloading, Loading, Material transfers

Risk management measures

Exposure routes : skin

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Personal protective equipment : Wear suitable gloves tested according to EN 374.

Use safety glasses.

Use suitable protective clothing.

Application Type (Usage) : Material transfers

Internal use

Exposure routes : inhalation

Technical conditions and measures : Local exhaust system

Effectiveness (measures) : 80%

Organizational measures : Ensure workers are trained to minimize exposure.

to prevent/limit releases, dispersion

and exposures

Ensure that control measures are regularly reviewed and maintained.

Supervision in place to check that the risk management measures in

place are being used correctly and that operating conditions are

being followed.

It assumes that a good basic standard of occupational hygiene is in

place

Technical conditions and measures : Handle the substance in a closed system.

To avoid exposure, collect samples through a closed loop or other

system.

Technical conditions and measures : Remote filling / transfer equipment

Material transfers

Transportation in closed pipelines.

# 1.2.11 ES 1 - CS 11: Control of worker exposure: Formulation and repackaging (Transportation of substance or mixture into small containers (closed filling line, including weighing)) (PROC9)

#### Characteristic features of the product

Concentration of the substance in the mixture/article: <= 100%

Physical form (at the time of use) : Solid substance, low dustiness Comment : Increased temperature

Frequency and duration of use

Length of exposure : <= 4 h

Frequency of use : 1 use per day

Frequency of use : 350 times per year

Human factors unaffected by risk management

Dermal exposure : Assumes that potential skin contact is limited to internal

side of hand / one hand / palm.

It includes a skin contact area of up to : 480 cm2

Comment : Loading and unloading, Loading

Other operating conditions affecting worker exposure

Outdoor / Indoor : Indoor and outdoor use

Comment : Loading and unloading, Loading, Material transfers

Risk management measures

according to Regulation (EC) No. 1907/2006

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Exposure routes : skin

Personal protective equipment : Wear suitable gloves tested according to EN 374.

Use safety glasses.

Use suitable protective clothing.

Application Type (Usage) : Material transfers

Internal use : inhalation

Exposure routes
Technical conditions and measures

: Local exhaust system

Effectiveness (measures) : 80%

Organizational measures

to prevent/limit releases, dispersion

and exposures

: Ensure workers are trained to minimize exposure.

Ensure that control measures are regularly reviewed and maintained.

Supervision in place to check that the risk management measures in place are being used correctly and that operating conditions are

being followed.

It assumes that a good basic standard of occupational hygiene is in

place

Technical conditions and measures : Handle the substance in a closed system.

To avoid exposure, collect samples through a closed loop or other

system.

Technical conditions and measures : Remote filling / transfer equipment

Material transfers

Transportation in closed pipelines.

### 1.2.12 ES 1 - CS 12: Control of worker exposure: Formulation and repackaging (Use as a laboratory reagent) (PROC15)

#### Characteristic features of the product

Concentration of the substance in the mixture/article : <= 100%

Physical form (at the time of use) : Solid substance, low dustiness Comment : Increased temperature

Frequency and duration of use

Length of exposure : <= 4 h

Frequency of use : 1 use per day

Frequency of use : 350 times per year

Human factors unaffected by risk management

Dermal exposure : Palm of one hand

It includes a skin contact area of up to : 240 cm2

Other operating conditions affecting worker exposure

Outdoor / Indoor : Indoor and outdoor use

Risk management measures

Exposure routes : skin

Personal protective equipment : Wear suitable gloves tested according to EN 374.

Use safety glasses.

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Use suitable protective clothing.

Application Type (Usage) : Material transfers

> Internal use : inhalation

Exposure routes

Technical conditions and measures

: Local exhaust system

Effectiveness (measures)

: 80%

Organizational measures

to prevent/limit releases, dispersion

and exposures

: Ensure workers are trained to minimize exposure.

Ensure that control measures are regularly reviewed and maintained.

Supervision in place to check that the risk management measures in place are being used correctly and that operating conditions are

being followed.

It assumes that a good basic standard of occupational hygiene is in

Technical conditions and measures : Handle the substance in a closed system.

To avoid exposure, collect samples through a closed loop or other

system.

Technical conditions and measures : Remote filling / transfer equipment

Material transfers

Transportation in closed pipelines.

#### 1.3. ES 1 Estimate of exposure and reference to its origin

#### 1.3.1 ES 1 - CS 1: Environmental exposure and release: Formulation and repackaging (Formulation into mixture) (ERC2)

Air release path	Release rate 0 kg/day 0 Release estimation method	
	kg/day	EUSES v2.1
Waste	1.24 kg/	EUSES v2.1
water	day	EUSES v2.1

protection target	Exposure estimation and reference to its source (EUSES v2.1)	RCR
Fresh water	1.00 µg/l	0.086
Sediment in fresh water	21.0 µg/kg live weight	0.077
Soil	86.0 µg/kg dry weight	0.086
Waste water treatment plant	6.2 µg/l	0.0144
Secondary poisoning	0.054 mg/kg bw/day (Only the highest exposure levels are given.)	0.0081
Indirect human exposure through the environment	0.00015 mg/kg body weight/day	< 0.01

1.3.2 ES 1 - CS 2: Worker Exposure: Formulation and Repackaging (Chemical manufacturing or refining in a closed process with no likelihood of exposure or in processes with equivalent control conditions) (PROC1)

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Route of exposure and type of effects	Exposure estimation	RCR
cutaneous	0.007 mg/kg bw/day (ECETOC TRA worker v3, Level 1)	< 0.01
inhalation	0.002 mg/m³ (ECETOC TRA worker v3, Level 1)	< 0.01
combined routes		< 1

# 1.3.3 ES 1 - CS 3: Worker Exposure: Formulation and Repackaging (Chemical production or refining in a closed manufacturing process with occasional controlled exposure or a process with equivalent conditions to prevent release) (PROC2)

Route of exposure and type of effects	Exposure estimation	RCR
cutaneous	0.27 mg/kg bw/day (ECETOC TRA worker v3, Level 1)	0.09
inhalation	0.002 mg/m³ (ECETOC TRA worker v3, Level 1)	< 0.01
combined routes		< 1

# 1.3.4 ES 1 - CS 4: Worker exposure: Formulation and repackaging (Manufacturing or formulation in the chemical industry in closed batch processes with occasionally controlled exposure or in processes with equivalent control conditions) (PROC3)

Route of exposure and type of effects	Exposure estimation	RCR
cutaneous	0.14 mg/kg bw/day (ECETOC TRA worker v3, Level 1)	0.05
inhalation	0.02 mg/m³ (ECETOC TRA worker v3, Level 1)	0.03
combined routes		< 1

### 1.3.5 ES 1 - CS 5: Worker Exposure: Formulation and Repackaging (Mixing or Mixing in Batch Manufacturing Processes) (PROC5)

Route of exposure and type of effects	Exposure estimation	RCR
cutaneous	0.54 mg/kg bw/day (ECETOC TRA worker v3, Level 1)	0.18
inhalation	0.1 mg/m³ (ECETOC TRA worker v3, Level 1)	0.17
combined routes		< 1

### 1.3.6 ES 1 - CS 6: Worker exposure: Formulation and repackaging (Transportation of substance or preparation (filling/discharging) in non-specialized facilities) (PROC8a)

Route of exposure and species Exposure estimation RC	oute of exposure and species	e of exposure and species Exposure estimation	RCR
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effects		
cutaneous	0.54 mg/kg bw/day (ECETOC TRA worker v3, Level 1)	0.18
inhalation	0.1 mg/m³ (ECETOC TRA worker v3, Level 1)	0.17
combined routes		< 1

### 1.3.7 ES 1 - CS 7: Worker exposure: Formulation and repackaging (Transport of substance or preparation (filling/discharging) in non-specialized facilities) (PROC8a)

Route of exposure and type of effects	Exposure estimation	RCR
cutaneous	0.82 mg/kg bw/day (ECETOC TRA worker v3, Level 1)	0.27
inhalation	0.3 mg/m³ (ECETOC TRA worker v3, Level 1)	0.5
combined routes		< 1

### 1.3.8 ES 1 - CS 8: Worker exposure: Formulation and repackaging (Transportation of substance or mixture (filling/discharging) in specialized facilities) (PROC8b)

Route of exposure and type of effects	Exposure estimation	RCR
cutaneous	2.74 mg/kg bw/day (ECETOC TRA worker v3, Level 1)	0.91
inhalation	0.02 mg/m³ (ECETOC TRA worker v3, Level 1)	0.03
combined routes		< 1

### 1.3.9 ES 1 - CS 9: Worker exposure: Formulation and repackaging (Transportation of substance or mixture (filling/discharging) in specialized facilities) (PROC8b)

Route of exposure and type of effects	Exposure estimation	RCR
cutaneous	1.37 mg/kg bw/day (ECETOC TRA worker v3, Level 1)	0.46
inhalation	0.10 mg/m³ (ECETOC TRA worker v3, Level 1)	0.17
combined routes	-	< 1

### 1.3.10 ES 1 - CS 10: Worker exposure: Formulation and repackaging (Transportation of substance or mixture into small containers (closed filling line, including weighing)) (PROC9)

Route of exposure and type of effects	Exposure estimation	RCR
cutaneous	1.37 mg/kg bw/day (ECETOC TRA worker v3, Level 1)	0.46
inhalation	0.02 mg/m³ (ECETOC TRA worker v3, Level 1)	0.03
combined routes		< 1

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### 1.3.11 ES 1 - CS 11: Worker exposure: Formulation and repackaging (Transportation of substance or mixture into small containers (closed filling line, including weighing)) (PROC9)

Route of exposure and type of effects	Exposure estimation	RCR
cutaneous	1.37 mg/kg bw/day (ECETOC TRA worker v3, Level 1)	0.46
inhalation	0.10 mg/m³ (ECETOC TRA worker v3, Level 1)	0.17
combined routes		< 1

### 1.3.12 ES 1 - CS 12: Worker exposure: Formulation and repackaging (Use as a laboratory reagent) (PROC15)

Route of exposure and type of effects	Exposure estimation	RCR
cutaneous	0.34 mg/kg bw/day (ECETOC TRA worker v3, Level 1)	0.11
inhalation	0.10 mg/m³ (ECETOC TRA worker v3, Level 1)	0.17
combined routes		< 1

### 1.4. ES 1 Guidance for the downstream user to evaluate whether he is working within the limits given by the exposure scenario

No information available.

## 2. ES 2: Consumer use; cosmetics, preparations for personal care

#### 2.1. Name

cosmetics, personal care preparations (PC39)	
Environment	
CS1: Consumer use (Widespread use of non-reactive production aids (which does not result in the substance being incorporated into or onto an article; indoors))	ERC8a
Consumer	
CS2: Consumer use (cosmetics, personal care products)	PC39

#### 2.2. ES 2 Conditions of use affecting exposure

according to Regulation (EC) No. 1907/2006

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# 2.2.1 ES 2 - CS 1: Environmental exposure control: Consumer use (Widespread use of non-reactive production aids (which does not result in the substance being incorporated into or on the article; indoors)) (ERC8a)

#### Characteristic features of the product

Concentration of the substance in the mixture/article :<3%

Physical form (at the time of use): Liquid Notes: Includes use at ambient temperature.

**Quantity used** 

Quantity used : 0.31 kg/day

Frequency and duration of use

Permanent exposure : 1 use per day

Permanent exposure : 365 times per year

#### Environmental factors unaffected by risk management

Receiving flow rate: 18,000 m3/d

surface water

#### Technical conditions and measures / Organizational measures

Comment : Follow the instructions for use / storage.

#### Conditions and measures related to the sewage treatment plant

Type of wastewater treatment plant : Municipal wastewater treatment plant

Flow rate of water from the sewage

treatment plant

: 2,000 m3/d

#### Waste management measures

Waste management : Combustion, Not applicable
Waste management : Waste dump, Not applicable
Waste management : Recycling/recovery, Not applicable

### 2.2.2 ES 2 - CS 2: Control of customer exposure: Consumer use (cosmetics, personal care products) (PC39)

Comment : No human health exposure assessment is present.

In accordance with Article 14, paragraph 5b of REACH Regulation (EC) No.

1907/2006, it is not necessary to carry out an exposure

assessment and risk characterization with regard to human health for end-

use cosmetic products within the scope of Directive 76/78/EEC.

#### 2.3. ES 2 Estimate of exposure and reference to its origin

according to Regulation (EC) No. 1907/2006

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# 2.3.1 ES 2 - CS 1: Exposure and release to the environment: Consumer use (Widespread use of non-reactive production aids (which does not result in the substance being incorporated into or on the object; indoors)) (ERC8a)

Air release path	Release rate 0 kg/day 0	Release estimation method
	kg/dav	EUSES v2.1
Waste	0.31 kg/	EUSES v2.1
water	day	EUSES v2.1

protection target	Exposure estimation and reference to its source (EUSES v2.1)	RCR
Fresh water	0.66 µg/l	0.051
Sediment in fresh water	56.0 µg/kg live weight	0.045
Soil	21.4 µg/kg dry weight	0.021
Waste water treatment plant	1.6 µg/l	< 0.01
Secondary poisoning	0.04 mg/kg bw/day (Only the highest exposure levels are given.)	< 0.01
Indirect human exposure through the environment	Not applicable. In accordance with Article 14, paragraph 5b of REACH Regulation (EC) No. 1907/2006, it is not necessary to carry out an exposure assessment and risk characterization with regard to human health for end-use cosmetic products within the scope of Directive 76/78/EEC.	

## 2.4. ES 2 Guidance for the downstream user to evaluate whether he is working within the limits given by the exposure scenario

Follow the instructions for use / storage.