

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Revision date: 12/11/2024 Supersedes version of: 1/9/2023 Version: 4.0

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

1.1. Product identifier

Product form : Mixture Product name Aeliteflo

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

Relevant identified uses

Use of the substance/mixture : For Rx Only

1.3. Details of the supplier of the safety data sheet

Manufacturer

BISCO, Inc.

1100 W. Irving Park Rd. 60193 Schaumburg, IL

T 1-800-247-3368 or 1-847-534-6000

T 33-4-90-42-92-92

EC Representative:

208, allée de la Coudoulette

13680 Lançon de Provence

BISICO France

France

sales@bisco.com - www.bisco.com

1.4. Emergency telephone number

: CHEMTREC - 24-Hour Hazmat Emergency Communications Center Emergency number

Domestic: 1-800-424-9300 Outside the U.S.: 1-703-527-3887, collect calls accepted

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS07

Signal word (CLP)

Contains

Hazard statements (CLP)

Precautionary statements (CLP)

Triethylene Glycol Dimethacrylate; Tert-butyl Peroxybenzoate

: H317 - May cause an allergic skin reaction. : P261 - Avoid breathing dust, fume, vapours.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P280 - Wear protective gloves, protective clothing, eye protection. P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

P321 - Specific treatment (see supplemental first aid instruction on this label). P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse.

P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation, a licensed

hazardous-waste disposal contractor or collection site except for empty clean containers

which can be disposed of as non-hazardous waste.

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2.3. Other hazards

Contains no PBT and/or vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

Component	
Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	Ethoxylated Bis A Dimethacrylate (41637-38-1), Triethylene Glycol Dimethacrylate (109-16-0), Tert-butyl Peroxybenzoate (614-45-9)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	Ethoxylated Bis A Dimethacrylate (41637-38-1), Triethylene Glycol Dimethacrylate (109-16-0), Tert-butyl Peroxybenzoate (614-45-9)

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethoxylated Bis A Dimethacrylate	CAS-No.: 41637-38-1	10 - 30	Aquatic Chronic 4, H413
Triethylene Glycol Dimethacrylate	CAS-No.: 109-16-0 EC-No.: 203-652-6	5 - 10	Skin Sens. 1B, H317
Polybutanediol Dimethacrylate 600	CAS-No.: 28883-57-0	5 - 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Fumed Silica	CAS-No.: 68611-44-9 EC-No.: 271-893-4	1 - 5	Not classified
Tert-butyl Peroxybenzoate	CAS-No.: 614-45-9 EC-No.: 210-382-2	< 1	Org. Perox. C, H242 Acute Tox. 4 (Inhalation), H332 Skin Irrit. 2, H315 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 3, H412

Full text of H- and EUH-statements: see section 16

Components - Nanoform

Fumed Silica (68611-44-9)	
Name of (set of) nanoform(s) Fumed Silica	
Number based particle size distribution	16 nm
Particle shape	Crystal
Specific surface area	90 - 130 m2/g

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing and wash it before reuse. If

skin irritation or rash occurs: Get medical advice/attention.

Rinse immediately with plenty of water. Remove contact lenses, if present and easy to do.

First-aid measures after eye contact

Rinse immediately with plenty of water. Remove contact lenses, if present and easy Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact : May cause an allergic skin reaction.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained

breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust, fume,

vapours.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information

refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid

breathing dust, fume, vapours. Avoid contact with skin and eyes.

Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash

contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protection equipment

Personal protective equipment symbol(s):







Eye and face protection

Eye protection:

Safety glasses

Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid Colour : Tooth. Appearance : Paste. Odour : Acrylic. Odour threshold : Not available Melting point : Not available Freezing point : Not applicable **Boiling** point : Not available Flammability : Non flammable. Lower explosion limit : Not applicable Upper explosion limit : Not applicable : > 38 °C Flash point Auto-ignition temperature : Not applicable : Not available Decomposition temperature : Not available pΗ : Not available pH solution Viscosity, kinematic : Not applicable Solubility : Not available Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available

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Vapour pressure at 50°C : Not available
Density : Not available
Relative density : Not applicable
Relative vapour density at 20°C : Not applicable
Particle size : Not available

See section 3 for more information about nano properties.

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Ethoxylated Bis A Dimethacrylate (41637-38-1)		
LD50 oral rat > 2000 mg/kg Source: ECHA		
LD50 dermal rat > 2000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female Read-across, Dermal, 15 day(s))		
Triethylene Glycol Dimethacrylate (109-16-0)		
LD50 oral rat	10837 mg/kg Source: NLM,THOMSON	
LD50 dermal > 2000 mg/kg bodyweight (US EPA, 14 day(s), Mouse, Male, Experimental value, Skin day(s))		
Polybutanediol Dimethacrylate 600 (28883-57-0)		
LD50 oral rat 14500 mg/kg		
Tert-butyl Peroxybenzoate (614-45-9)		
LD50 oral rat 1012 mg/kg		

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Tert-butyl Peroxybenzoate (614-45-9)	
LD50 dermal rat	> 2000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Skin, 14 day(s))
Fumed Silica (68611-44-9)	•
LD50 oral rat	> 5000 mg/kg (Rat, Literature study, Oral)
Skin corrosion/irritation :	Not classified
Ethoxylated Bis A Dimethacrylate (41637-38-	1)
рН	4.7 (< 0.01 %, 20 °C, OECD 105: Water Solubility)
Triethylene Glycol Dimethacrylate (109-16-0)	
рН	6.8 - 7.2
Tert-butyl Peroxybenzoate (614-45-9)	
pH	No data available in the literature
Fumed Silica (68611-44-9)	
рН	3.7 - 4.7 (4 %, 20 °C)
Serious eye damage/irritation :	Not classified
Ethoxylated Bis A Dimethacrylate (41637-38-	1)
рН	4.7 (< 0.01 %, 20 °C, OECD 105: Water Solubility)
Triethylene Glycol Dimethacrylate (109-16-0	
рН	6.8 - 7.2
Tert-butyl Peroxybenzoate (614-45-9)	
рН	No data available in the literature
Fumed Silica (68611-44-9)	
рН	3.7 - 4.7 (4 %, 20 °C)
Respiratory or skin sensitisation :	May cause an allergic skin reaction.
	Not classified
	Not classified
Polybutanediol Dimethacrylate 600 (28883-57	7-0)
IARC group	4 - Probably not carcinogenic to humans
Reproductive toxicity :	
3 1	Not classified
Polybutanediol Dimethacrylate 600 (28883-57	,
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure :	Not classified
Triethylene Glycol Dimethacrylate (109-16-0)	
LOAEC (inhalation, rat, gas, 90 days)	350 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other:
NOAEL (oral, rat, 90 days)	1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)
NOAEC (inhalation, rat, gas, 90 days)	100 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other:

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Tert-butyl Peroxybenzoate (614-45-9)		
NOAEL (oral, rat, 90 days)	≈ 30 mg/kg bodyweight Animal: rat, Guideline: other:	
Aspiration hazard :	Not classified	
Aeliteflo		
Viscosity, kinematic	Not applicable	
Ethoxylated Bis A Dimethacrylate (41637-38-1)		
Viscosity, kinematic No data available in the literature		
Tert-butyl Peroxybenzoate (614-45-9)		
Viscosity, kinematic No data available in the literature		
Fumed Silica (68611-44-9)		
Viscosity, kinematic	Not applicable	

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

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Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse

effects in the environment.

: Not classified

Hazardous to the aquatic environment, short-term

Hazardous to the aquatic environment, long-term : Not classified

(chronic)

(chronic)		
Ethoxylated Bis A Dimethacrylate (41637-38-1)		
LC50 - Fish [1]	> 100 mg/l Source: ECAH	
EC50 72h - Algae [1]	> 100 mg/l Source: ECAH	
Triethylene Glycol Dimethacrylate (109-16-0)		
LC50 - Fish [1]	16.4 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)	
EC50 72h - Algae [1]	> 100 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)	
EC50 72h - Algae [2]	72.8 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)	
ErC50 algae	> 100 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, Nominal concentration)	
LOEC (chronic)	100 mg/l Test organisms (species): Daphnia magna Duration: '21 d'	
NOEC (chronic)	32 mg/l Test organisms (species): Daphnia magna Duration: '21 d'	
Tert-butyl Peroxybenzoate (614-45-9)		
LC50 - Fish [1]	1.6 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)	
EC50 - Crustacea [1]	11 mg/l Test organisms (species): Daphnia magna	
EC50 72h - Algae [1]	0.8 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)	
EC50 72h - Algae [2]	0.4 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)	

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Tert-butyl Peroxybenzoate (614-45-9)		
ErC50 algae	0.8 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, GLP)	
Fumed Silica (68611-44-9)		
LC50 - Fish [1]	> 10000 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Brachydanio rerio, Experimental value, Nominal concentration)	
EC50 - Crustacea [1]	> 10000 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 24 h, Daphnia magna, Experimental value, Nominal concentration)	

12.2. Persistence and degradability

Aeliteflo		
Persistence and degradability	Rapidly degradable	
Ethoxylated Bis A Dimethacrylate (41637-38-1)	
Persistence and degradability	Not readily biodegradable in water.	
Triethylene Glycol Dimethacrylate (109-16-0)		
Persistence and degradability	Readily biodegradable in water.	
Polybutanediol Dimethacrylate 600 (28883-57-0)		
Persistence and degradability	Rapidly degradable	
Tert-butyl Peroxybenzoate (614-45-9)		
Persistence and degradability	Readily biodegradable in water.	
ThOD	2.14 g O ₂ /g substance	
Fumed Silica (68611-44-9)		
Persistence and degradability	Biodegradability: not applicable.	

12.3. Bioaccumulative potential

Ethoxylated Bis A Dimethacrylate (41637-38-1)		
Partition coefficient n-octanol/water (Log Pow)	5.62 (Practical experience/observation, OECD 117: Partition Coefficient (n-octanol/water), HPLC method)	
Bioaccumulative potential	High potential for bioaccumulation (Log Kow > 5).	
Triethylene Glycol Dimethacrylate (109-16-0)		
Partition coefficient n-octanol/water (Log Pow)	2.3 (Experimental value, OECD 117: Partition Coefficient (n-octanol/water), HPLC method)	
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).	
Tert-butyl Peroxybenzoate (614-45-9)		
Partition coefficient n-octanol/water (Log Pow)	3 (Experimental value, OECD 117: Partition Coefficient (n-octanol/water), HPLC method, 25 °C)	
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).	
Fumed Silica (68611-44-9)		
Bioaccumulative potential	Not bioaccumulative.	

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12.4. Mobility in soil

Ethoxylated Bis A Dimethacrylate (41637-38-1)		
Surface tension No data available in the literature		
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	2.56 - 3.88 (log Koc, Calculated value)	
Ecology - soil	Low potential for mobility in soil.	
Triethylene Glycol Dimethacrylate (109-16-0)		
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	1.89 (log Koc, SRC PCKOCWIN v2.0, Calculated value)	
Ecology - soil	Highly mobile in soil.	
Tert-butyl Peroxybenzoate (614-45-9)		
Surface tension	No data available in the literature	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	2.3 (log Koc, QSAR, Calculated value)	
Ecology - soil	Low potential for adsorption in soil.	
Fumed Silica (68611-44-9)		
Ecology - soil	Low potential for mobility in soil.	

12.5. Results of PBT and vPvB assessment

Component	
Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	Ethoxylated Bis A Dimethacrylate (41637-38-1), Triethylene Glycol Dimethacrylate (109-16-0), Tert-butyl Peroxybenzoate (614-45-9)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	Ethoxylated Bis A Dimethacrylate (41637-38-1), Triethylene Glycol Dimethacrylate (109-16-0), Tert-butyl Peroxybenzoate (614-45-9)

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not regulated Proper Shipping Name (IMDG) : Not regulated Proper Shipping Name (IATA) : Not regulated

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Proper Shipping Name (ADN) : Not regulated Proper Shipping Name (RID) : Not regulated

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not regulated

IMDG

Transport hazard class(es) (IMDG) : Not regulated

IATA

Transport hazard class(es) (IATA) : Not regulated

ADN

Transport hazard class(es) (ADN) : Not regulated

RID

Transport hazard class(es) (RID) : Not regulated

14.4. Packing group

Packing group (ADR) : Not regulated Packing group (IMDG) : Not regulated Packing group (IATA) : Not regulated Packing group (ADN) : Not regulated Packing group (RID) : Not regulated

14.5. Environmental hazards

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

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REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Supersedes version of	Modified
	Revision date	Modified
3	Composition/information on ingredients	Modified

Full text of H- and EUH-statements:		
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4	
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard, Category 1	
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard, Category 3	
Aquatic Chronic 4	Hazardous to the aquatic environment - Chronic Hazard, Category 4	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
H242	Heating may cause a fire.	
H315	Causes skin irritation.	
H317	May cause an allergic skin reaction.	
H319	Causes serious eye irritation.	
H332	Harmful if inhaled.	
H335	May cause respiratory irritation.	
H400	Very toxic to aquatic life.	
H412	Harmful to aquatic life with long lasting effects.	
H413	May cause long lasting harmful effects to aquatic life.	
Org. Perox. C	Organic Peroxides, Type C	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	

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Full text of H- and EUH-statements:	
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1B	Skin sensitisation, category 1B
STOT SE 3	Specific target organ toxicity - Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.