

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Revision date: 3/16/2023 Supersedes version of: 8/6/2018 Version: 4.0

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

1.1. Product identifier

Product form : Mixture

Product name : TheraCem Ca Base

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For Rx Only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

ManufacturerEC REPBISCO, Inc.BISICO France

1100 W. Irving Park Rd.208, allée de la CoudouletteSchaumburg, IL 6019313680 Lançon de ProvenceUSAFrance

T 1-800-247-3368 or 1-847-534-6000 T 33-4-90-42-92-92

www.bisco.com

1.4. Emergency telephone number

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

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 corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Skin sensitisation, Category 1 H317
Specific target organ toxicity - Single exposure, Category 3, Respiratory H335

tract irritation

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

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning

Contains : Portland Cement, BisGMA, Ytterbium w/ Barium Glass

Hazard statements (CLP) : H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation.

Precautionary statements (CLP) : P261 - Avoid breathing dust, fume, vapours.
P264 - Wash hands thoroughly after handling.

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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.

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312 - Call a POISON CENTER, doctor if you feel unwell.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P332+P313 - If skin irritation occurs: Get medical advice/attention.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

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.

2.3. Other hazards

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

Component	
Ethoxylated Bis A Dimethacrylate (41637-38-1)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
Portland Cement (65997-15-1)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
Titanium Dioxide (13463-67-7)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

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 is 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 %

Component		
	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 is 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

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ytterbium w/ Barium Glass	CAS-No.: NA	30 - 50	Eye Irrit. 2, H319 STOT SE 3, H335
Ethoxylated Bis A Dimethacrylate	CAS-No.: 41637-38-1	10 - 30	Aquatic Chronic 4, H413
Portland Cement	CAS-No.: 65997-15-1 EC-No.: 266-043-4	10 - 30	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ytterbium Fluoride	CAS-No.: 13760-80-0 EC-No.: 237-354-2	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319
Brombenzenesulfinic Acid, Sodium Dihydrate	CAS-No.: 175278-64-5	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
BisGMA	CAS-No.: 1565-94-2 EC-No.: 216-367-7	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335
Titanium Dioxide	CAS-No.: 13463-67-7 EC-No.: 236-675-5 EC Index-No.: 022-006-00-2	< 1	Carc. 2, H351
Acetyl-2-Thiourea	CAS-No.: 591-08-2 EC-No.: 209-699-9	< 1	Acute Tox. 2 (Oral), H300

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a poison center or a

doctor if you feel unwell.

First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash

occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy

to do. 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.

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

Symptoms/effects after inhalation : May cause respiratory irritation.

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

Symptoms/effects after eye contact : May cause eye irritation.

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.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

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

eyes.

6.1.2. 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 : Avoid breathing dust, fume, vapours. Avoid contact with skin and eyes. Wear personal

protective equipment.

Hygiene measures : Wash contaminated clothing before reuse. Contaminated work clothing should not be

allowed out of the workplace. 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 container tightly closed. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):







8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

Vapour pressure at 50°C

No additional information available

8.2.3. 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 : Straw.

Appearance : Viscous Resin Paste.

Odour : Acrylic. Odour threshold Not available Melting point Not available Freezing point Not applicable Boiling point Not available Flammability Non flammable. **Explosive limits** Not applicable Lower explosion limit Not applicable Not applicable Upper explosion limit Not applicable Flash point Auto-ignition temperature Not applicable Decomposition temperature Not available рΗ Not available pH solution Not available : Not applicable Viscosity, kinematic Solubility Not available Partition coefficient n-octanol/water (Log Kow) Not available Not available Vapour pressure

: Not available

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Density : Not available Relative density : Not applicable Relative vapour density at 20°C : Not applicable Not available Particle size Particle size distribution Not available Particle shape Not available Particle aspect ratio Not available Particle aggregation state Not available Particle agglomeration state : Not available Particle specific surface area : Not available Particle dustiness : Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

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))	
Acetyl-2-Thiourea (591-08-2)		
LD50 oral rat	50 mg/kg Source: National Library of Medicine/Hazardous Substances Data Bank	

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Ytterbium Fluoride (13760-80-0)	
LD50 oral rat	> 2000 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 420 (Acute Oral Toxicity - Fixed Dose Method), Guideline: EU Method B.1 bis (Acute Oral Toxicity - Fixed Dose Procedure)
Titanium Dioxide (13463-67-7)	
LD50 oral rat	> 2000 mg/kg bodyweight (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s))
LC50 Inhalation - Rat	> 5.09 mg/l (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male, Experimental value, Inhalation (dust), 14 day(s))
LC50 Inhalation - Rat (Dust/Mist)	> 6.82 mg/l Source: ECHA
Skin corrosion/irritation :	Causes skin irritation.
Portland Cement (65997-15-1)	
рН	11 - 13.5 (20 °C)
Ethoxylated Bis A Dimethacrylate (41637-38-	1)
рН	4.7 (0.0002 %, 20 °C, OECD 105: Water Solubility)
Acetyl-2-Thiourea (591-08-2)	
рН	6 (17.3 %)
Ytterbium Fluoride (13760-80-0)	
рН	4.53 Temp.: 20 °C
Titanium Dioxide (13463-67-7)	
рН	7 Source: ECHA
Serious eye damage/irritation :	Causes serious eye irritation.
Portland Cement (65997-15-1)	
рН	11 - 13.5 (20 °C)
Ethoxylated Bis A Dimethacrylate (41637-38-	1)
рН	4.7 (0.0002 %, 20 °C, OECD 105: Water Solubility)
Acetyl-2-Thiourea (591-08-2)	
рН	6 (17.3 %)
Ytterbium Fluoride (13760-80-0)	
рН	4.53 Temp.: 20 °C
Titanium Dioxide (13463-67-7)	
рН	7 Source: ECHA
Respiratory or skin sensitisation :	May cause an allergic skin reaction.
Germ cell mutagenicity : Carcinogenicity :	Not classified Not classified
Brombenzenesulfinic Acid, Sodium Dihydrat	
IARC group	4 - Probably not carcinogenic to humans
Ytterbium Fluoride (13760-80-0)	
IARC group	4 - Probably not carcinogenic to humans

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Titanium Dioxide (13463-67-7)		
IARC group	2B - Possibly carcinogenic to humans	
Reproductive toxicity :	Not classified	
STOT-single exposure :	May cause respiratory irritation.	
Portland Cement (65997-15-1)		
STOT-single exposure	May cause respiratory irritation.	
Brombenzenesulfinic Acid, Sodium Dihydrate	(175278-64-5)	
STOT-single exposure	May cause respiratory irritation.	
BisGMA (1565-94-2)		
STOT-single exposure	May cause respiratory irritation.	
Ytterbium w/ Barium Glass (NA)		
STOT-single exposure	May cause respiratory irritation.	
STOT-repeated exposure :	Not classified	
Aspiration hazard :	Not classified	
TheraCem Ca Base		
Viscosity, kinematic	Not applicable	
Portland Cement (65997-15-1)		
Viscosity, kinematic	Not applicable (solid)	
Ethoxylated Bis A Dimethacrylate (41637-38-1)		
Viscosity, kinematic	No data available in the literature	
Titanium Dioxide (13463-67-7)		
Viscosity, kinematic	Not applicable (solid)	

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

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

effects in the environment.

: Not classified

: Not classified

Hazardous to the aquatic environment, short-term

(acute

Hazardous to the aquatic environment, long-term (chronic)

(chronic)		
Portland Cement (65997-15-1)		
LC50 - Fish [1]	> 1000 mg/l (96 h, Pisces)	
Ethoxylated Bis A Dimethacrylate (41637-38-1)		
LC50 - Fish [1]	> 100 mg/l Source: ECAH	
EC50 72h - Algae [1]	> 100 mg/l Source: ECAH	
Acetyl-2-Thiourea (591-08-2)		
LC50 - Fish [1]	3417 mg/l Source: Ecological Structure Activity Relationships	

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BisGMA (1565-94-2)		
LC50 - Fish [1]	0.537 mg/l Source: ECOSAR	
Ytterbium Fluoride (13760-80-0)		
EC50 - Crustacea [1]	> 0.52 mg/l Test organisms (species): Daphnia magna	
Titanium Dioxide (13463-67-7)		
LC50 - Fish [1]	> 100 mg/l	
EC50 - Crustacea [1]	> 1000 mg/l (Invertebrata, Fresh water)	
EC50 72h - Algae [1]	> 50 mg/l Source: ECHA	

12.2. Persistence and degradability

Portland Cement (65997-15-1)		
Persistence and degradability	Biodegradability: not applicable.	
Chemical oxygen demand (COD)	Not applicable (inorganic)	
ThOD	Not applicable (inorganic)	
BOD (% of ThOD)	Not applicable	
Ethoxylated Bis A Dimethacrylate (41637-38-1)		
Persistence and degradability	Not readily biodegradable in water.	
Acetyl-2-Thiourea (591-08-2)		
Persistence and degradability	Biodegradability in water: no data available.	
BisGMA (1565-94-2)		
Persistence and degradability	Biodegradability in water: no data available.	
Titanium Dioxide (13463-67-7)		
Persistence and degradability	Biodegradability: not applicable.	
Chemical oxygen demand (COD)	Not applicable (inorganic)	
ThOD	Not applicable (inorganic)	

12.3. Bioaccumulative potential

Portland Cement (65997-15-1)		
Bioaccumulative potential	No bioaccumulation data available.	
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).	
Acetyl-2-Thiourea (591-08-2)		
Partition coefficient n-octanol/water (Log Pow)	-0.27 Source: National Library of Medicine	
Bioaccumulative potential	Not bioaccumulative.	
BisGMA (1565-94-2)		
Partition coefficient n-octanol/water (Log Pow)	4.94 Source: ChemIDplus	
Bioaccumulative potential	No bioaccumulation data available.	

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Ytterbium Fluoride (13760-80-0)	
Partition coefficient n-octanol/water (Log Pow)	0.22 Source: EPISUITE
Titanium Dioxide (13463-67-7)	
Bioaccumulative potential	Not bioaccumulative.

12.4. Mobility in soil

Portland Cement (65997-15-1)		
Surface tension	No data available in the literature	
Ecology - soil	No (test)data on mobility of the substance available.	
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.	
Acetyl-2-Thiourea (591-08-2)		
Mobility in soil	22 Source: HSDB	
Titanium Dioxide (13463-67-7)		
Surface tension	No data available in the literature	
Ecology - soil	Low potential for mobility in soil.	

12.5. Results of PBT and vPvB assessment

No additional information available

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

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

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Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

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

IMDG

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

IATA

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

ADN

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

RID

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

14.4. Packing group

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

14.5. Environmental hazards

Dangerous for the environment : No Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

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

15.1.1. 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)

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)

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)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes				
Section	Changed item	Change	Comments	
	Issue date	Removed		
	Revision date	Added		
	Supersedes version of	Added		
2.2	Precautionary statements (CLP)	Modified		
3	Composition/information on ingredients	Modified		

Full text of H- and EUH-statements:	
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Chronic 4	Hazardous to the aquatic environment – Chronic Hazard, Category 4
Carc. 2	Carcinogenicity, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H300	Fatal if swallowed.
H315	Causes skin irritation.

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Full text of H- and EUH-statements:		
H317	May cause an allergic skin reaction.	
H319	Causes serious eye irritation.	
H335	May cause respiratory irritation.	
H351	Suspected of causing cancer.	
H413	May cause long lasting harmful effects to aquatic life.	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1	Skin sensitisation, Category 1	
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.