

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Issue date: 2/22/2022 Version: 1.0

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

Product identifier

Product form : Mixture Product name : UltraSEP

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

Relevant identified uses 1.2.1.

Use of the substance/mixture : For Rx Only

1.2.2. Uses advised against

No additional information available

Details of the supplier of the safety data sheet

Manufacturer:

Reliance Orthodontic Products, Inc. 1540 West Thorndale Ave. Itasca, IL 60143 USA 630-773-4009, during normal business hours www.RelianceOrthodontics.com

EC Representative:

Emergo Europe, Prinsessgracht 20 2514 AP

The Hague, The Netherlands

Australian Sponsor: Emergo Australia, 201 Sussex St. Darling Park,

Tower II. Level

Sydney, NSW 2000 Australia

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

Classification of the substance or mixture

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

Flammable liquids Category 2 Skin corrosion/irritation Category 2 H315 Serious eye damage/eye irritation, Category 2 H319 Skin sensitization, Category 1 H317

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapor. May cause respiratory irritation. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation

2.2. **Label elements**

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

Hazard pictograms (CLP)





Signal word (CLP) Danger

Hazardous ingredients 2-Hydroxyethyl Methacrylate

Hazard statements (CLP) H225 - Highly flammable liquid and vapor.

H315 - Causes skin irritation.

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

Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

P233 - Keep container tightly closed.

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P240 - Ground and bond container and receiving equipment.

P241 - Use explosion-proof electrical/ventilating/lighting equipment.

P261 - Avoid breathing fume/mist/vapours

P264 - Wash hands thoroughly after handling.

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 water.

P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

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. P370+P378 - In case of fire: Use media other than water to extinguish.

P403+P235 - Store in a well-ventilated place. Keep cool.

P501 - Dispose of contents, container to hazardous or special waste collection point, in accordance with local/regional/national regulations.

2.3. Other hazards

No additional information available

SECTION 3: Composition/Information on ingredients

Substances

Not applicable

3.2. **Mixtures**

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Hydroxyethyl Methacrylate	(CAS-No.) 868-77-9 (EC-No.) 212-782-2 (EC Index-No.) 607-124-00-X	10 – 30	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317
Ethyl 4-Dimethylaminobenzoate	(CAS-No.) 10287-53-3 (EC-No.) 233-634-3	1 – 5	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Camphorquinone	(CAS-No.) 10373-78-1 (EC-No.) 233-814-1	1 – 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

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 : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical

advice. Call a poison center/doctor/physician if you feel unwell.

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

center/doctor/physician if you feel unwell.

First-aid measures after skin contact Wash contaminated clothing before reuse. Specific treatment (see First aid measures on this

label). Rinse skin with water/shower. Remove/Take off immediately all contaminated clothing. If

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

First-aid measures after eve contact : Rinse immediately with plenty of water for 15 minutes, Remove contact lenses, if present and

easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists. 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.

Rinse mouth with water. Do not induce vomiting. Obtain emergency medical attention. Call a First-aid measures after ingestion poison center/doctor/physician if you feel unwell.

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

: May cause respiratory irritation. Symptoms/effects after inhalation

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

Symptoms/effects after eye contact Causes eye irritation.

Symptoms/effects after ingestion Swallowing a small quantity of this material will result in serious health hazard.

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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 : Sand. Water spray. Dry powder. Foam. Carbon dioxide.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapor.

Explosion hazard : May form flammable/explosive vapor-air mixture.

Hazardous decomposition products in case of

firo

: Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any

chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. 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

General measures : Remove ignition sources. Use special care to avoid static electric charges. No open flames. No

smoking.

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Evacuate unnecessary personnel. No open flames, no sparks, and no

smoking. Avoid breathing fume/mist/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. Equip cleanup crew with

proper protection. For further information refer to section 8: "Exposure controls/personal

protection".

Emergency procedures : Ventilate area

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Soak up spills with inert solids, such as clay or

diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

Notify authorities if product enters sewers or public waters.

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

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed

: Handle empty containers with care because residual vapors are flammable.

Precautions for safe handling

Do not breathe fume/mist/vapours. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor. No open flames. No smoking. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapors may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Use only outdoors or in a well-ventilated

area. Avoid contact with skin and eyes.

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

Technical measures

: Proper grounding procedures to avoid static electricity should be followed. Keep in a cool, well-ventilated place away from heat. Use only non-sparking tools. Ground/bond container and receiving equipment.

Storage conditions

: Keep only in the original container in a cool, well ventilated place away from : heat/sunlight. Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store locked up.

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Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight. Heat sources.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

Wear protective gloves/protective clothing/eye protection/face protection

Eye protection:

Chemical goggles or safety glasses.

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Wear appropriate mask



Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid Appearance Yellow liquid. Color Yellow. Odor Ethanol odor. No data available Odor threshold No data available Hq Relative evaporation rate (butyl acetate=1) No data available Melting point : Not applicable Freezing point : No data available Boiling point : No data available Flash point No data available Auto-ignition temperature No data available Decomposition temperature : No data available

Flammability (solid, gas) : Flammable liquid and vapor

Vapor pressure : No data available
Relative vapor density at 20 °C : No data available
Relative density : No data available
Solubility : No data available

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Partition coefficient n-octanol/water (Log Pow) : No data available Viscosity, kinematic : No data available Viscosity, dynamic : No data available Explosive properties : No data available Oxidizing properties : No data available Explosion limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Flammable liquid and vapor. Highly flammable liquid and vapor.

10.2. Chemical stability

Stable under normal conditions. Highly flammable liquid and vapor. May form flammable/explosive vapor-air mixture.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Not established.

10.4. Conditions to avoid

Protect from sunlight. Extremely high or low temperatures. Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Carbon dioxide. Carbon monoxide. May release flammable gases.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

2-Hydroxyethyl Methacrylate (868-77-9)	
LD50 oral rat	5564 mg/kg body weight (Rat, Experimental value, Oral)
LD50 dermal rabbit	> 5000 mg/kg (24 h, Rabbit, Male, Experimental value, Dermal)
Ethyl 4-Dimethylaminobenzoate (10287-53-3)	
LD50 oral rat	> 2000 mg/kg (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s))

LD50 oral rat

> 2000 mg/kg (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s))

LD50 dermal rat

> 2000 mg/kg (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal, 15 day(s))

 Skin corrosion/irritation
 : Causes skin irritation.

 Serious eye damage/irritation
 : Causes serious eye irritation.

 Respiratory or skin sensitization
 : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified Carcinogenicity : Not classified Reproductive toxicity : Not classified

STOT-single exposure : Not classified STOT-repeated exposure : Not classified Aspiration hazard : Not classified

Potential Adverse human health effects and : Based on available data, the classification criteria are not met. Harmful if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

symptoms

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

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Hazardous to the aquatic environment, short-

term (acute)

Hazardous to the aquatic environment, long-

term (chronic)

: Not classified

: Not classified

2-Hydroxyethyl Methacrylate (868-77-9)	
LC50 - Fish [1]	> 100 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Oryzias latipes, Semi-static system, Fresh water, Experimental value, GLP)
EC50 - Crustacea [1]	380 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, GLP)
ErC50 algae	836 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, GLP)

	Static system, Fresh water, Experimental value, GLP)
Ethyl 4-Dimethylaminobenzoate (10287-53-3)	
LC50 - Fish [1]	1.9 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Oncorhynchus mykiss, Semi-static system, Fresh water, Experimental value)
EC50 - Crustacea [1]	4.5 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, GLP)
EC50 72h - Algae [1]	2.8 mg/l (OECD 201: Alga, Growth Inhibition Test, Pseudokirchneriella subcapitata, Semistatic system, Fresh water, Experimental value, GLP)

12.2. Persistence and degradability

UltraSEP		
Persistence and degradability	Not established.	
2-Hydroxyethyl Methacrylate (868-77-9)		
Persistence and degradability	Biodegradability in soil: no data available. Readily biodegradable in water.	
Ethyl 4-Dimethylaminobenzoate (10287-53-3)		
Persistence and degradability	Not readily biodegradable in water.	
Camphorquinone (10373-78-1)		
Persistence and degradability	Biodegradability in water: no data available.	
ThOD	2.41 g O₂/g substance	

12.3. Bioaccumulative potential

UltraSEP	
Bioaccumulative potential	Not established.
2-Hydroxyethyl Methacrylate (868-77-9)	
BCF - Fish [1]	1.3 – 1.5 (Pisces, Calculated value)
Partition coefficient n-octanol/water (Log Pow)	0.42 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 25 °C)
Bioaccumulative potential	Not bioaccumulative.
Ethyl 4-Dimethylaminobenzoate (10287-53-3)	
Partition coefficient n-octanol/water (Log Pow)	3.2 (Experimental value, OECD 117: Partition Coefficient (n-octanol/water), HPLC method, 25 °C)
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).
Camphorquinone (10373-78-1)	
Bioaccumulative potential	No bioaccumulation data available.

12.4. Mobility in soil

2-Hydroxyethyl Methacrylate (868-77-9)	
Surface tension	No data available in the literature
Partition coefficient n-octanol/water (Log Koc)	1.63 (log Koc, Calculated value)
Ecology - soil	Adsorbs into the soil.
Ethyl 4-Dimethylaminobenzoate (10287-53-3)	
Partition coefficient n-octanol/water (Log Koc)	2.8 (log Koc, OECD 121: Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC), Experimental value, GLP)
Ecology - soil	Low potential for adsorption in soil.

12.5. Results of PBT and vPvB assessment

Component	
2-Hydroxyethyl Methacrylate (868-77-9)	This substance/mixture does not meet the PBT criteria of REACH, annex XIII
	This substance/mixture does not meet the vPvB criteria of REACH, annex XIII

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Component	
Ethyl 4-Dimethylaminobenzoate (10287-53-3)	This substance/mixture does not meet the PBT criteria of REACH, annex XIII This substance/mixture does not meet the vPvB criteria of REACH, annex XIII

12.6. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Additional information : Handle empty containers with care because residual vapors are flammable. Flammable vapors

may accumulate in the container.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number

UN-No. (ADR) : 1170 UN-No. (IMDG) : 1170 UN-No. (IATA) : 1170 UN-No. (ADN) : 1170 UN-No. (RID) : 1170

14.2. UN proper shipping name

Proper Shipping Name (ADR) : ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Proper Shipping Name (IMDG) : ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

Proper Shipping Name (IATA) : Ethanol solution

Proper Shipping Name (ADN) : ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Proper Shipping Name (RID) : ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

Transport document description (ADR) : UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III, (D/E)
Transport document description (IMDG) : UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III

Transport document description (IATA) : UN 1170 Ethanol solution, 3, III

Transport document description (ADN) : UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III
Transport document description (RID) : UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : 3
Hazard labels (ADR) : 3

IMDG

Transport hazard class(es) (IMDG) : 3
Hazard labels (IMDG) : 3



IATA

Transport hazard class(es) (IATA) : 3
Hazard labels (IATA) : 3

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ADN

Transport hazard class(es) (ADN) : 3
Hazard labels (ADN) : 3



RID

Transport hazard class(es) (RID) : 3
Hazard labels (RID) : 3



14.4. Packing group

Packing group (ADR) : III
Packing group (IMDG) : III
Packing group (IATA) : III
Packing group (ADN) : III
Packing group (RID) : III

14.5. Environmental hazards

Dangerous for the environment : No Marine pollutant : No

Other information : No supplementary information available

: S2

14.6. Special precautions for user

- Overland transport

Classification code (ADR) : F1
Special provision (ADR) : 144, 601
Limited quantities (ADR) : 51
Excepted quantities (ADR) : E1

Packing instructions (ADR) : P001, IBC03, LP01, R001

Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions : T2

(ADR)

Portable tank and bulk container special : TP1

provisions (ADR)

Tank code (ADR) : LGBF
Vehicle for tank carriage : FL
Transport category (ADR) : 3
Special provisions for carriage - Packages : V12

(ADR)

Special provisions for carriage - Operation

(ADR)

Hazard identification number (Kemler No.) : 30

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Orange plates 30 1170

: D/E Tunnel restriction code (ADR)

- Transport by sea

Special provision (IMDG) : 144, 223 Limited quantities (IMDG) : 5 L : E1 Excepted quantities (IMDG) P001, LP01 Packing instructions (IMDG) : IBC03 IBC packing instructions (IMDG)

Tank instructions (IMDG) : T2 Tank special provisions (IMDG) : TP1 : F-E EmS-No. (Fire) S-D EmS-No. (Spillage) Stowage category (IMDG) : A

: Colourless, volatile liquids.Pure ETHANOL: flashpoint 13°C c.c. Explosive limits: 3.3% to Properties and observations (IMDG)

19% Miscible with water.

- Air transport

: E1 PCA Excepted quantities (IATA) PCA Limited quantities (IATA) Y344 PCA limited quantity max net quantity (IATA) : 10L PCA packing instructions (IATA) 355 PCA max net quantity (IATA) 60L CAO packing instructions (IATA) 366 : 220L CAO max net quantity (IATA)

Special provision (IATA) : A3, A58, A180

ERG code (IATA) : 3L

- Inland waterway transport

Classification code (ADN) : F1 : 144, 601 Special provision (ADN) Limited quantities (ADN) : 5 L Excepted quantities (ADN) : E1 Equipment required (ADN) : PP, EX, A Ventilation (ADN) : VE01 : 0 Number of blue cones/lights (ADN)

- Rail transport

: F1 Classification code (RID) Special provision (RID) : 144, 601 Limited quantities (RID) 5L Excepted quantities (RID) : E1

: P001, IBC03, LP01, R001 Packing instructions (RID)

Mixed packing provisions (RID) : MP19 Portable tank and bulk container instructions T2

(RID)

Portable tank and bulk container special

provisions (RID)

: TP1

Tank codes for RID tanks (RID) : LGBF Transport category (RID) : 3 Special provisions for carriage - Packages : W12

(RID)

: CE4

Colis express (express parcels) (RID) Hazard identification number (RID) : 30

Transport in bulk according to Annex II of Marpol and the IBC Code

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

Contains no REACH substances with Annex XVII restrictions

Contains no REACH candidate substance

Contains no REACH Annex XIV 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

Full text of H- and EUH-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids Category 2
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H225	Highly flammable liquid and vapor.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

SDS EU (REACH Annex II)

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.

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