

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

### 1.1. Product identifier

Product form : Mixture  
Product name : Assure

### 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

#### Manufacturer:

Reliance Orthodontic Products, Inc. 1540 West Thorndale Ave.  
Itasca, IL 60143 USA  
630-773-4009, during normal business hours  
[www.RelianceOrthodontics.com](http://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 20  
Sydney, NSW 2000 Australia

### 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]

Flammable liquids, Category 2 H225  
Skin corrosion/irritation, Category 2 H315  
Serious eye damage/eye irritation, Category 2 H319  
Skin sensitisation, Category 1 H317

Full text of H statements : see section 16

#### Adverse physicochemical, human health and environmental effects

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

### 2.2. Label elements

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

Hazard pictograms (CLP) :



GHS02

GHS07

Signal word (CLP) : Danger  
Hazardous ingredients : 2-Hydroxyethyl Methacrylate; BisGMA  
Hazard statements (CLP) : H225 - Highly flammable liquid and vapour  
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  
P240 - Ground and bond container and receiving equipment.  
P241 - Use explosion-proof ventilating equipment.

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P261 - Avoid breathing vapours  
P264 - Wash hands thoroughly after handling  
P272 - Contaminated work clothing should not be allowed out of the workplace  
P280 - Wear eye protection, face protection, protective gloves  
P302+P352 - IF ON SKIN: Wash with plenty of soap and water  
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.  
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 First aid measures 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 carbon dioxide (CO<sub>2</sub>), dry extinguishing powder, dry sand to extinguish  
P403+P235 - Store in a well-ventilated place. Keep cool  
P501 - Dispose of contents and container to a hazardous or special waste collection point, a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste, hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation, an approved waste disposal plant.

### 2.3. Other hazards

No additional information available

## 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]
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
BisGMA	(CAS-No.) 1565-94-2	10 - 30	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317
4-Dimethylaminobenzoic Acid	(CAS-No.) 619-84-1 (EC-No.) 210-615-8	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Proprietary	(CAS-No.) Proprietary (EC-No.) Proprietary (EC Index-No.) Proprietary	< 1	Flam. Liq. 2, H225 Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335

#### Specific concentration limits:

Name	Product identifier	Specific concentration limits
Proprietary	(CAS-No.) Proprietary (EC-No.) Proprietary (EC Index-No.) Proprietary	(C >= 1) STOT SE 3, H335

Full text of H-statements: see section 16

## 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 : 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 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 skin contact : Irritation. May cause an allergic skin reaction.  
Symptoms/effects after eye contact : Eye irritation.

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

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapour.

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

#### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. No open flames, no sparks, and no smoking. Avoid contact with skin and eyes. Avoid breathing mist, vapours.

#### 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 : Take up liquid spill into absorbent material. 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 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. 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 vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Avoid contact with skin and eyes. Avoid breathing mist, vapours.

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 : Ground/bond container and receiving equipment.

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

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Proprietary (Proprietary)		
EU	IOELV TWA (mg/m <sup>3</sup> )	8.4 mg/m <sup>3</sup> (Proprietary; EU; Time-weighted average exposure limit 8 h; Indicative occupational exposure limit value)
EU	IOELV TWA (ppm)	2 ppm (Proprietary; EU; Time-weighted average exposure limit 8 h; Indicative occupational exposure limit value)
EU	IOELV STEL (mg/m <sup>3</sup> )	12.6 mg/m <sup>3</sup> (Proprietary; EU; Short time value; Indicative occupational exposure limit value)
EU	IOELV STEL (ppm)	3 ppm (Proprietary; EU; Short time value; Indicative occupational exposure limit value)

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Proprietary (Proprietary)		
Belgium	Limit value (mg/m <sup>3</sup> )	4.2 mg/m <sup>3</sup> (Triéthylamine; Belgium; Time-weighted average exposure limit 8 h)
Belgium	Limit value (ppm)	1 ppm (Triéthylamine; Belgium; Time-weighted average exposure limit 8 h)
Belgium	Short time value (mg/m <sup>3</sup> )	12.6 mg/m <sup>3</sup> (Triéthylamine; Belgium; Short time value)
Belgium	Short time value (ppm)	3 ppm (Triéthylamine; Belgium; Short time value)
France	VME (mg/m <sup>3</sup> )	4.2 mg/m <sup>3</sup> (Triéthylamine; France; Time-weighted average exposure limit 8 h; VRC: Valeur réglementaire contraignante)
France	VME (ppm)	1 ppm (Triéthylamine; France; Time-weighted average exposure limit 8 h; VRC: Valeur réglementaire contraignante)
France	VLE (mg/m <sup>3</sup> )	12.6 mg/m <sup>3</sup> (Triéthylamine; France; Short time value; VRC: Valeur réglementaire contraignante)
France	VLE (ppm)	3 ppm (Triéthylamine; France; Short time value; VRC: Valeur réglementaire contraignante)
Netherlands	Grenswaarde TGG 8H (mg/m <sup>3</sup> )	4.2 mg/m <sup>3</sup> (Proprietary; Netherlands; Time-weighted average exposure limit 8 h; Public occupational exposure limit value)
Netherlands	Grenswaarde TGG 8H (ppm)	1 ppm (Proprietary; Netherlands; Time-weighted average exposure limit 8 h; Public occupational exposure limit value)
Netherlands	Grenswaarde TGG 15MIN (mg/m <sup>3</sup> )	12.6 mg/m <sup>3</sup> (Proprietary; Netherlands; Short time value; Public occupational exposure limit value)
Netherlands	Grenswaarde TGG 15MIN (ppm)	3 ppm (Proprietary; Netherlands; Short time value; Public occupational exposure limit value)
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	8 mg/m <sup>3</sup> Proprietary; United Kingdom; Time-weighted average exposure limit 8 h; Workplace exposure limit (EH40/2005)
United Kingdom	WEL TWA (ppm)	2 ppm Proprietary; United Kingdom; Time-weighted average exposure limit 8 h; Workplace exposure limit (EH40/2005)
United Kingdom	WEL STEL (mg/m <sup>3</sup> )	17 mg/m <sup>3</sup> Proprietary; United Kingdom; Short time value; Workplace exposure limit (EH40/2005)
United Kingdom	WEL STEL (ppm)	4 ppm Proprietary; United Kingdom; Short time value; Workplace exposure limit (EH40/2005)
USA - ACGIH	Local name	Proprietary
USA - ACGIH	ACGIH TWA (ppm)	0.5 ppm
USA - ACGIH	ACGIH STEL (ppm)	1 ppm
USA - ACGIH	Remark (ACGIH)	URT irr; visual impair; Skin; A4
USA - OSHA	Local name	Proprietary
USA - OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	100 mg/m <sup>3</sup>
USA - OSHA	OSHA PEL (TWA) (ppm)	25 ppm

### 8.2. Exposure controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### Hand protection:

Protective gloves

#### Eye protection:

Safety glasses

#### Skin and body protection:

Wear suitable protective clothing

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

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### 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	: Liquid
Appearance	: Clear liquid.
Colour	: Pale yellow.
Odour	: Slight Acetone.
Odour threshold	: No data available
pH	: 4.3 - 4.5
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: ≈ 56 °C
Flash point	: -20 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Flammable Not applicable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: 2.6 - 2.8 vol %

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Highly flammable liquid and vapour.

### 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

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

### 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 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 bodyweight (Rat; Experimental value)
LD50 dermal rabbit	> 5000 mg/kg bodyweight (Rabbit; Experimental value)

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4-Dimethylaminobenzoic Acid (619-84-1)	
LD50 oral rat	> 5000 mg/kg (Rat)

Proprietary (Proprietary)	
LD50 oral rat	> 460 mg/kg (Rat; Equivalent or similar to OECD 401; Experimental value; 730 mg/kg bodyweight; Rat)
LD50 dermal rabbit	416 mg/kg (Rabbit; Experimental value; Equivalent or similar to OECD 402; 580 mg/kg bodyweight; Rabbit)
LC50 inhalation rat (mg/l)	> 4.2 mg/l/4h (Rat)

Skin corrosion/irritation	: Causes skin irritation. pH: 4.3 - 4.5
Serious eye damage/irritation	: Causes serious eye irritation. pH: 4.3 - 4.5
Respiratory or skin sensitisation	: 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

## 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.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Not classified

2-Hydroxyethyl Methacrylate (868-77-9)	
LC50 fish 1	227 mg/l (LC50; 96 h)
EC50 Daphnia 1	171 mg/l (NOEC; OECD 202: Daphnia sp. Acute Immobilisation Test; 48 h; Daphnia magna; Static system; Fresh water; Experimental value)
EC50 Daphnia 2	380 mg/l (EC50; OECD 202: Daphnia sp. Acute Immobilisation Test; 48 h; Daphnia magna; Static system; Fresh water; Experimental value)
Threshold limit algae 1	836 mg/l (ErC50; OECD 201: Alga, Growth Inhibition Test; 72 h; Pseudokirchneriella subcapitata; Static system; Fresh water; Experimental value)
Threshold limit algae 2	345 mg/l (EbC50; OECD 201: Alga, Growth Inhibition Test; 72 h; Pseudokirchneriella subcapitata; Static system; Fresh water; Experimental value)

Proprietary (Proprietary)	
EC50 Daphnia 2	17 mg/l (LC50; ASTM; 48 h; Ceriodaphnia dubia; Semi-static system; Fresh water; Experimental value)

### 12.2. Persistence and degradability

2-Hydroxyethyl Methacrylate (868-77-9)	
Persistence and degradability	Readily biodegradable in water. Biodegradability in soil: no data available. Adsorbs into the soil.

4-Dimethylaminobenzoic Acid (619-84-1)	
Persistence and degradability	Biodegradability in water: no data available.

Proprietary (Proprietary)	
Persistence and degradability	Readily biodegradable in water. Low potential for adsorption in soil. Photodegradation in the air.
Biochemical oxygen demand (BOD)	< 0.001 g O <sub>2</sub> /g substance
Chemical oxygen demand (COD)	1.02 g O <sub>2</sub> /g substance

### 12.3. Bioaccumulative potential

2-Hydroxyethyl Methacrylate (868-77-9)	
BCF fish 1	1.3 - 1.5 (BCF)
Log Pow	-0.55 - 0.49 (0.42; Experimental value; OECD 107: Partition Coefficient (n-octanol/water); Shake Flask Method; 25 °C)
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).

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4-Dimethylaminobenzoic Acid (619-84-1)	
Bioaccumulative potential	No bioaccumulation data available.

Proprietary (Proprietary)	
BCF fish 1	< 0.5 (BCF; OECD 305: Bioconcentration: Flow-Through Fish Test; 42 days; Cyprinus carpio; Fresh water)
Log Pow	1.45 (Experimental value; Other)
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).

### 12.4. Mobility in soil

Proprietary (Proprietary)	
Surface tension	0.021 N/m (20 °C)
Log Koc	log Koc, Other; 2.56; Calculated value

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. 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.  
Additional information : Flammable vapours may accumulate in the container.

## SECTION 14: Transport information

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

### 14.1. UN number

UN-No. (ADR) : 1090  
UN-No. (IMDG) : Not regulated  
UN-No. (IATA) : Not regulated  
UN-No. (ADN) : Not regulated  
UN-No. (RID) : Not regulated

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : ACETONE  
Proper Shipping Name (IMDG) : Not regulated  
Proper Shipping Name (IATA) : Not regulated  
Proper Shipping Name (ADN) : Not regulated  
Proper Shipping Name (RID) : Not regulated  
Transport document description (ADR) : UN 1090 ACETONE, 3, II, (D/E)

### 14.3. Transport hazard class(es)

#### ADR

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



#### 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

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

### 14.4. Packing group

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

### 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

Classification code (ADR) : F1  
Limited quantities (ADR) : 1I  
Excepted quantities (ADR) : E2  
Packing instructions (ADR) : P001, IBC02, R001  
Mixed packing provisions (ADR) : MP19  
Portable tank and bulk container instructions (ADR) : T4  
Portable tank and bulk container special provisions (ADR) : TP1  
Tank code (ADR) : LGBF  
Vehicle for tank carriage : FL  
Transport category (ADR) : 2  
Special provisions for carriage - Operation (ADR) : S2, S20  
Hazard identification number (Kemler No.) : 33  
Orange plates :



Tunnel restriction code (ADR) : D/E  
EAC code : •2YE

#### - Transport by sea

Not regulated

#### - Air transport

Not regulated

#### - Inland waterway transport

Not regulated

#### - Rail transport

Not regulated

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

Not applicable

## 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 substance on the REACH candidate list  
Contains no REACH Annex XIV substances

#### 15.1.2. National regulations



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### Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

### Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

### Denmark

Classification remarks : Emergency management guidelines for the storage of flammable liquids must be followed

Recommendations Danish Regulation : Young people below the age of 18 years are not allowed to use the product  
Pregnant/breastfeeding women working with the product must not be in direct contact with the product

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Revision date :

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
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
H225	Highly flammable liquid and vapour
H302	Harmful if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
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*