

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

1.1. Product identifier

Product form : Mixture
Product name : Light Bond Filled Sealant with Fluoride

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, (800) 323-4348, 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 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]

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Skin sensitisation, Category 1	H317
Hazardous to the aquatic environment — Chronic Hazard, Category 3	H412

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Harmful in contact with skin. Harmful if swallowed. 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) :



GHS07

Signal word (CLP) :

Warning

Hazardous ingredients :

Triethylene Glycol Dimethacrylate ; BisGMA

Hazard statements (CLP) :

H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H412 - Harmful to aquatic life with long lasting effects.

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Precautionary statements (CLP)

: P261 - Avoid breathing vapours.
P264 - Wash hands thoroughly after handling.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - IF ON SKIN: Wash with plenty of soap and 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 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.
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, a hazardous or special waste collection point.

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]
Triethylene Glycol Dimethacrylate	(CAS-No.) 109-16-0 (EC-No.) 203-652-6	10 - 30	Skin Sens. 1, H317 Eye Irrit. 2, H319
Urethane Dimethacrylate	(CAS-No.) Proprietary	10 - 30	Eye Irrit. 2, H319 STOT SE 3, H336
Ethoxylated Bis A Dimethacrylate	(CAS-No.) 41637-38-1	5 - 10	Aquatic Chronic 4, H413
Tetrahydrofurfuryl Methacrylate	(CAS-No.) 2455-24-5 (EC-No.) 219-529-5	5 - 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
BisGMA	(CAS-No.) 1565-94-2 (EC-No.) 216-367-7	5 - 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 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 general

: Call a poison center or a doctor if you feel unwell. Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation

: Remove person to fresh air and keep comfortable for breathing. Allow affected person to breathe fresh air. Allow the victim to rest.

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. Wash with plenty of water/.... Wash contaminated clothing before reuse. Specific treatment (see First aid measures on this label).

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. Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion

: Rinse mouth. Call a poison center or a doctor if you feel unwell. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects after inhalation

: May cause an allergic skin reaction.

Symptoms/effects after skin contact

: Irritation. May cause an allergic skin reaction. Causes skin irritation.

Symptoms/effects after eye contact

: Eye irritation.

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

Treat symptomatically.

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide. Sand.
Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Combustible liquid.
Explosion hazard : May form flammable/explosive vapour-air mixture.
Hazardous decomposition products in case of fire : 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 the environment.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. Do not enter fire area without proper protective equipment, including respiratory protection.

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. Avoid contact with skin, eyes and clothing. Avoid breathing dust/fume/vapours. Evacuate unnecessary personnel.

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". Equip cleanup crew with proper 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.
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. See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Handle empty containers with care because residual vapours are flammable. Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Precautions for safe handling : Ensure good ventilation of the work station. Do not get in eyes, on skin, or on clothing. Wear personal protective equipment. Avoid breathing dust/fume/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 vapour. No open flames. No smoking.
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. Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Proper grounding procedures to avoid static electricity should be followed.
Storage conditions : Store in a well-ventilated place. Keep cool. Keep container closed when not in use. Protect from sunlight.
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.

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Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

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

Eye protection:

Safety glasses. 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	: Viscous Liquid.
Colour	: Pale Yellow.
Odour	: Acrylic.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=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)	: 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	: No data available

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. Combustible liquid. May form flammable/explosive vapour-air mixture.

10.3. Possibility of hazardous reactions

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

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7). Direct sunlight. Extremely high or low temperatures. Open flame. Overheating. Heat. Sparks.

10.5. Incompatible materials

Strong acids. Strong bases.

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10.6. Hazardous decomposition products

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

Triethylene Glycol Dimethacrylate (109-16-0)

LD50 oral rat	10837 mg/kg
LD50 dermal rat	N/A
LD50 dermal rabbit	N/A
LC50 inhalation rat (ppm)	N/A
LC50 inhalation rat (Dust/Mist - mg/l/4h)	N/A mg/l/4h
LC50 inhalation rat (Vapours - mg/l/4h)	N/A mg/l/4h

Urethane Dimethacrylate (Proprietary)

LD50 oral rat	N/A
LD50 dermal rat	N/A
LD50 dermal rabbit	N/A
LC50 inhalation rat (ppm)	N/A
LC50 inhalation rat (Dust/Mist - mg/l/4h)	N/A mg/l/4h
LC50 inhalation rat (Vapours - mg/l/4h)	N/A mg/l/4h

Ethoxylated Bis A Dimethacrylate (41637-38-1)

LD50 oral rat	> 2000 mg/kg bodyweight (OECD 423: Acute Oral Toxicity – Acute Toxic Class Method, Rat, Female, Read-across, Oral, 14 day(s))
LD50 dermal rat	> 2000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Read-across, Dermal)
LD50 dermal rabbit	N/A
LC50 inhalation rat (ppm)	N/A
LC50 inhalation rat (Dust/Mist - mg/l/4h)	N/A mg/l/4h
LC50 inhalation rat (Vapours - mg/l/4h)	N/A mg/l/4h

Skin corrosion/irritation	: Causes skin irritation.
Additional information	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
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

Triethylene Glycol Dimethacrylate (109-16-0)

LOAEL (oral, rat)	N/A mg/kg bodyweight
LOAEL (dermal, rat/rabbit)	N/A mg/kg bodyweight
LOAEC (inhalation, rat, gas)	N/A ppmv/4h
LOAEC (inhalation, rat, vapour)	N/A mg/l/4h
LOAEC (inhalation, rat, dust/mist/fume)	N/A mg/l/4h

Urethane Dimethacrylate (Proprietary)

LOAEL (oral, rat)	N/A mg/kg bodyweight
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LOAEL (dermal, rat/rabbit)	N/A mg/kg bodyweight
LOAEC (inhalation, rat, gas)	N/A ppmv/4h
LOAEC (inhalation, rat, vapour)	N/A mg/l/4h
LOAEC (inhalation, rat, dust/mist/fume)	N/A mg/l/4h

Ethoxylated Bis A Dimethacrylate (41637-38-1)

LOAEL (oral, rat)	N/A mg/kg bodyweight
LOAEL (dermal, rat/rabbit)	N/A mg/kg bodyweight
LOAEC (inhalation, rat, gas)	N/A ppmv/4h
LOAEC (inhalation, rat, vapour)	N/A mg/l/4h
LOAEC (inhalation, rat, dust/mist/fume)	N/A mg/l/4h

STOT-repeated exposure : Not classified

Triethylene Glycol Dimethacrylate (109-16-0)

LOAEL (oral, rat, 90 days)	N/A mg/kg bodyweight/day
LOAEL (dermal, rat/rabbit, 90 days)	N/A mg/kg bodyweight/day
LOAEC (inhalation, rat, gas, 90 days)	N/A ppmv/6h/day
LOAEC (inhalation, rat, vapour, 90 days)	N/A mg/l/6h/day
LOAEC (inhalation, rat, dust/mist/fume, 90 days)	N/A mg/l/6h/day

Urethane Dimethacrylate (Proprietary)

LOAEL (oral, rat, 90 days)	N/A mg/kg bodyweight/day
LOAEL (dermal, rat/rabbit, 90 days)	N/A mg/kg bodyweight/day
LOAEC (inhalation, rat, gas, 90 days)	N/A ppmv/6h/day
LOAEC (inhalation, rat, vapour, 90 days)	N/A mg/l/6h/day
LOAEC (inhalation, rat, dust/mist/fume, 90 days)	N/A mg/l/6h/day

Ethoxylated Bis A Dimethacrylate (41637-38-1)

LOAEL (oral, rat, 90 days)	N/A mg/kg bodyweight/day
LOAEL (dermal, rat/rabbit, 90 days)	N/A mg/kg bodyweight/day
LOAEC (inhalation, rat, gas, 90 days)	N/A ppmv/6h/day
LOAEC (inhalation, rat, vapour, 90 days)	N/A mg/l/6h/day
LOAEC (inhalation, rat, dust/mist/fume, 90 days)	N/A mg/l/6h/day

Aspiration hazard : Not classified

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

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.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Harmful to aquatic life with long lasting effects.

Tetrahydrofurfuryl Methacrylate (2455-24-5)

LC50 fish 1	34.7 mg/l (96 h, Pimephales promelas, Flow-through system)
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12.2. Persistence and degradability

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Persistence and degradability	Not established.
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Triethylene Glycol Dimethacrylate (109-16-0)

Persistence and degradability	Biodegradability in water: no data available.
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BisGMA (1565-94-2)

Persistence and degradability	Biodegradability in water: no data available.
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Tetrahydrofurfuryl Methacrylate (2455-24-5)

Persistence and degradability	Biodegradability in water: no data available.
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Ethoxylated Bis A Dimethacrylate (41637-38-1)

Persistence and degradability	Not readily biodegradable in water.
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12.3. Bioaccumulative potential

Light Bond Filled Sealant with Fluoride

Bioaccumulative potential	Not established.
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Triethylene Glycol Dimethacrylate (109-16-0)

Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).
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BisGMA (1565-94-2)

Log Pow	4.94 (Estimated value)
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Bioaccumulative potential	No bioaccumulation data available.
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Tetrahydrofurfuryl Methacrylate (2455-24-5)

Log Pow	1.3
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Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).
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Ethoxylated Bis A Dimethacrylate (41637-38-1)

Log Pow	5.30 - 5.62 (Experimental value, OECD 117: Partition Coefficient (n-octanol/water), HPLC method)
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Bioaccumulative potential	High potential for bioaccumulation (Log Kow > 5).
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12.4. Mobility in soil

Tetrahydrofurfuryl Methacrylate (2455-24-5)

Ecology - soil	No (test) data on mobility of the substance available.
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Ethoxylated Bis A Dimethacrylate (41637-38-1)

Log Koc	2.56 - 3.88 (log Koc, Calculated value)
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Ecology - soil	Low potential for mobility in soil.
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12.5. Results of PBT and vPvB assessment

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
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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.

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Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Dispose in a safe manner in accordance with local/national regulations.
Additional information	: Handle empty containers with care because residual vapours are flammable.
Ecology - waste materials	: Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN 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
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

No data available

Transport by sea

No data available

Air transport

No data available

Inland waterway transport

No data available

Rail transport

No data available

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

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Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 3, Highly hazardous to water (Classification according to AwSV, Annex 1)

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

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Other information : None.

Full text of H- and EUH-statements:	
Aquatic Chronic 4	Hazardous to the aquatic environment — Chronic Hazard, Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
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, Narcosis
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

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.