

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision date: 1/6/2020 Version: 5

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

1.1. Product identifier

Product form : Mixture

Product name : Light Bond Sealant with and without 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

Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation

Specific target organ toxicity — Single exposure, Category 3, Narcosis

H336

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

May cause drowsiness or dizziness. 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 : Urethane Dimethacrylate; BisGMA; Triethylene Glycol Dimethacrylate

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Hazard statements (CLP)

: 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.

: P261 - Avoid breathing vapours. Precautionary statements (CLP)

P264 - Wash hands thoroughly after handling.

P271 - Use only outdoors or in a well-ventilated area.

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.

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, a doctor if you feel unwell.

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.

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

P405 - Store locked up.

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.

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]
Urethane Dimethacrylate	(CAS-No.) Proprietary	30 - 50	Eye Irrit. 2, H319 STOT SE 3, H336
Triethylene Glycol Dimethacrylate	(CAS-No.) 109-16-0 (EC-No.) 203-652-6	10 - 30	Skin Sens. 1, H317 Eye Irrit. 2, H319
BisGMA	(CAS-No.) 1565-94-2 (EC-No.) 216-367-7	10 - 30	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335
Tetrahydrofurfuryl Methacrylate	(CAS-No.) 2455-24-5 (EC-No.) 219-529-5	10 - 20	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Fluoride	(CAS No) Proprietary (EC no) Proprietary	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 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. Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/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. Wash contaminated clothing before reuse. Specific treatment (see First aid measures on this label)

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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

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 : May cause drowsiness or dizziness.

Symptoms/effects after inhalation : May cause an allergic skin reaction. May cause drowsiness or dizziness. 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.

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

clothing. 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. Avoid breathing fume/vapours.

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 : Use only outdoors or in a well-ventilated area. Avoid breat

: Use only outdoors or in a well-ventilated area. Avoid breathing fume/vapours. Do not get in eyes, on skin, or on clothing. Wear personal protective equipment. 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.

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7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Proper grounding procedures to avoid static electricity should be followed.

Storage conditions : Keep container closed when not in use. Protect from sunlight. Store in a well-ventilated

place. Keep cool.

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:

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. Where exposure through inhalation may occur from use, respiratory protection equipment is recommended

Environmental exposure controls:

Avoid release to the environment.

Other information:

Viscosity, dynamic

Explosive properties

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 pН : No data available Relative evaporation rate (butylacetate=1) : No data available Melting point : Not applicable : No data available Freezing point : No data available Boiling point Flash point : No data available : No data available Auto-ignition temperature 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 : No data available Viscosity, kinematic

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: No data available

: No data available

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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.

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

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

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
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 : May cause respiratory irritation. May cause drowsiness or dizziness.

Additional information : May cause drowsiness or dizziness.

Urethane Dimethacrylate (Proprietar	y)
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

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LOAEC (inhalation, rat, vapour)	N/A mg/l/4h
LOAEC (inhalation, rat, dust/mist/fume)	N/A mg/l/4h

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

STOT-repeated exposure : Not classified

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

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

Aspiration hazard : Not classified

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

symptoms

SECTION 12: Ecological information

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

adverse effects in the environment.

Ecology - water : Harmful to aquatic life.

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)

12.2. Persistence and degradability

Light Bond Sealant with Fluoride

Persistence and degradability Not established.

BisGMA (1565-94-2)

Persistence and degradability Biodegradability in water: no data available.

Tetrahydrofurfuryl Methacrylate (2455-24-5)

Persistence and degradability Biodegradability in water: no data available.

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Triethylene Glycol Dimethacrylate (109-16-0)		
Persistence and degradability	Biodegradability in water: no data available.	
12.3. Bioaccumulative potential		
Light Bond Sealant with Fluoride		
Bioaccumulative potential	Not established.	

BisGMA (1565-94-2)	
Log Pow	4.94 (Estimated value)
Bioaccumulative potential	No bioaccumulation data available.

Tetrahydrofurfuryl Methacrylate (2455-24-5)	
Log Pow	1.3
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).

Triethylene Glycol Dimethacrylate (109-16-0)		
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).	
12.4. Mobility in soil		
Tetrahydrofurfuryl Methacrylate (2455-24-5)		
Ecology - soil	No (test)data on mobility of the substance available.	
12.5. Results of PBT and vPvB assessment		

12.5. Results of PBT and vPvB assessmen

No additional information available

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. 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
	Annual Control of the	

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

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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

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,

12th Ordinance Implementing the Federal : Is not subject of the 12. BlmSchV (Hazardous Incident Ordinance)

Immission Control Act - 12.BlmSchV

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

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Vruchtbaarheid

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Ontwikkeling

: None of the components are listed

: None of the components are listed

: 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

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SECTION 16: Other information

Other information : None.

Full text of H- and EUH-statements:		
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.	

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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