

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision date: 1/6/2020 Version: 3

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

1.1. Product identifier

Product form : Mixture

Product name : Light Cure Retainer

#### 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 <a href="https://www.relianceorthodontics.com">www.relianceorthodontics.com</a>

#### **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

Full text of H statements : see section 16

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

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)

1

GHS07

Signal word (CLP) : Warning
Hazardous ingredients : BisGMA

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

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

1/6/2020 EN (English) 1/8

# Safety Data Sheet

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

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.

P280 - Wear protective gloves/protective clothing/eye protection/face protection protective

gloves, face protection, eye 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 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]
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
Urethane Dimethacrylate	(CAS-No.) Proprietary	5 - 10	Eye Irrit. 2, H319 STOT SE 3, H336
Triethylene Glycol Dimethacrylate	(CAS-No.) 109-16-0 (EC-No.) 203-652-6	5 - 10	Skin Sens. 1, H317 Eye Irrit. 2, H319

Full text of H-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 (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 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

: Call a poison center or a doctor if you feel unwell. Rinse mouth. 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.

# **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

Hazardous decomposition products in case of fire : Toxic fumes may be released.

1/6/2020 EN (English) 2/8

# Safety Data Sheet

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

#### 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

#### 6.1.1. For non-emergency personnel

**Emergency procedures** 

: Ventilate spillage area. Avoid contact with skin and eyes. 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

: Mechanically recover the product. On land, sweep or shovel into suitable containers

Minimise generation of dust. 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

Precautions for safe handling

: Ensure good ventilation of the work station. Avoid contact with skin and eyes. 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.

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

Storage conditions

: Store in a well-ventilated place. Keep cool. Protect from sunlight. Keep container closed

when not in use.

Incompatible products

: Strong bases. Strong acids.

Incompatible materials

: Sources of ignition. Direct sunlight.

#### 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

1/6/2020 EN (English) 3/8

# Safety Data Sheet

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

#### 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 : Solid
Appearance : Paste.
Colour : Light yellow.
Odour : Acrylic.

Odour threshold : No data available : No data available рΗ Relative evaporation rate (butylacetate=1) : No data available : No data available Melting point Freezing point : Not applicable Boiling point : No data available Flash point : Not applicable Auto-ignition temperature : Not applicable Decomposition temperature : No data available Flammability (solid, gas) : Non flammable. Vapour pressure : No data available : No data available Relative vapour density at 20 °C : Not applicable Relative density Solubility : No data available Log Pow : No data available : No data available Viscosity, kinematic Viscosity, dynamic : No data available Explosive properties : No data available Oxidising properties : No data available **Explosive limits** : Not applicable

#### 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. Not established.

# 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.

#### 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.

# **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

# Safety Data Sheet

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

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 (Proprieta	ıry)
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
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
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

# Safety Data Sheet

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

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)

Hazardous to the aquatic environment, long-term

(chronic)

: Not classified

: Not classified

#### 12.2. Persistence and degradability

#### **Light Cure Retainer**

Persistence and degradability Not established.

# Triethylene Glycol Dimethacrylate (109-16-0)

Persistence and degradability Biodegradability in water: no data available.

#### BisGMA (1565-94-2)

Persistence and degradability Biodegradability in water: no data available.

#### 12.3. Bioaccumulative potential

#### **Light Cure Retainer**

Bioaccumulative potential Not established.

## **Triethylene Glycol Dimethacrylate (109-16-0)**

Bioaccumulative potential Low potential for bioaccumulation (Log Kow < 4).

# BisGMA (1565-94-2)

Log Pow 4.94 (Estimated value)

Bioaccumulative potential No bioaccumulation data available.

#### 12.4. Mobility in soil

No additional information available

# 12.5. Results of PBT and vPvB assessment

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.

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

1/6/2020 EN (English) 6/8

# Safety Data Sheet

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

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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)

ADF

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

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)

# Safety Data Sheet

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

12th Ordinance Implementing the Federal Immission Control Act - 12.BlmSchV

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

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 : None of the components are listed

giftige stoffen – Borstvoeding

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:		
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, Respiratory tract irritation	
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Narcosis	
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.	

#### 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.

1/6/2020 EN (English) 8/8