

Safety Data Sheet

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

Revision date: 10/17/2021 Version: 4.0

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

Product identifier

Product form : Mixture

: Excel Regular Part B Product name

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

Relevant identified uses

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 20 Sydney, NSW 2000 Australi

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]

Skin corrosion/irritation Category 2 Serious eye damage/eye irritation, Category H319

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. Toxic to aquatic life.

H317

Label elements

Skin sensitization, Category 1

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning

Hazardous ingredients : Triethylene Glycol Dimethacrylate ; BisGMA; Benzoyl Peroxide

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

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

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

P264 - Wash hands thoroughly after handling.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P280 - Wear protective gloves/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 supplemental first aid instruction on this label).

P332+P313 - If skin irritation occurs: Get medical advice/attention.

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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]
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
Triethylene Glycol Dimethacrylate	(CAS-No.) 109-16-0 (EC-No.) 203-652-6	10 – 30	Skin Sens. 1B, H317
Benzoyl Peroxide	(CAS-No.) 94-36-0 (EC-No.) 202-327-6 (EC Index-No.) 617-008-00-0	< 1	Org. Perox. B, H241 Skin Sens. 1, H317 Eye Irrit. 2, H319

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 after inhalation : Remove person to fresh air and keep comfortable for breathing.

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.

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/doctor/physician 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.

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.

5.2. Special hazards arising from the substance or mixture

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

fire

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

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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

For containment : Collect spillage.

Methods for cleaning up : Mechanically recover the product.

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. Avoid contact with skin and eyes. Wear personal

protective equipment. Avoid breathing dust/fume/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

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

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.

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



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 : Solid
Appearance : Paste.
Color : Light Beige.
Odor : Acrylic.

Odor threshold : No data available

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: No data available Relative evaporation rate (butyl acetate=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 Non flammable. Flammability (solid, gas) No data available Vapor pressure Relative vapor density at 20 °C No data available Relative density No data available Solubility : No data available Partition coefficient n-octanol/water (Log Pow) No data available Viscosity, kinematic Not applicable Viscosity, dynamic : No data available Explosive properties : No data available No data available Oxidizing properties **Explosion 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.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

Reproductive toxicity

10.6. Hazardous decomposition products

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

: Not classified

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
Benzoyl Peroxide (94-36-0)	
LD50 oral rat	> 5000 mg/kg body weight Animal: rat, Animal sex: male
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

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

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Triethylene Glycol Dimethacrylate	(109-16-0)	
NOAEL (oral,rat,90 days)	1000 mg/kg body weight Animal: rat, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	
Aspiration hazard	: Not classified	
Excel Regular Catalyst		
Viscosity, kinematic	Not applicable	

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Toxic to aquatic life. Hazardous to the aquatic environment, short- : Not classified

term (acute)

Hazardous to the aquatic environment, long- : Not classified

term (chronic)

Triethylene Glycol Dimethacrylate (109-16-0)		
LC50 - Fish [1]	16.4 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)	
EC50 72h - Algae [1]	> 100 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)	
EC50 72h - Algae [2]	72.8 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)	
ErC50 algae	> 100 mg/l (Equivalent or similar to EU Method C.3, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value)	
LOEC (chronic)	rronic) 100 mg/l Test organisms (species): Daphnia magna Duration: '21 d'	
NOEC (chronic)	32 mg/l Test organisms (species): Daphnia magna Duration: '21 d'	
Benzoyl Peroxide (94-36-0)		
LC50 - Fish [1]	0.0602 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Oncorhynchus mykiss, Semi-static system, Fresh water, Experimental value, GLP)	
EC50 - Crustacea [1]	0.11 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, GLP)	
ErC50 algae	0.0711 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Pseudokirchneriella subcapitata Static system, Fresh water, Experimental value, GLP)	

12.2. Persistence and degradability

Friethylene Glycol Dimethacrylate (109-16-0)		
Persistence and degradability	Readily biodegradable in water.	
BisGMA (1565-94-2)		
Persistence and degradability	Biodegradability in water: no data available.	
Benzoyl Peroxide (94-36-0)		
Persistence and degradability	Readily biodegradable in water.	

12.3. Bioaccumulative potential

Triethylene Glycol Dimethacrylate (109-16-0)		
Partition coefficient n-octanol/water (Log Pow)	2.3 (Practical experience/observation, EU Method A.8: Partition Coefficient)	
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).	
BisGMA (1565-94-2)		
Partition coefficient n-octanol/water (Log Pow)	4.94 (Estimated value)	
Bioaccumulative potential	No bioaccumulation data available.	
Benzoyl Peroxide (94-36-0)		
Partition coefficient n-octanol/water (Log Pow)	3.2 (Experimental value, OECD 117: Partition Coefficient (n-octanol/water), HPLC method, 22 °C)	
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).	

12.4. Mobility in soil

Triethylene Glycol Dimethacrylate (109-16-0)		
Partition coefficient n-octanol/water (Log Koc)	1.89 (log Koc, Calculated value)	
Ecology - soil	Highly mobile in soil.	
Benzoyl Peroxide (94-36-0)		
Surface tension	No data available (test not performed)	
Partition coefficient n-octanol/water (Log Koc)	3.8 (log Koc, OECD 121: Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC), Experimental value)	

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Benzoyl Peroxide (94-36-0)	
Ecology - soil	Low potential for mobility in soil.

12.5. Results of PBT and vPvB assessment

	Component	
	Triethylene Glycol Dimethacrylate (109-16-0)	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
Benzoyl Peroxide (94-36-0)		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

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.

SECTION 14: Transport information

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

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

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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 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:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Org. Perox. B	Organic Peroxides, Type B
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization, Category 1
Skin Sens. 1B	Skin sensitization, Category 1B
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H241	Heating may cause a fire or explosion.
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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