Therma Cure

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Revision date: 3/15/2024 Version: 1.1

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

1.1. Product identifier

Product form : Mixture
Product name : Therma Cure

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/Importer/Representative/User/Distributor:
Reliance Orthodontic Products, Inc.
1540 W. Thorndale Ave
Itasca, IL 60143 USA
T 630-773-4009, during normal business hours
regulatory@relianceorthodontics.com
www.RelianceOrthodontics.com

U.S. Federal Register:
According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
FDA Registration: 1420089

Australian Sponsor:
Emergo Australia, 201 Sussex St.
Darling Park, Tower II, Level 20
Sydney, NSW 2000 Australia
T +61 2 9006 1662

EC Representative:
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands
T +31 70 345 8570

Switzerland Representative:
MedEnvoy Global BV
Leidschendam-Voorburg, Zug Branch Office
Gotthardstrasse 28, 6302 Zug, Switzerland
T +41 41 462 01 42

U.K. Person Responsible:
Emergo Consulting (UK) Limited
c/o Cr360 - UL International Compass House, Vision Park Histon
Cambridge CB24 9BZ
England, United Kingdom
T +44(0) 1223 772 671

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
Specific target organ toxicity - Single exposure, Category 3, Respiratory tract irritation	H335

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning

Contains : BisGMA; Triethylene Glycol Dimethacrylate; Benzoyl Peroxide

Hazard statements (CLP) : H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.

Precautionary statements (CLP) : P261 - Avoid breathing dust, fume, 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.
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, doctor if you feel unwell.
P321 - Specific treatment (see supplemental first aid instruction on this label).
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.
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.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

Component	
Triethylene Glycol Dimethacrylate (109-16-0)	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
Benzoyl Peroxide (94-36-0)	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
Fused Silica (60676-86-0)	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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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]
Fused Silica	CAS-No.: 60676-86-0 EC-No.: 262-373-8	50 - 75	Acute Tox. 4 (Inhalation), H332 Skin Irrit. 2, H315
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	5 - 10	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 Eye Irrit. 2, H319 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M=10)

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 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.

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 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. Avoid contact with skin and eyes. Avoid breathing dust, fume, 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	:	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

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:
Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:
Safety glasses

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

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
Colour	:	Light Beige.
Appearance	:	Paste.
Odour	:	Acrylic.
Odour threshold	:	Not available
Melting point	:	Not available
Freezing point	:	Not applicable
Boiling point	:	Not available
Flammability	:	Non flammable.
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable
Flash point	:	Not applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
pH	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not applicable
Relative vapour density at 20°C	:	Not applicable
Particle size	:	Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

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

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 hazard classes as defined in Regulation (EC) No 1272/2008

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 Source: NLM,THOMSON
LD50 dermal	> 2000 mg/kg bodyweight (US EPA, 14 day(s), Mouse, Male, Experimental value, Skin, 14 day(s))

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

Fused Silica (60676-86-0)	
LD50 dermal rabbit	> 5000 mg/kg bodyweight Animal: rabbit
LC50 Inhalation - Rat	> 2.08 mg/l air Animal: rat

Skin corrosion/irritation : Causes skin irritation.

Triethylene Glycol Dimethacrylate (109-16-0)	
pH	6.8 - 7.2

Benzoyl Peroxide (94-36-0)	
pH	No data available in the literature

Serious eye damage/irritation : Causes serious eye irritation.

Triethylene Glycol Dimethacrylate (109-16-0)	
pH	6.8 - 7.2

Benzoyl Peroxide (94-36-0)	
pH	No data available in the literature

Respiratory or skin sensitisation : May cause an allergic skin reaction.
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified

Triethylene Glycol Dimethacrylate (109-16-0)	
IARC group	4 - Probably not carcinogenic to humans

Benzoyl Peroxide (94-36-0)	
IARC group	3 - Not classifiable

Fused Silica (60676-86-0)	
IARC group	3 - Not classifiable

Reproductive toxicity : Not classified
STOT-single exposure : May cause respiratory irritation.

BisGMA (1565-94-2)	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : Not classified

Triethylene Glycol Dimethacrylate (109-16-0)	
LOAEC (inhalation, rat, gas, 90 days)	350 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other:
NOAEL (oral, rat, 90 days)	1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)
NOAEC (inhalation, rat, gas, 90 days)	100 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other:

Fused Silica (60676-86-0)	
NOAEL (oral, rat, 90 days)	> 5000 mg/kg bodyweight Animal: rat, Animal sex: male

Aspiration hazard : Not classified

Therma Cure	
Viscosity, kinematic	Not applicable

Benzoyl Peroxide (94-36-0)	
Viscosity, kinematic	No data available (test not performed)

11.2. Information on other hazards

No additional information available

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) : Not classified

BisGMA (1565-94-2)	
LC50 - Fish [1]	0.537 mg/l Source: ECOSAR

Triethylene Glycol Dimethacrylate (109-16-0)	
LC50 - Fish [1]	66.369 mg/l Source: ECOSAR
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 (OECD 201: Alga, Growth Inhibition Test, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, Nominal concentration)
LOEC (chronic)	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

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

Triethylene Glycol Dimethacrylate (109-16-0)	
Persistence and degradability	Readily biodegradable in water.

Benzoyl Peroxide (94-36-0)	
Persistence and degradability	Readily biodegradable in water.

Fused Silica (60676-86-0)	
Persistence and degradability	Biodegradability in soil: not applicable. Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable (inorganic)
ThOD	Not applicable (inorganic)

12.3. Bioaccumulative potential

BisGMA (1565-94-2)	
Partition coefficient n-octanol/water (Log Pow)	4.94 (Estimated value)
Bioaccumulative potential	No bioaccumulation data available.

Triethylene Glycol Dimethacrylate (109-16-0)	
Partition coefficient n-octanol/water (Log Pow)	2.3 (Experimental value, OECD 117: Partition Coefficient (n-octanol/water), HPLC method)
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).

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).

Fused Silica (60676-86-0)	
Bioaccumulative potential	No bioaccumulation data available.

12.4. Mobility in soil

Triethylene Glycol Dimethacrylate (109-16-0)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	1.89 (log Koc, SRC PCKOCWIN v2.0, Calculated value)
Ecology - soil	Highly mobile in soil.

Benzoyl Peroxide (94-36-0)	
Surface tension	No data available (test not performed)
Organic Carbon Normalized Adsorption Coefficient (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)
Ecology - soil	Low potential for mobility in soil.

Fused Silica (60676-86-0)	
Ecology - soil	No (test)data on mobility of the substance available.

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 regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
Benzoyl Peroxide (94-36-0)	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
Fused Silica (60676-86-0)	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

12.6. Endocrine disrupting properties

No additional information available

12.7. 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 or ID number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not regulated
Proper Shipping Name (IMDG) : Not regulated
Proper Shipping Name (IATA) : Not regulated
Proper Shipping Name (ADN) : Not regulated
Proper Shipping Name (RID) : Not regulated

14.3. Transport hazard class(es)

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

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

14.4. Packing group

Packing group (ADR) : Not regulated
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
Not regulated

Transport by sea
Not regulated

Air transport
Not regulated

Inland waterway transport
Not regulated

Rail transport
Not regulated

14.7. Maritime transport in bulk according to IMO instruments

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

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic 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

Indication of changes

Section	Changed item	Change	Comments
	Revision date	Added	
	Issue date	Removed	
	Supersedes version of	Added	
1.3	Display additional SDS EU addresses	Added	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	
4.2	Symptoms/effects after eye contact	Modified	
6.1	Emergency procedures	Modified	
7.1	Precautions for safe handling	Modified	

Full text of H- and EUH-statements:	
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H241	Heating may cause a fire or explosion.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
Org. Perox. B	Organic Peroxides, Type B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1B	Skin sensitisation, category 1B
STOT SE 3	Specific target organ toxicity - Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

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.