

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 3/21/2018 Version: 9

SECTION 1: Identification

Identification

Product form : Mixture Product name : Therma Cure

Recommended use and restrictions on use

Use of the substance/mixture : For RX only

Supplier

Manufacturer:

Reliance Orthodontic Products, Inc. 1540 West Thorndale Ave.

Itasca, IL 60143 USA

630-773-4009, during normal business hours

www.RelianceOrthodontics.com

Emergency telephone number

: CHEMTREC - 24-Hour Hazmat Emergency Communications Center Emergency number

Domestic: 1-800-424-9300 Outside the U.S.: 1-703-527-3887, collect calls accepted

SECTION 2: Hazard(s) identification

Classification of the substance or mixture

GHS-US classification

Skin corrosion/irritation H315 Causes skin irritation

Category 2

Serious eye damage/eye H320 Causes eye irritation

irritation Category 2B

May cause an allergic skin reaction H317

Skin sensitization, Category

Hazardous to the aquatic H401 Toxic to aquatic life

environment - Acute

Hazard Category 2

Full text of H statements : see section 16

GHS Label elements, including precautionary statements

GHS-US labeling

Hazard pictograms (GHS-US)



Hazard statements (GHS-US) H315 - Causes skin irritation

H317 - May cause an allergic skin reaction

H320 - Causes eye irritation H401 - Toxic to aquatic life

: P261 - Avoid breathing vapors Precautionary statements (GHS-US)

P264 - Wash hands thoroughly after handling

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

P273 - Avoid release to the environment. P280 - Wear face protection, eye protection

P302+P352 - If on skin: Wash with plenty of Wash skin with 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. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse.

P363 - Wash contaminated clothing before reuse.

P501 - Dispose in a safe manner in accordance with local/national regulations

Other hazards which do not result in classification

No additional information available

EN (English US) Page 1

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS-US classification
Fused Silica	(CAS-No.) 60675-86-0	50 - 75	Skin Irrit. 2, H315
BisGMA	(CAS-No.) 1565-94-2	10 - 30	Skin Irrit. 2, H315 Eye Irrit. 2B, H320 Skin Sens. 1, H317
Proprietary	(CAS-No.) Proprietary	1 - 5	Skin Sens. 1B, H317
Dibenzoyl Peroxide, technically pure	(CAS-No.) 94-36-0	<1	Org. Perox. B, H241 Eye Irrit. 2, H319 Skin Sens. 1, H317 Aquatic Acute 1, H400

Full text of hazard classes and H-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 (acute and delayed)

Symptoms/effects after skin contact : Irritation. May cause an allergic skin reaction.

Symptoms/effects after eye contact : Mild eye irritation.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.

5.2. Specific hazards arising from the chemical

Reactivity : The product is non-reactive under normal conditions of use, storage and transport.

5.3. Special protective equipment and precautions for fire-fighters

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 mist, vapors.

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.

EN (English US) 2/7

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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 mist, vapors.

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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Fused Silica	(60675-86-0)	
Not applicable		
Proprietary (Prop	prietary)	
Not applicable		
BisGMA (1565-94	4-2)	
Not applicable		
Dibenzoyl Perox	ide, technically pure (94-36-0)	
ACGIH	ACGIH TWA (mg/m³)	5 mg/m³ ((Dibenzoyl Peroxide; France; Time-weighted average exposure limit 8 h); USA; Time-weighted average exposure limit 8 h; TLV - Adopted Value)

8.2. Appropriate engineering controls

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

Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

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

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 pH : No data available Melting point : No data available Freezing point : Not applicable Boiling point : No data available

EN (English US) 3/7

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Flash point : Not applicable Relative evaporation rate (butyl acetate=1) : No data available Flammability (solid, gas) : Non flammable. Vapor pressure : No data available : No data available Relative vapor density at 20 °C Relative density : Not applicable Solubility : No data available Log Pow : No data available : Not applicable Auto-ignition temperature : No data available Decomposition temperature Viscosity, kinematic : Not applicable Viscosity, dynamic : No data available Explosion limits : Not applicable Explosive properties : No data available Oxidizing properties : 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.

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 toxicological effects

Acute toxicity : Not classified

Fused Silica (60675-86-0)		
LD50 oral rat	N/A	
LD50 dermal rat	N/A	
LD50 dermal rabbit	N/A	
LC50 inhalation rat (ppm)	N/A	
Proprietary (Proprietary)		
LD50 oral rat	> 2000 mg/kg body weight (OECD 423: Acute Oral Toxicity – Acute Toxic Class Method, Rat, Male/female, Experimental value)	
LD50 dermal rat	> 2000 mg/kg body weight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male/female, Experimental value)	
LC50 inhalation rat (mg/l)	> 2.28 mg/l (Equivalent or similar to OECD 403, 4 h, Rat, Male/female, Experimental value)	

Dibenzoyl Peroxide, technically pure (94-36-0)	
LD50 oral rat	> 5000 mg/kg (Rat)
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes eye irritation.
Respiratory or skin sensitization	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified

EN (English US) 4/7

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Carcinogenicity : Not classified

Fused Silica (60675-86	0)
IARC group	4 - Probably not carcinogenic to humans

Reproductive toxicity : Not classified Specific target organ toxicity – single exposure : Not classified

Fused Silica (60675-86-0)	
LOAEL (oral,rat)	N/A mg/kg body weight
LOAEL (dermal,rat/rabbit)	N/A mg/kg body weight
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

Specific target organ toxicity – repeated : Not classified

exposure

Fused Silica (60675-86-0)	
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

Symptoms/effects after skin contact : Irritation. May cause an allergic skin reaction.

Symptoms/effects after eye contact : Mild eye irritation.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Toxic to aquatic life.

Proprietary (Proprietary)	
LC50 fish 1	> 100 mg/l (EU Method C.1, 96 h, Brachydanio rerio, Semi-static system, Fresh water, Experimental value)
EC50 Daphnia 1	> 100 mg/l (EU Method C.2, 48 h, Daphnia magna, Static system, Fresh water, Experimental value)
ErC50 (algae)	> 100 mg/l (EU Method C.3, 72 h, Scenedesmus subspicatus, Static system, Fresh water, Weight of evidence)

Dibenzoyl Peroxide, technically pure (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)
EC50 Daphnia 1	0.11 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value)

12.2. Persistence and degradability

Proprietary (Proprietary)	
Persistence and degradability	Readily biodegradable in water.

Dibenzoyl Peroxide, technically pure (94-36-0) Persistence and degradability Readily biodegradable in water.

12.3. Bioaccumulative potential

Proprietary (Proprietary)	
BCF other aquatic organisms 1	3.2 (Estimated value)
Log Pow	2.1 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 21 °C)
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).

EN (English US) 5/7

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Dibenzoyl Peroxide, technically pure (94-36-0)	
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

Proprietary (Proprietary)	
Log Koc	3.23 (log Koc, Calculated value)
Ecology - soil	Adsorbs into the soil. Low potential for mobility in soil.

Dibenzoyl Peroxide, technically pure (94-36-0)	
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	Adsorbs into the soil.

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Other information : No supplementary information available.

Transportation of Dangerous Goods

Transport by sea

Air transport

SECTION 15: Regulatory information

15.1. US Federal regulations

Dibenzoyl Peroxide, technically pure (94-36-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory Subject to reporting requirements of United States SARA Section 313

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

EN (English US) 6/7

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Dibenzoyl Peroxide, technically pure (94-36-0)

U.S. - New Jersey - Right to Know Hazardous Substance List

SECTION 16: Other information

:

Full text of H-phrases:

H241	Heating may cause a fire or explosion
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H320	Causes eye irritation
H400	Very toxic to aquatic life
H401	Toxic to aquatic life

SDS US (GHS HazCom 2012)

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

EN (English US) 7/7