

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Revision date: 1/18/2023 Supersedes version of: 3/6/2020 Version: 2.0

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

1.1. Product identifier

Product form : Mixture

Product name : TheraCal PT Catalyst

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

ManufacturerEC REPBISCO, Inc.BISICO France

1100 W. Irving Park Rd.208, allée de la CoudouletteSchaumburg, IL 6019313680 Lançon de ProvenceU.S.A.France

T 1-800-247-3368 or 1-847-534-6000 T 33-4-90-42-92-92

www.bisco.com

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 H335

tract irritation

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

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning

Contains : Benzoyl Peroxide, Triethylene Glycol Dimethacrylate, Ytterbium Fluoride , BisGMA

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.

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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).

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.

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

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]
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
Barium Zirconate	CAS-No.: 12009-21-1 EC-No.: 234-546-8 EC Index-No.: 056-002-00-7	5 - 10	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332
Ytterbium Fluoride	CAS-No.: 13760-80-0 EC-No.: 237-354-2	1-5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

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Name	Product identifier	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Benzoyl Peroxide	CAS-No.: 94-36-0 EC-No.: 202-327-6 EC Index-No.: 617-008-00-0	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 general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical

advice.

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. If skin irritation or rash occurs: Get medical advice/attention.

Take off contaminated clothing. Wash contaminated clothing before reuse.

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 : Rinse mouth. Do NOT induce vomiting. 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 : 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

Firefighting instructions : 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.

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.

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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. Avoid

breathing dust, fume, vapours. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash

contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool. Keep container closed when not in use.

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:

Avoid all unnecessary exposure.

Personal protective equipment symbol(s):







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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.

Other information:

Particle aggregation state

Particle dustiness

Particle agglomeration state Particle specific surface area

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
Colour : White.

Appearance : Flowable Paste.

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

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Not availableNot available

: Not available

: Not available

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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

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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

Acute toxicity (innaiation)	: NOT Classified
Benzoyl Peroxide (94-36-0)	
LD50 oral rat	> 5000 mg/kg bodyweight Animal: rat, Animal sex: male
Triethylene Glycol Dimethacrylate	(109-16-0)
LD50 oral rat	10837 mg/kg Source: NLM,THOMSON
Ytterbium Fluoride (13760-80-0)	
LD50 oral rat	> 2000 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 420 (Acute Oral Toxicity - Fixed Dose Method), Guideline: EU Method B.1 bis (Acute Oral Toxicity - Fixed Dose Procedure)
Barium Zirconate (12009-21-1)	
LD50 oral rat	1980 mg/kg bodyweight Animal: rat, Animal sex: male, Guideline: EPA OPP 81-1 (Acute Oral Toxicity)
Skin corrosion/irritation	: Causes skin irritation.
Benzovi Peroxide (94-36-0)	

No data available in the literature

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Benzoyl Peroxide (94-36-0) pH No data available in the literature Triethylene Glycol Dimethacrylate pH 6.8 - 7.2 Ytterblum Fluoride (13760-80-0) pH 4.53 Temp.: 20 °C Respiratory or skin sensitisation Germ cell mutagenicity : Not classified Germ cell mutagenicity : Not classified Benzoyl Peroxide (94-36-0) IARC group 3 - Not classifiable Triethylene Glycol Dimethacrylate (109-16-0) IARC group 4 - Probably not carcinogenic to humans Ytterblum Fluoride (13760-80-0) IARC group 4 - Probably not carcinogenic to humans Ytterblum Fluoride (13760-80-0) IARC group 4 - Probably not carcinogenic to humans Ytterblum Fluoride (13760-80-0) IARC group 5 - Vot classified STOT-single exposure 8 May cause respiratory irritation. Ytterblum Fluoride (13760-80-0) STOT-single exposure 8 May cause respiratory irritation. STOT-single exposure 9 May cause respiratory irritation. STOT-repeated exposure 1 Not classified Triethylene Glycol Dimethacrylate 109-16-0) LOAEC (inhalation, rat, gas, 90 days) 30 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other: NOAEC (inhalation, rat, gas, 90 days) 100 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other:	Triethylene Glycol Dimethacrylate	(109-16-0)
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A - Probably not carcinogenic to humans Reproductive toxicity : Not classified : May cause respiratory irritation. Ytterbium Fluoride (13760-80-0) STOT-single exposure May cause respiratory irritation. BisGMA (1565-94-2) STOT-single exposure May cause respiratory irritation. STOT-repeated 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) 1000 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other: Aspiration hazard : Not classified TheraCal PT Catalyst Viscosity, kinematic Not applicable Benzoyl Peroxide (94-36-0)	IARC group	4 - Probably not carcinogenic to humans
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Viscosity, kinematic Not applicable Benzoyl Peroxide (94-36-0)	Aspiration hazard :	Not classified
Benzoyl Peroxide (94-36-0)	TheraCal PT Catalyst	
	Viscosity, kinematic	Not applicable
Viscosity, kinematic No data available (test not performed)	Benzoyl Peroxide (94-36-0)	
	Viscosity, kinematic	No data available (test not performed)

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11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

11.2.2. Other information

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.

Ecology - water
Hazardous to the aquatic environment, short-term

(acute)

: Not classified

: Toxic to aquatic life.

 $\label{thm:long-term} \mbox{Hazardous to the aquatic environment, long-term}$

: Not classified

(chronic)

0.0602 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Oncorhynchus mykiss, Semistatic system, Fresh water, Experimental value, GLP)		
0.11 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, GLP)		
0.0711 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, GLP)		
(109-16-0)		
16.4 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)		
> 100 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)		
72.8 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)		
> 100 mg/l (Equivalent or similar to EU Method C.3, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value)		
100 mg/l Test organisms (species): Daphnia magna Duration: '21 d'		
32 mg/l Test organisms (species): Daphnia magna Duration: '21 d'		
> 0.52 mg/l Test organisms (species): Daphnia magna		
Barium Zirconate (12009-21-1)		
> 1000 mg/l Test organisms (species): Daphnia magna		
201.4 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)		

12.2. Persistence and degradability

TheraCal PT Catalyst		
Persistence and degradability Not established.		
Benzoyl Peroxide (94-36-0)		
Persistence and degradability	Readily biodegradable in water.	

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Triethylene 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.		

12.3. Bioaccumulative potential

TheraCal PT Catalyst		
Bioaccumulative potential	Not established.	
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).	
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).	
Ytterbium Fluoride (13760-80-0)		
Partition coefficient n-octanol/water (Log Pow)	0.22 Source: EPISUITE	
BisGMA (1565-94-2)		
Partition coefficient n-octanol/water (Log Pow)	4.94 (Estimated value)	
Bioaccumulative potential	No bioaccumulation data available.	

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

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

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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

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

14.6. Special precautions for user

Overland transport

No data available

Transport by sea

No data available

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Air transport

No data available

Inland waterway transport

No data available

Rail transport

No data available

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	
	Supersedes version of	Added	
	Issue date	Removed	

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Indication of changes			
Section	Changed item	Change	Comments
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	

Other information : None.

Full text of H- and EUH-statements:		
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4	
Acute Tox. 4 (Oral)	Acute toxicity (oral), 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.	
H302	Harmful if swallowed.	
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.



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Revision date: 1/18/2023 Supersedes version of: 3/6/2020 Version: 2.0

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

1.1. Product identifier

Product form : Mixture

Product name : TheraCal PT Base

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

ManufacturerEC REPBISCO, Inc.BISICO France

1100 W. Irving Park Rd.

Schaumburg, IL 60193

208, allée de la Coudoulette
13680 Lançon de Provence
U.S.A.

France

U.S.A. France T 1-800-247-3368 or 1-847-534-6000 T 33-4-90-42-92-92

www.bisco.com

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]

Serious eye damage/eye irritation, Category 2 H319
Skin sensitisation, Category 1 H317
Specific target organ toxicity - Single exposure, Category 3, Respiratory H335

Specific target organ toxicity - Single exposure, Category 3, Respiratory

tract irritation

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, SG-Mix Cement

Hazard statements (CLP) : 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.

 $\hbox{P280 - Wear protective gloves, protective clothing, eye protection.}$

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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

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 %

Component	
SG-Mix Cement(N/A)	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]
SG-Mix Cement	CAS-No.: N/A	50 - 75	Eye Irrit. 2, H319 STOT SE 3, H335
BisGMA	CAS-No.: 1565-94-2 EC-No.: 216-367-7	5 - 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335
Barium Zirconate	CAS-No.: 12009-21-1 EC-No.: 234-546-8 EC Index-No.: 056-002-00-7	1 - 5	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332

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 general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical

advice.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

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First-aid measures after skin contact : Wash skin with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

Take off contaminated clothing. Wash contaminated clothing before reuse.

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 : Rinse mouth. Do NOT induce vomiting. 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 : 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 : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash

contaminated clothing before reuse.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions

: Store in a well-ventilated place. Keep cool. Keep container closed when not in use.

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:

Avoid all unnecessary exposure.

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

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8.2.3. Environmental exposure controls

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

Colour : Tooth / Yellow. Appearance : Flowable Paste. : Acrylic. Odour Odour threshold : Not available Melting point : Not available : Not applicable Freezing point : Not available Boiling point : Non flammable. Flammability : Not applicable **Explosive limits** Lower explosion limit Not applicable Not applicable Upper explosion limit Flash point Not applicable Auto-ignition temperature Not applicable Decomposition temperature Not available Not available Not available

рΗ pH solution Not applicable Viscosity, kinematic Not available Solubility Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available Vapour pressure at 50°C Not available Density : Not available : Not applicable Relative density Relative vapour density at 20°C : Not applicable Particle size : Not available Particle size distribution : Not available : Not available Particle shape

: Not available Particle aspect ratio Particle aggregation state : Not available Particle agglomeration state : Not available Particle specific surface area : Not available Particle dustiness : 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.

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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

Barium 2	irconate ((12009-21-1))
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LD50 oral rat	1980 mg/kg bodyweight Animal: rat, Animal sex: male, Guideline: EPA OPP 81-1 (Acute
	Oral Toxicity)

Skin corrosion/irritation : Not classified

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.

BisGMA (1565-94-2)

STOT-single exposure May cause respiratory irritation.

SG-Mix Cement (N/A)

STOT-single exposure May cause respiratory irritation.

STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

TheraCal PT Base

Viscosity, kinematic Not applicable

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

11.2.2. Other information

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

symptoms

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.

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Hazardous to the aquatic environment, short-term

(acute)

Hazardous to the aquatic environment, long-term : Not classified

(chronic)

: Not classified

Barium Zirconate (12009-21-1)	
EC50 - Crustacea [1]	> 1000 mg/l Test organisms (species): Daphnia magna
5 11	201.4 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)

12.2. Persistence and degradability

TheraCal PT Base		
Persistence and degradability Not established.		
BisGMA (1565-94-2)		
Persistence and degradability	Biodegradability in water: no data available.	

12.3. Bioaccumulative potential

TheraCal PT Base		
Bioaccumulative potential	Not established.	
BisGMA (1565-94-2)		
Partition coefficient n-octanol/water (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. 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

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

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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

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. Maritime transport in bulk according to IMO instruments

Not applicable

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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
	Supersedes version of	Added	
	Revision date	Added	
	Issue date	Removed	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Hazard statements (CLP)	Modified	
2.2	Precautionary statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	

Other information : None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4

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Full text of H- and EUH-statements:		
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
H302	Harmful if swallowed.	
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.	
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	

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.