



TheraCal PT Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Revision date: 1/23/2025 Supersedes version of: 1/18/2023 Version: 3.0

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

Relevant identified uses

Use of the substance/mixture : For Rx Only

1.3. Details of the supplier of the safety data sheet

Manufacturer

BISCO, Inc.
1100 W. Irving Park Rd.
60193 Schaumburg, IL
U.S.A
T 1-800-247-3368 or 1-847-534-6000
sales@bisco.com - www.bisco.com

EC REP

BISICO France
208, allée de la Coudoulette
13680 Lançon de Provence
France
T 33-4-90-42-92-92

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, H335
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.

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

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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 and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

Component	
Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	Silicon Dioxide (7631-86-9)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	Silicon Dioxide (7631-86-9)

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 substance(s) are 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	
Substance(s) not 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	SG-Mix Cement (N/A)

SECTION 3: Composition/information on ingredients

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
Silicon Dioxide	CAS-No.: 7631-86-9 EC-No.: 231-545-4	5 - 10	Not classified
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

Components - Nanoform

Silicon Dioxide (7631-86-9)	
Name of (set of) nanoform(s)	Silicon Dioxide
Number based particle size distribution	5 - 50 nm
Particle shape	Crystal

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Specific surface area	175 - 225 m2/g
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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.
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released.
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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.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust, fume, vapours.
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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".
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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.

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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.

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

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



Eye and face protection

Eye protection:

Safety glasses

Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Tooth / Yellow.
Appearance	: Flowable 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

See section 3 for more information about nano properties.

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.

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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

Silicon Dioxide (7631-86-9)

LD50 oral rat	3160 mg/kg Source: TOMES; HAZARTEXT
LD50 dermal rabbit	> 5000 mg/kg Source: ECHA
LC50 Inhalation - Rat	> 5.01 mg/l (OECD 436: Acute inhalation toxicity-acute toxic class method, 4 h, Rat, Male / female, Experimental value, Inhalation (aerosol), 15 day(s))
LC50 Inhalation - Rat (Dust/Mist)	5.01 mg/l Source: ECHA

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)
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Skin corrosion/irritation : Not classified

Silicon Dioxide (7631-86-9)

pH	3.5 - 4.4
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Serious eye damage/irritation : Causes serious eye irritation.

Silicon Dioxide (7631-86-9)

pH	3.5 - 4.4
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Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Silicon Dioxide (7631-86-9)

IARC group	3 - Not classifiable
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Reproductive toxicity : Not classified

STOT-single exposure : May cause respiratory irritation.

BisGMA (1565-94-2)

STOT-single exposure	May cause respiratory irritation.
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SG-Mix Cement (N/A)

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

Aspiration hazard : Not classified

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Viscosity, kinematic	Not applicable
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Silicon Dioxide (7631-86-9)

Viscosity, kinematic	Not applicable (solid)
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11.2. Information on other hazards

No additional information available

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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

Silicon Dioxide (7631-86-9)

LC50 - Fish [1]	10000 mg/l Source: ECHA
EC50 - Crustacea [1]	> 5000 mg/l Source: ECHA
EC50 72h - Algae [1]	> 173.1 mg/l Source: ECHA

BisGMA (1565-94-2)

LC50 - Fish [1]	0.537 mg/l Source: ECOSAR
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Barium Zirconate (12009-21-1)

EC50 - Crustacea [1]	> 1000 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	201.4 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)

12.2. Persistence and degradability

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Persistence and degradability	Not established.
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Silicon Dioxide (7631-86-9)

Persistence and degradability	Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable (inorganic)
ThOD	Not applicable (inorganic)

BisGMA (1565-94-2)

Persistence and degradability	Biodegradability in water: no data available.
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Barium Zirconate (12009-21-1)

Persistence and degradability	Rapidly degradable
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SG-Mix Cement (N/A)

Persistence and degradability	Rapidly degradable
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12.3. Bioaccumulative potential

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Bioaccumulative potential	Not established.
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Silicon Dioxide (7631-86-9)

Bioaccumulative potential	Not bioaccumulative.
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BisGMA (1565-94-2)

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

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12.4. Mobility in soil

Silicon Dioxide (7631-86-9)

Surface tension	No data available in the literature
Ecology - soil	No (test)data on mobility of the substance available.

12.5. Results of PBT and vPvB assessment

Component

Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	Silicon Dioxide (7631-86-9)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	Silicon Dioxide (7631-86-9)

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 applicable
Proper Shipping Name (IMDG) : Not regulated
Proper Shipping Name (IATA) : Not regulated
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 regulated

IATA

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

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

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

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14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not regulated
Packing group (IATA)	: Not regulated
Packing group (ADN)	: Not applicable
Packing group (RID)	: Not applicable

14.5. Environmental hazards

Other information	: No supplementary information available
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14.6. Special precautions for user

Overland transport

No data available

Transport by sea

Not regulated

Air transport

Not regulated

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

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)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

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)

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15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes

Section	Changed item	Comments
	Revision date	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
3	Composition/information on ingredients	Modified

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
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.