

### 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.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]

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

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.

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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. Odour : Acrylic. 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 рΗ Not available

pH solution Not available 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 : 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 size distribution : Not available
Particle shape : Not available
Particle aspect ratio : Not available
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 Zirc	onate (1	12009-2	1-1)
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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 a

: Based on available data, the classification criteria are not met

### **SECTION 12: Ecological information**

#### 12.1. Toxicity

symptoms

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

: Not classified

(acute)

Hazardous to the aquatic environment, long-term

: Not classified

(chronic)

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

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 EUF	I-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.