



TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Revision date: 1/21/2025 Supersedes version of: 3/16/2023 Version: 5.0

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

1.1. Product identifier

Product form : Mixture
Product name : TheraCem Ca 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]

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,	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 :

Portland Cement; BisGMA; Ytterbium w/ Barium Glass

Hazard statements (CLP) :

H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
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.

Precautionary statements (CLP) :

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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 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	Portland Cement (65997-15-1), Ethoxylated Bis A Dimethacrylate (41637-38-1), Titanium Dioxide (13463-67-7)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	Portland Cement (65997-15-1), Ethoxylated Bis A Dimethacrylate (41637-38-1), Titanium Dioxide (13463-67-7)

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	Ytterbium w/ Barium Glass (NA)

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ytterbium w/ Barium Glass	CAS-No.: NA	30 - 50	Eye Irrit. 2, H319 STOT SE 3, H335
Ethoxylated Bis A Dimethacrylate	CAS-No.: 41637-38-1	10 - 30	Aquatic Chronic 4, H413
Portland Cement	CAS-No.: 65997-15-1 EC-No.: 266-043-4	10 - 30	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335
Ytterbium Fluoride	CAS-No.: 13760-80-0 EC-No.: 237-354-2	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319
Fumed Silica	CAS-No.: 68611-44-9 EC-No.: 271-893-4	1 - 5	Not classified
Brombenzenesulfonic Acid, Sodium Dihydrate	CAS-No.: 175278-64-5	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
BisGMA	CAS-No.: 1565-94-2 EC-No.: 216-367-7	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335
Titanium Dioxide	CAS-No.: 13463-67-7 EC-No.: 236-675-5 EC Index-No.: 022-006-00-2	< 1	Carc. 2, H351
Acetyl-2-Thiourea	CAS-No.: 591-08-2 EC-No.: 209-699-9	< 1	Acute Tox. 2 (Oral), H300

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

Components - Nanoform

Fumed Silica (68611-44-9)	
Name of (set of) nanoform(s)	Fumed Silica
Number based particle size distribution	16 nm
Particle shape	Crystal
Specific surface area	90 - 130 m ² /g
Ytterbium Fluoride (13760-80-0)	
Name of (set of) nanoform(s)	Ytterbium Fluoride
Number based particle size distribution	30 - 70 nm
Particle shape	Crystal
Specific surface area	< 50 m ² /g

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Irritation. May cause an allergic skin reaction.
Symptoms/effects after eye contact	: May cause 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.
------------------------------	----------------------------------

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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

For non-emergency personnel

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

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 : Avoid breathing dust, fume, vapours. Avoid contact with skin and eyes. Wear personal protective equipment.
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 container tightly closed. Keep cool.

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.

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Personal protection equipment

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Straw.
Appearance	: Viscous Resin 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

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Fumed Silica (68611-44-9)

LD50 oral rat	> 5000 mg/kg (Rat, Literature study, Oral)
---------------	--

Ethoxylated Bis A Dimethacrylate (41637-38-1)

LD50 oral rat	> 2000 mg/kg Source: ECHA
---------------	---------------------------

LD50 dermal rat	> 2000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Read-across, Dermal, 15 day(s))
-----------------	---

Acetyl-2-Thiourea (591-08-2)

LD50 oral rat	50 mg/kg Source: National Library of Medicine/Hazardous Substances Data Bank
---------------	--

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)
---------------	---

Titanium Dioxide (13463-67-7)

LD50 oral rat	> 2000 mg/kg bodyweight (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s))
---------------	--

LC50 Inhalation - Rat	5.09 mg/l (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male, Experimental value, Inhalation (dust), 14 day(s))
-----------------------	---

LC50 Inhalation - Rat (Dust/Mist)	> 6.82 mg/l Source: ECHA
-----------------------------------	--------------------------

Skin corrosion/irritation : Causes skin irritation.

Portland Cement (65997-15-1)

pH	11 - 13.5 (20 °C)
----	-------------------

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Fumed Silica (68611-44-9)	
pH	3.7 - 4.7 (4 %, 20 °C)
Ethoxylated Bis A Dimethacrylate (41637-38-1)	
pH	4.7 (< 0.01 %, 20 °C, OECD 105: Water Solubility)
Acetyl-2-Thiourea (591-08-2)	
pH	6 (17.3 %)
Ytterbium Fluoride (13760-80-0)	
pH	4.53 Temp.: 20 °C
Titanium Dioxide (13463-67-7)	
pH	7 Source: ECHA
Serious eye damage/irritation	: Causes serious eye irritation.
Portland Cement (65997-15-1)	
pH	11 - 13.5 (20 °C)
Fumed Silica (68611-44-9)	
pH	3.7 - 4.7 (4 %, 20 °C)
Ethoxylated Bis A Dimethacrylate (41637-38-1)	
pH	4.7 (< 0.01 %, 20 °C, OECD 105: Water Solubility)
Acetyl-2-Thiourea (591-08-2)	
pH	6 (17.3 %)
Ytterbium Fluoride (13760-80-0)	
pH	4.53 Temp.: 20 °C
Titanium Dioxide (13463-67-7)	
pH	7 Source: ECHA
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Brombenzenesulfinic Acid, Sodium Dihydrate (175278-64-5)	
IARC group	4 - Probably not carcinogenic to humans
Ytterbium Fluoride (13760-80-0)	
IARC group	4 - Probably not carcinogenic to humans
Titanium Dioxide (13463-67-7)	
IARC group	2B - Possibly carcinogenic to humans
Reproductive toxicity	: Not classified
STOT-single exposure	: May cause respiratory irritation.
Portland Cement (65997-15-1)	
STOT-single exposure	May cause respiratory irritation.
Brombenzenesulfinic Acid, Sodium Dihydrate (175278-64-5)	
STOT-single exposure	May cause respiratory irritation.

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

BisGMA (1565-94-2)	
STOT-single exposure	May cause respiratory irritation.
Ytterbium w/ Barium Glass (NA)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
TheraCem Ca Base	
Viscosity, kinematic	Not applicable
Portland Cement (65997-15-1)	
Viscosity, kinematic	Not applicable (solid)
Fumed Silica (68611-44-9)	
Viscosity, kinematic	Not applicable
Ethoxylated Bis A Dimethacrylate (41637-38-1)	
Viscosity, kinematic	No data available in the literature
Titanium Dioxide (13463-67-7)	
Viscosity, kinematic	Not applicable (solid)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

Portland Cement (65997-15-1)	
LC50 - Fish [1]	> 1000 mg/l (96 h, Pisces)
Fumed Silica (68611-44-9)	
LC50 - Fish [1]	> 10000 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Brachydanio rerio, Experimental value, Nominal concentration)
EC50 - Crustacea [1]	> 10000 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 24 h, Daphnia magna, Experimental value, Nominal concentration)
Ethoxylated Bis A Dimethacrylate (41637-38-1)	
LC50 - Fish [1]	> 100 mg/l Source: ECAH
EC50 72h - Algae [1]	> 100 mg/l Source: ECAH
Acetyl-2-Thiourea (591-08-2)	
LC50 - Fish [1]	3417 mg/l Source: Ecological Structure Activity Relationships

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

BisGMA (1565-94-2)	
LC50 - Fish [1]	0.537 mg/l Source: ECOSAR
Ytterbium Fluoride (13760-80-0)	
EC50 - Crustacea [1]	> 0.52 mg/l Test organisms (species): Daphnia magna
Titanium Dioxide (13463-67-7)	
LC50 - Fish [1]	> 100 mg/l
EC50 - Crustacea [1]	> 1000 mg/l (Invertebrata, Fresh water, Literature study)
EC50 72h - Algae [1]	> 50 mg/l Source: ECHA

12.2. Persistence and degradability

TheraCem Ca Base	
Persistence and degradability	Rapidly degradable
Portland Cement (65997-15-1)	
Persistence and degradability	Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable (inorganic)
ThOD	Not applicable (inorganic)
BOD (% of ThOD)	Not applicable
Fumed Silica (68611-44-9)	
Persistence and degradability	Biodegradability: not applicable.
Ethoxylated Bis A Dimethacrylate (41637-38-1)	
Persistence and degradability	Not readily biodegradable in water.
Acetyl-2-Thiourea (591-08-2)	
Persistence and degradability	Biodegradability in water: no data available.
Brombenzenesulfonic Acid, Sodium Dihydrate (175278-64-5)	
Persistence and degradability	Rapidly degradable
BisGMA (1565-94-2)	
Persistence and degradability	Biodegradability in water: no data available.
Ytterbium Fluoride (13760-80-0)	
Persistence and degradability	Rapidly degradable
Ytterbium w/ Barium Glass (NA)	
Persistence and degradability	Rapidly degradable
Titanium Dioxide (13463-67-7)	
Persistence and degradability	Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable (inorganic)
ThOD	Not applicable (inorganic)

12.3. Bioaccumulative potential

Portland Cement (65997-15-1)	
Bioaccumulative potential	No bioaccumulation data available.

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Fumed Silica (68611-44-9)	
Bioaccumulative potential	Not bioaccumulative.
Ethoxylated Bis A Dimethacrylate (41637-38-1)	
Partition coefficient n-octanol/water (Log Pow)	5.62 (Practical experience/observation, OECD 117: Partition Coefficient (n-octanol/water), HPLC method)
Bioaccumulative potential	High potential for bioaccumulation (Log Kow > 5).
Acetyl-2-Thiourea (591-08-2)	
Partition coefficient n-octanol/water (Log Pow)	-0.27 Source: National Library of Medicine
Bioaccumulative potential	Not bioaccumulative.
BisGMA (1565-94-2)	
Partition coefficient n-octanol/water (Log Pow)	4.94 Source: ChemIDplus
Bioaccumulative potential	No bioaccumulation data available.
Ytterbium Fluoride (13760-80-0)	
Partition coefficient n-octanol/water (Log Pow)	0.22 Source: EPISUITE
Titanium Dioxide (13463-67-7)	
Bioaccumulative potential	Not bioaccumulative.
12.4. Mobility in soil	
Portland Cement (65997-15-1)	
Surface tension	No data available in the literature
Ecology - soil	No (test)data on mobility of the substance available.
Fumed Silica (68611-44-9)	
Ecology - soil	Low potential for mobility in soil.
Ethoxylated Bis A Dimethacrylate (41637-38-1)	
Surface tension	No data available in the literature
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	2.56 - 3.88 (log Koc, Calculated value)
Ecology - soil	Low potential for mobility in soil.
Acetyl-2-Thiourea (591-08-2)	
Mobility in soil	22 Source: HSDB
Titanium Dioxide (13463-67-7)	
Surface tension	No data available in the literature
Ecology - soil	Low potential for mobility in soil.
12.5. Results of PBT and vPvB assessment	
Component	
Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	Portland Cement (65997-15-1), Ethoxylated Bis A Dimethacrylate (41637-38-1), Titanium Dioxide (13463-67-7)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	Portland Cement (65997-15-1), Ethoxylated Bis A Dimethacrylate (41637-38-1), Titanium Dioxide (13463-67-7)

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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

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

Other information : No supplementary information available

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

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)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

TheraCem Ca Base

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

SECTION 16: Other information

Indication of changes

Section	Changed item	Comments
	Revision date	Modified
	Supersedes version of	Modified
2.2	Precautionary statements (CLP)	Modified
3	Composition/information on ingredients	Modified

Full text of H- and EUH-statements:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Chronic 4	Hazardous to the aquatic environment - Chronic Hazard, Category 4
Carc. 2	Carcinogenicity, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H300	Fatal if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer.
H413	May cause long lasting harmful effects to aquatic life.
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.