

Product Name: BIOTEMP

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

1.1- Product Identification

Product Name : BioTemp
Product Code : BCT
Product Description : Dental temporary filling material
Packing Available : 2g

1.2- Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Temporary filling material for root canal. Used by dental professional only. For dental use only.

1.3- Details of the supplier of the safety data sheet

Manufacturer : Prime Dental Products Pvt Ltd.
Address : Plot No. A-148, Road No. 24, MIDC, Wagle Industrial Estate, Thane (West)- 400604, Maharashtra, India
Email : info@prime-dental.com
Web : www.prime-dental.com

1.4- Emergency contact details

Telephone : +919272235922 / +919272235925

SECTION 2: Composition/information on ingredients

2.1- Mixture

Component	C.A.S.	EINECS	Classification*	Weight%	LD50
Calcium Hydroxide	1305-62-0	215-137-3	H314	<35	Oral (Rat): 7,340 mg/kg.
Barium Sulphate	7727-43-7	231-784-4	NA	<30	Oral (Rat): 307,000 mg/kg
Tricalcium silicate	12168-85-3	Not Available	H317, H319	15-45%	NA
Dicalcium silicate	1344-95-2	Not Available	H317, H319	15-45%	NA

*For wording of the listed 'R' phrases and 'H' statements see section 16

SECTION 3: Identification of Hazards

3.1- Hazard Description : "C" Corrosion (Calcium Hydroxide)

3.2- Information concerning to particular hazards to man and environment

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

On Skin: Causes serious severe skin burns

On Eyes: Causes serious eye damage

By Accidental Ingestion: Harmful if ingested

By Inhalation: May cause irritation

SECTION 4: First aid measures

4.1- Description of first aid measures

Contact with skin: Wash with soap and water. Get medical attention if irritation develops or persists.

Contact with eyes: Flush eyes with plenty of water. Get medical attention, if irritation persists.

Ingestion: Give water. DO NOT induce vomiting. Consult a physician if ingested in large amounts.

Inhalation: Not applicable

SECTION 5: Fire-Fighting Measures

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- 5.1- Recommended extinguishers:** Water spray, CO2 or powders. Fight large fires with water spray or alcohol resistant spray
- 5.2- Extinguishers not to be used:** None in particular.
- 5.3- Risks arising from combustion:** Avoid inhaling the fumes.
- 5.4- Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental Release Measures

- 6.1 Measures for personal safety:** Wear self-contained respiratory protective device.
- 6.2 Measures for environmental protection:** Do not allow product to reach sewage system or any water courses.
- 6.3 Measures for cleaning/collecting:** Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Use neutralizing agent.

SECTION 7: Handling and Storage

- 7.1- Handling product:** Is intended for dental use only.
- 7.2- Information for safe handling:** No special measures required. Observe normal care for working with chemicals.
- 7.3- Information about fire and explosion protection:** No special measures required.
- 7.4- Storage requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- 7.5- Information about storage in one common storage facility:** Not required.
- 7.6- Further information about storage conditions:** Protect from heat and direct sunlight.

SECTION 8: Exposure Controls/Personal Protection

- 8.1- Additional information about design of technical facilities:** No further data; see section 7.

8.2- Ingredients with limit values that require monitoring at the workplace:

Calcium Hydroxide - WEL (Great Britain):

Short-term value: 4* mg/m³

Long-term value: 5 1* mg/m³

*respirable fraction

Barium Sulphate - WEL (Great Britain):

Short-term value: 4* mg/m³

Long-term value: 10* 4** mg/m³

*inhalable dust **respirable dust

8.3- Personal protective equipment:

- a. Respiratory protection** : Not required when used as per declared indications.
- b. Protection of hands** : The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
- c. Eye protection** : Safety glasses
- d. Body protection** : Protective work clothing

SECTION 9: Physical and Chemical Properties

9.1- Physical Properties:

Form : Paste

Color : White to off-white

Odour : None

9.2- Chemical Properties:

Melting point/Melting range : Undetermined

Boiling point/Boiling range : Undetermined

Ignition temperature : Undetermined

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Flash point	: Undetermined
Self-igniting	: Product is not self-igniting.
Danger of explosion	: Product does not present an explosion hazard.
Density	: 1.4-1.8 g/cm ³
Solubility in / Miscibility with Water	: Partially soluble

SECTION 10: Stability and Reactivity

10.1- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.2- Dangerous reactions: No dangerous reactions known

10.3 Dangerous decomposition products: No dangerous decomposition products known

SECTION 11: Stability and Reactivity

11.1- Acute toxicity

Calcium Hydroxide LD50: Oral (Rat): 7,340 mg/kg

Barium Sulphate LD50: Oral (Rat): 307,000 mg/kg

11.2- Primary irritant effect : Nil

11.3- On the skin : Causes severe skin burns

11.4- On the eye : Causes severe eye damage

11.5- Sensitization : No sensitizing effects known.

SECTION 12: Ecological Information

12.1- Environmental data: Can be toxic to aquatic environment.

Barium Sulphate LC50: 32 mg/l (daphnia)

SECTION 13: Disposal Consideration

13.1- Product Recommendation: Must not be disposed together with household garbage. Do not allow product to reach sewage system.

13.2- Uncleaned Packaging Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport Information

14.1- Air (ICAO/IATA)

Primary Hazard Class/Division : Undetermined

14.2- Road (RID/ADR)

Primary Hazard Class/Division : Undetermined

14.3- Vessel (IMO/IMDG/RID/ADR)

Primary Hazard Class/Division : Undetermined

SECTION 15: Regulatory Information

15.1- Safety, health and environmental regulations/legislation specific for the substance or mixture

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2- Chemical safety assessment : See Section 11

SECTION 16: Additional Information

16.1- 'R' phrases and 'H' statement:

H314: Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

16.2- Prepared by: Tanay Thakkar

Product Name: BIOTEMP

16.3- Manufacturer Disclaimer: For Dental Use Only, Use as directed.

The information and recommendations are taken from sources (raw material MSDS(s) and manufacturer's knowledge) believed to be accurate; however, Prime Dental Products Pvt Ltd, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.
