

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

1.1- Product Identification

Product Name : Restorite Cal
Product Code : RCA
Product Description : Light cured calcium hydroxide cavity base/liner
Packing Available : 2g

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

Relevant identified uses : Light cured calcium hydroxide cavity base/liner. 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.in
Web : www.prime-dental.in

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
Bis-GMA	1565-94-2	NA	H315, H317, H319	20-60	Ingestion (rat): 11,700 mg/kg
Calcium Hydroxide	1305-62-0	215-137-3	H314	1-20	Oral (rat): 7,340 mg/kg
TEGDMA	109-16-0	203-652-6	H317	5-30	Oral (rat): 10,837 mg/kg

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

SECTION 3: Identification of Hazards

3.1- Hazard Description : Not Applicable

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: Irritant, may cause temporary redness. Mild local irritation and sensitization. Intensive or continuous contact with skin may cause swelling, blistering

On Eyes: Irritant, may cause burning, redness, pain.

By Accidental Ingestion: Harmful if ingested, gastrointestinal irritation. Abdominal pain, nausea, vomiting, dizziness.

By Inhalation: Irritant to respiratory tract, sore throat, coughing, shortness of breath, dizziness, nausea.

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: Supply fresh air. Get medical attention if uncomfortable

SECTION 5: Fire-Fighting Measures

5.1- Recommended extinguishers: Water, CO2, foam, or chemical powders, depending on the materials involved in the fire. Fight large fires with water spray or alcohol resistant foam.

- 5.2- Extinguishers not to be used:** Water with full jet
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 protective equipment. Keep unprotected person away.
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, sawdust). Ensure adequate ventilation.

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 and exposure to light.

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
8.3- Personal protective equipment:
a. Respiratory protection : Exposure under intended use no special precaution is required.
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 : Yellowish
Odour : Characteristic odour

9.2- Chemical Properties:

Melting point/Melting range	: Undetermined
Boiling point/Boiling range	: Undetermined
Ignition temperature	: Undetermined
Flash point	: Not applicable
Self-igniting	: Product is not self-igniting.
Danger of explosion	: Product does not present an explosion hazard.
Density	: 1.2 g/ml
Solubility in / Miscibility with Water	: Partly 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 under normal conditions.

10.4- Avoid: Exposure to heat and direct sunlight/light

SECTION 11: Stability and Reactivity

11.1- Acute toxicity-

Bis-GMA : LD50 Ingestion (rat)- 11,700 mg/kg

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

TEGDMA : LD50 Oral (rat)- 10,837 mg/kg

11.2- Primary irritant effect-

On the skin : May cause skin irritation

On the eye : May cause irritating effect.

Sensitization : May be possible through skin contact.

SECTION 12: Ecological Information

12.1- Environmental data: No data available. Contact Env. Dept.

SECTION 13: Disposal Consideration

13.1- Product Recommendation: Dispose of contents/ container in accordance with the local/regional/national/international regulations. Incinerate in a permitted waste incineration facility.

13.2- EPA Hazardous Waste Number (RCRA): D001 (Ignitable)

SECTION 14: Transport Information

14.1- Air (ICAO/IATA)

Primary Hazard Class/Division : No classification

14.2- Road (RID/ADR)

Primary Hazard Class/Division : No classification

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

Primary Hazard Class/Division : No classification

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.

H315: Causes skin irritation

H317: May cause an allergic skin reaction

H319: Causes serious eye irritation

16.2- Prepared by: Tanay Thakkar

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.
