PRIME™ DENTAL PRODUCTS PVT LTD
Established in 1987

SAFETY DATA SHEET

Product Name: RESTORITE BULK FILL PACKABLE

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Pages: 3

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

1.1- Product Identification

Product Name : Restorite Bulk Fill Packable
Product Code : RBP
Product Description : Dental filling material
Packing Available : 4g syringe

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

Relevant identified uses : Dental filling material. 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
TMDM	2082-81-7	218-218-1	H317	2.5-10	Oral (rat): >5,000 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 allergic skin reaction.
On Eyes: May cause irritation.
By Accidental Ingestion: May cause gastrointestinal irritation.
By Inhalation: Not applicable.

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: DO NOT induce vomiting. Consult a physician if ingested.
Inhalation: Supply fresh air. Get medical attention if uncomfortable

SECTION 5: Fire-Fighting Measures

5.1- Recommended extinguishers: Water, CO_2, foam, or chemical powders, depending on the materials involved in the fire.
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: Not required
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. Store away from food stuff.

SECTION 8: Exposure Controls/Personal Protection

8.1- Additional information about design of technical facilities: No further data; see section 7.
8.2- Personal protective equipment:
General protective and hygienic measure: Keep away from foodstuffs, beverages and feed. Avoid contact with the eyes and skin. Wash hands before breaks and at the end of work.

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	: Thick paste
Color	: Different according to coloring
Odour	: Weak, characteristic

9.2- Chemical Properties:

Melting point/Melting range	: <-20^{0}C
Boiling point/Boiling range	: 251^{0}C
Ignition temperature	: 400^{0}C
Flash point	: 113^{0}C
Self-igniting	: Product is not self-igniting.
Danger of explosion	: Product does not present an explosion hazard.
Density	: Undertermined
Solubility in / Miscibility with Water	: Not miscible.

SECTION 10: Stability and Reactivity

10.1- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
10.2- Dangerous reactions: In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.
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-
TMDM : LD50 Oral (rat)- >5,000 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: Hazardous for water. Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground.

SECTION 13: Disposal Consideration

13.1- Product Recommendation: Dispose of contents/ container in accordance with the local/regional/national/international regulations. Alcohol is a recommended cleaning agent.

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:
H317: May cause an allergic skin reaction
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.