

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

### **1.1- Product Identification**

Product Name : GingiSafe  
Product Description : Dental composite barrier material  
Packing Available : 1.2ml syringe

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

Relevant identified uses : Dental composite barrier 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](mailto:info@prime-dental.in)  
Web : [www.prime-dental.in](http://www.prime-dental.in)

### **1.4- Emergency contact details**

Telephone : +919272235922 / +919272235925

## **SECTION 2: Composition/information on ingredients**

### **2.1- Mixture**

<b>Component</b>	<b>C.A.S.</b>	<b>EINECS</b>	<b>Classification*</b>	<b>Weight%</b>	<b>LD50</b>
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, CO2, 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.

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## **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.

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## **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

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## **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°C

Boiling point/Boiling range : 251°C

Ignition temperature : 400°C

Flash point : 113°C

Self-igniting : Product is not self-igniting.

Danger of explosion : Product does not present an explosion hazard.

Density : Undetermined

Solubility in / Miscibility with Water : Not miscible.

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## **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

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## **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.

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## **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.

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## **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.

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## **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

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## **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

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## **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.

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