

Product Name: RC PEX

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

### **1.1- Product Identification**

Product Name : RC PEX  
Product Code : RCP  
Product Description : Dental temporary filling material with iodoform  
Packing Available : 3g

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

Relevant identified uses : Temporary filling material with iodoform 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.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>
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

\*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**

**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.

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## **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/m<sup>3</sup>

Long-term value: 5 1\* mg/m<sup>3</sup>

\*respirable fraction

Barium Sulphate - WEL (Great Britain):

Short-term value: 4\* mg/m<sup>3</sup>

Long-term value: 10\* 4\*\* mg/m<sup>3</sup>

\*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 : Yellow

Odour : Characteristic

**9.2- Chemical Properties:**

Melting point/Melting range : Undetermined

Boiling point/Boiling range : Undetermined

Ignition temperature : Undetermined

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<sup>3</sup>

Solubility in / Miscibility with Water : Partially soluble

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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:** No dangerous reactions known

**10.3 Dangerous decomposition products:** No dangerous decomposition products known

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## **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.

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## **SECTION 12: Ecological Information**

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

Barium Sulphate LC50: 32 mg/l (daphnia)

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## **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.

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## **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

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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:**

H314: Causes severe skin burns and eye damage.

**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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