

# **SAFETY DATA SHEET**

**Premier® Implant Cement™, Base**

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## **1. Chemical Product and Company Identification**

Product Name: **Premier® Implant Cement™**

### **Premier® Dental Products Company**

1710 Romano Drive

Plymouth Meeting, PA 19462

Phone: 610-239-6000 Fax: 610-239-6171

**Emergency Phone:** 610-239-6000

### **Indications:**

Premier® Implant Cement is a non-eugenol temporary cement for luting implant-retained crowns.

### **Contraindications:**

Do not use on patients with known sensitivity or allergy to resins. Wash exposed area completely to remove material. If an allergic reaction is observed, consult a physician immediately and discontinue use with this patient.

## **2. Hazards Identification**

**Acute Health Hazards:** May cause eye, respiratory and skin irritation in high concentration.

**Chronic Health Hazards:** Material is not known to cause significant health problems

**Signs and Symptoms of Exposure:** High concentrations can cause eye and respiratory irritation. Prolonged skin exposure can cause dryness

**Primary routes of exposure:** Inhalation, skin contact, eye contact.

**Carcinogenicity:** NTP - no, OSHA - no, IARC – no.

**Hazard symbol:**



## **3. Composition / Information on Hazardous Ingredients**

<b>Amount (wt)</b>	<b>Hazardous Ingredients</b>	<b>CAS #</b>	<b>Hazard Identification &amp; Risk Phrases</b>
8% - 19%	Triethylglycoldimethacrylate	109-16-0	Irritant, R36/37/38, R43
5% - 12%	2-Hydroxyethylmethacrylate	868-77-9	Irritant, R36/38-43
1% - 3%	Co-initiator	10287-53-3	Irritant, R36/37/38
1% - 5%	Fumed Silica	112945-52-5	R36/37/38

✓ **Additional information: For the wording of the listed risk phrases refer to section 16.**

## **4. First Aid Measures**

**In case of inhalation:** If irritation occurs, take victim to open air. If breathing difficulty persists, consult a physician.

**In case of skin contact:** Wash with soap and water.

**In case of eye contact:** Flush with large quantities of water for 15 minutes. Consult a physician.

**In case of ingestion:** Consult a physician.

## 5. Fire-Fighting Measures

**Flash point:** N/A

**Extinguishing Media:** Carbon dioxide, water spray, dry chemical

**Special Fire Fighting Procedures:** Avoid a direct jet of water.

**Unusual Fire and Explosion Hazards:** None.

## 6. Accidental Release Measures

**Environmental Precautions:** Avoid seepage into sewers and water supplies.

**Clean-Up Procedure:** Contain spill and pick up material with a suitable absorbent material. Place absorbent into a container for later disposal.

## 7. Handling and Storage

**Handling:** No special measures necessary if handled according to instruction

**Storage:** Keep container tightly closed when not in use. Store in a cool dry location. Keep material in original packaging.

Storage away from light, open flames, contamination and prolonged storage above 24°C (75°F).

## 8. Exposure Controls / Personal Protection

**Exposure Controls:** Use only in well-ventilated areas

**Respiratory Protection:** Avoid inhalation of vapors. No special protection under normal use.

**Hand and Skin Protection:** Avoid unnecessary skin contact. Wear latex gloves when handling

**Eye Protection:** Wear safety goggles or safety glasses with side shields when handling,

**Hygiene Measures:** Remove spilled material from skin and clothing. Do not eat or drink when handling this material

## 9. Physical and Chemical Properties

**Appearance:** White paste

**Odor:** Specific odor

**Boiling Point:** N/A

**Evaporation Rate (Water = 1):** N/A

**Vapor Density (Air = 1):** N/A

**Solubility in Water:** Insoluble

## 10. Stability and Reactivity

**Stability:** This material is stable.

**Hazardous Reactions:** None if handled according to directions

**Hazardous Polymerization:** May occur.

**Conditions to Avoid:** Heat, UV light

**Incompatibility:** Free radicals, reducing agents, heavy metal ions

**Hazardous Decomposition Products:** Carbon dioxide, water, carbon monoxide, acrylic decomposition products, depending on conditions of heating and burning.

## 11. Toxicological Information

**Acute oral toxicity:** LD50 (rat) > 5000mg/KG

**Irritation of Skin:** Dryness and irritation possible upon prolonged exposure

**Allergic Effects:** Methacrylate sensitive individuals may exhibit an allergic reaction.

## 12. Ecological Information

Do not discharge into sewers or water supplies

**Environmental persistence and degradability:** no data available

**Ecotoxicity:** no data available

## 13. Disposal Considerations

May be disposed of in landfill or Incinerator In accordance with local, state and federal regulations

## 14. Transport Information

<b>UN-Number:</b>	
<b>DOT, ADR/ADN, ADN, IMDG, IATA</b>	Non-Regulated Material
<b>UN proper shipping name:</b>	
<b>DOT, ADR/ADN, ADN, IMDG, IATA</b>	Non-Regulated Material
<b>Transport hazard class(es):</b>	
<b>DOT, ADR/ADN, ADN, IMDG, IATA</b>	
<b>Class:</b>	Non-Regulated Material
<b>Packing group:</b>	
<b>DOT, ADR/ADN, IMDG, IATA</b>	Non-Regulated Material
<b>Environmental hazards:</b>	Not applicable.
<b>Special precautions for user:</b>	Not applicable.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:</b>	Not applicable.
<b>UN "Model Regulation":</b>	Non-Regulated Material

## 15. Regulatory Information

This product requires classification according to the criteria of EC.

The product is a medical device according to the EC-directive 93/42.

15.1 UN Number

15.2 National regulations

15.3 EU number

15.4 Hazard symbols



15.5 Hazard designation

**Irritant**

15.6 Risk phrases

**36/37/38 Irritating to eyes, respiratory system and skin**

**43 May cause sensitization by skin contact**

15.7 Safety phrases

**S: 2, 9, 16, 23, 26, 28, 24/25, 37/39**

**2 Keep out of the reach of children.**

**9 Keep container in a well-ventilated place.**

**16 Keep away from sources of ignition - No smoking.**

**23 Do not breathe vapour.**

**26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advise.**

**28 After contact with skin, wash immediately with plenty of water and soap.**

**24/25 Avoid contact with skin and eyes.**

**37/39 Wear suitable gloves and eye/face protection.**

**U.S.-O.S.H.A. Status:** This material is not hazardous under the criteria of the U.S Federal Hazard Communication Standard.

**16. Other Information**

**Premier's revision date:** 10/15/2024

**Revision number:** 11

**Relevant R-phrases**

**36/37/38/43:** Irritating to eyes, respiratory system and skin

**Irritant**

Material should be maintained in original containers. Empty containers should not be re-used.

**ANSI/NFPA 704 Data**

Fire = 1

Health = 0

Reactivity = 0

Specific Hazard = None

**Supplier's number: 073014**

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