

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

075800826

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

075800834

# **MATERIAL SAFETY DATA SHEET**

## **Premier Implant Cement, Catalyst**

Revision D *EU acc. To ISO 11014*

Last Revised: 06-06-2011

Approved for Use: 06-06-2011

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

Product Name: **Premier Implant Cement**

**Manufacturer:**

**Premier Dental Products Company**

1710 Romano Drive

Plymouth Meeting, PA 19462

Phone: 610-239-6053 Fax: 610-239-6171

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

<b>Hazardous Ingredients</b>	<b>CAS #</b>	<b>Hazard Identification &amp; Risk Phrases</b>
Triethylenglycoldimethacrylate	109-16-0	Xi
Benzoyl Peroxide	94-36-0	Explosive, Xi
Fumed Silica	112945-52-5	R36/37/38

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

### **3. 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.

### **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:** Pink 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

14.1 Transport at land	ADR	RID
	UN Number	Kemler Number
	Packing Group	
	Proper shipping name	
14.2 Transport at sea	ADNR	IMDG
	UN Number	
	EMS	MFAG
	Packing Group	
14.3 Air transport	Proper shipping name	
	ICAO / IATA-DGR	
	UN Number	
	Proper shipping name	
	Subsidiary Risk	
	Labels	
	Packing Group	

**U.S. DOT Shipping Name:** Not Regulated

**U.S. DOT Hazard Class:** None

**U.N./N.A. Number** None

**U.S. DOT Packing Group:** None

**Other:** Not considered hazardous cargo

## 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**

**15.6 Risk phrases**

**15.7 Safety phrases**

**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**

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall establish a legally valid contractual relationship.

### **Relevant R-phrases**

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

### **Xi 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

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This information is based on data considered accurate. However, no warranty is expressed or implied regarding the accuracy of these data, or the results to be obtained from use thereof. In no event will the manufacturer or distributor be responsible for damages of any nature whatsoever resulting from the use of, or reliance upon this information. General properties described herein are to be regarded as guides and are not guaranteed for all samples.

061139 Rev6

# **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>Hazardous Ingredients</b>	<b>CAS #</b>	<b>Hazard Identification &amp; Risk Phrases</b>
Triethylglycoldimethacrylate	109-16-0	Irritant, R36/37/38, R43
2-Hydroxyethylmethacrylate	868-77-9	Irritant, R36/38-43
Co-initiator	10287-53-3	Irritant, R36/37/38
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

14.1 Transport at land	<b>ADR</b>	<b>RID</b>
	<b>UN Number</b>	<b>Kemler Number</b>
	<b>Packing Group</b>	
	<b>Proper shipping name</b>	
14.2 Transport at sea	<b>ADNR</b>	<b>IMDG</b>
	<b>UN Number</b>	
	<b>EMS</b>	<b>MFAG</b>
	<b>Packing Group</b>	
14.3 Air transport	<b>Proper shipping name</b>	
	<b>ICAO / IATA-DGR</b>	
	<b>UN Number</b>	
	<b>Proper shipping name</b>	
	<b>Subsidiary Risk</b>	
	<b>Labels</b>	
	<b>Packing Group</b>	

**U.S. DOT Shipping Name:** Not Regulated

**U.S. DOT Hazard Class:** None

**U.N./N.A. Number** None

**U.S. DOT Packing Group:** None

**Other:** Not considered hazardous cargo

## 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 advice.  
**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:** 11/12/2015

**Revision number:** 9

**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: 041415**

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The information contained herein is based on our present knowledge. However, this information shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Premier Dental Products Company makes no warranties, express or implied with respect to, and assumes no responsibility or liability for, the accuracy or completeness of the information contained herein. Premier Dental Products Company urges persons receiving this information to make their own determination as to the information suitability for their particular application.

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111554 Rev9