SAFETY DATA SHEET

Premier IntegraCem[™] Adhesive Resin Cement, Catalyst

1. Chemical product and company identification

Product Name: Premier IntegraCem[™] Adhesive Resin Cement, Catalyst

Premier® Dental Products Company

1710 Romano Drive

Plymouth Meeting, PA 19462

PH: 610-239-6000 FAX: 610-239-6171

Emergency Phone: 610-239-6000

Indications for use:

Premier IntegraCem is a resin, dual-cure universal dental cement. IntegraCem can be used for the cementation of endodontic posts, restorations to enamel, dentin or metal, amalgam bonding, porcelain repair, and orthodontic attachment bonding.

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 concentrations.

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 symbols: **(!)**

3. Composition / Information on Ingredients

Hazardous Ingredients	CAS#	Hazard Identification & Risk Phrases
Bis-GMA	1565-94-2	N/E
Triethylenglycoldimethacrylate	109-16-0	Irritant
4-Methacryloxyethyltrimellitic acid	70293-55-9	Xn; R22-36/38-43
Benzoyl Peroxide	94-36-0	Explosive, Irritant
Treated Fumed Silica	67762-90-7	N/Ē

[✓] 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/E

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. Clean spill area with detergent and water.

7. Handling and Storage

Handling: No special measures necessary if handled according to instructions.

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

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/Range**: 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 and contamination.

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 : LD_{50} (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

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:

14.3 Air transport

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

()

Irritant

15.5 Hazard designation

15.6 Risk phrases 22 Harmful if swallowed.

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

43 May cause sensitization by skin contact.

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

Premier's revision date: 09-16-2014

Revision number: 3

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

22 Harmful if swallowed.

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

43 May cause sensitization by skin contact.

Irritant

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

ANSI/NFPA 704 Data:

 $\begin{aligned} & \text{Fire} = 1 \\ & \text{Health} = 0 \\ & \text{Reactivity} = 0 \\ & \text{Specific Hazard} = \text{None} \end{aligned}$

Supplier date: 07-30-2014

This SDS is offered solely for your information, consideration and investigation. This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. Premier Dental Products Company provides no warranties; either expressed or implied, and assumes no responsibility for the accuracy or completeness of data 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.

091460 Rev3