SAFETY DATA SHEET
ZR-Cem™ Self-Adhesive Universal Resin Cement, Catalyst

1. Chemical Product and Company Identification
   Product Name: ZR-Cem™
   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:
   ZR-Cem adhesive resin cement is a prescription only, dual cured, radiopaque resin cement intended to be used for cementation of porcelain, ceramic, resin, metal-based inlays/onlays, crowns, bridges, core build up material, posts and veneers. It is also used for cementation of crown restorations to implants.

   Contraindications:
   Do not use on patients with known sensitivity or allergy to methacrylate 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
   ! Irritating to eyes and skin

3. Composition / Information on Ingredients

   Hazardous Ingredients  CAS #  Hazard Identification & Risk Phrases
   Triethylenglycoldimethacrylate  109-16-0  Xi, R36/37/38, R43
   Composition of acrylic resins  79-41-4  Nn, C, R21/22-35

   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. Clean spill area with detergent and water.

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.
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/ Natural 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: 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
        UN Number
        RID
        Kemler Number
        Packing Group
        Proper shipping name
    14.2 Transport at sea
        ADNR
        UN Number
        IMDG
        EMS
        MFAG
        Packing Group
        Proper shipping name
    14.3 Air transport
        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 | ![Xi] |
| 15.5 Hazard designation | Xi: Irritant |
| 15.6 Risk phrases | R: 36, 37/38, 43  
22 Harmful if swallowed. 36  
Irritating to eyes.  
37/38 Irritating to 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: 23-July-2019  
Revision number: 0

Relevant R-phrases
36/37/38: Irritating to eyes respiratory system and skin.  
43: May cause sensitization by skin contact  
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

Supplier’s number: 05032019

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