

SAFETY DATA SHEET

ZR-Cem™ Self-Adhesive Universal Resin Cement, Base

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 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 Symbol



Irritating to eyes and skin

3. Composition / Information on Hazardous Ingredients

Hazardous Ingredients	CAS #	Hazard Identification & Risk Phrases
HEMA	868-77-9	Xi, R36/38, R43
Triethyleneglycoldmethacrylate	109-16-0	Xi, R36/37/38, R43
Copper(II) chloride dehydrate (3% aqueous solution)	10125-13-0	Xi, N, R21/22, R38, R41, R50
Photoinitiators	10373-78-1	Xi, R36/37/38
10-methacryloyldodecylphosphonate	85590-00-7	Xi, R36/37/39

✓ **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 / Yellow

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	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	
14.3 Air transport	ICAO / IATA-DGR	

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 description	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: 04-June-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

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.

0719083 Rev0

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	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	
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

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.

0719086 Rev0