

Safety Data Sheet

B.J.M. Laboratories Ltd.® ActiveCEM™ Resin Modified Glass Ionomer Cement, self-adhesive triple-cure permanent resin cement for professional dental use, Base

Form 70010/B-MSDS, Rev.0

Last revised: 22-Jun-2022

Approved for use: 22-Jun-2022

1. Chemical product and company identification

Product Name: ActiveCEM™ Resin Modified Glass Ionomer Cement for professional dental use, Base

Manufacturer:

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2. Composition / Information on Ingredients

Hazardous Ingredients	CAS #	Hazard Identification & Risk Phrases
Composition of Acrylic Resins	79-41-4	Xn, C, R21/22-35
HEMA	868-77-9	Xi, R36/38, R43
Triethyleneglycoldimethacrylate	109-16-0	Xi, R36/37/38, R43
Copper (II) chloride dihydrate (3% aqueous solution)	10125-13-0	Xn, N, R21/22, R38, R41, R50
Photoinitiators	10373-78-1	Xi, R36/37/38
10-methacryloyldodecylphosphonate	85590-00-7	Xi, R36/37/39
Acrylic Copolymer	35464-54-1, 7732-18-5	H315, H317, H320
Tartaric Acid	87-69-4	H315, H319

✓ 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 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.

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: 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.

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Dispose of completely cured (or polymerized) material in a permitted industrial waste facility. As a disposal alternative, incinerate uncured product in a permitted waste incineration facility. Proper destruction may require the use of additional fuel during incineration processes. If no other disposal options are available, waste product that has been completely cured or polymerized may be placed in a landfill properly designed for industrial waste.

Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations.

14. Transport Information:

14.1 Transport at land	ADR	RID
	UN Number	Kemler Number
14.2 Transport at sea	Packing Group	
	Proper shipping name	
	ADNR	IMDG
	UN Number	
14.3 Air transport	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:

This product requires classification according to the criteria of EC.

The product is a medical device according to the EC-directive 93/42/EEC and and MDR 2017/745.

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

Classification according to EU Directives 1999/45/EC:

R: R36/38, R38-41, R43, N, R51/53

36 Irritating to eyes.

37/38 Irritating to respiratory system and skin.

43 May cause sensitization by skin contact.

Classification (Regulation (EC) No 1272/2008:

H302, H315, H316f, H317, H318, H411

Oral: Acute toxicity, 4, H302

Skin irritation, 2, H315

Eye irritation, 1, H320

Skin sensitization, 1, H317

Chronic aquatic toxicity, 2, H411.

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

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.

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

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.
