

Material Safety Data Sheet**Cem-Implant™ Base****1. Chemical Product and Company Identification****Product Name:** Cem-Implant™ Implant Cement, Base RX**Manufacturer:****B.J.M. Laboratories Ltd.**

12 Hassadna St., Industrial Park, Or-Yehuda 6022011, Israel.

Telephone: 972-3-7353000 / Fax. 972-3-7353020

2. Composition / Information on Hazardous Ingredients

Hazardous Ingredients	CAS #	Hazard Identification & Risk Phrases
Triethylglycoldimethacrylate	109-16-0	Xi, R36/37/38, R43
2-Hydroxyethylmethacrylate	868-77-9	Xi, R36/38-43
Co-initiator	10287-53-3	Xi, R36/37/38
Fumed Silica	112945-52-5	R36/37/38
Pink Pigment	1309-37-1	N/E
TiO ₂	13463-67-7	N/E

✓ **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: 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	ADR UN Number Packing Group Proper shipping name	RID Kemler Number
14.2 Transport at sea	ADNR UN Number EMS Packing Group Proper shipping name	IMDG MFAG
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
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

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

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.
