

SAFETY DATA SHEET

ROOT CANAL SEALING MATERIAL

1. Chemical Product and Company Identification

Product Name: ROOT CANAL SEALING MATERIAL, Paste A

Manufacturer: B.J.M. Laboratories Ltd.

Address: 12 Hassadna Street, Industrial Park, Or-Yehuda, 6022011, Israel.

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

2. Composition / Information of Hazardous Ingredients

Hazardous Ingredients	CAS#	Hazard Identification & Risk Phrases
Bisphenol -A-(epichlorhydrin) and Epoxy resin (MW≤700)	25068-38-6	Xi, N, R36/38, R43, R51/53
Zirconium Oxide	1314-23-4	Xi, R36/37/38
Fumed Silica	112926-00-8 7631-86-9	R36/37/38

✓ <u>Additional information:</u> For the wording of the listed risk phrases refer to section 16.

3. Hazards Identification Xi Irritant

<u>Acute Health Hazards:</u> May cause eye, respiratory and skin irritation. <u>Chronic Health Hazards:</u> Material is not known to cause significant health problems.

<u>Signs and Symptoms of Exposure:</u> 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 Cause of Inhalation

If irritation occurs, take victim to open air.

In case of skin contact: wash with soap and water.

<u>In case of eye contact:</u> Flush with large quantities of water for 15 minutes.

Consult a physician.

In case of ingestion: Consult a physician.

Page 1 of 5

5. Fire-Fighting Measures

Flashpoint: N/A

Extinguishing Media: Carbon dioxide, water spray, foam or dry

Revision 3 EU acc. To ISO 11014 Last revised: 09-May-2016 Approved for use: 09-May-2016



chemical

<u>Special Fire Fighting Procedures:</u> Avoid a direct jet of water. Unusual Fire and Explosion Hazards: None.

6. Accidental Release Measures

<u>Environmental Precautions:</u> Avoid seepage into suvers and water supplies. <u>Clean-Up Procedure:</u> 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

<u>Handling:</u> No special measures necessary if handled according to instructions. <u>Storage:</u> 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.

<u>Hand and Skin Protection:</u> Avoid unnecessary skin contact. Wear latex gloves when handling.

<u>Hygiene Measures:</u> Remove spilled material from skin and clothing. Do not eat or drink when handling this material.

9. Physical and Chemical Properties

Appearance: Yellow paste.

Odor: Specific odor.

Boling Point/ Range: N/A

Evaporation Bate (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

<u>Hazardous Polymerization:</u> May occur. <u>Conditions to Avoid:</u> Heat; UV-light.

Incompatibility: Free radicals, reducing agents, heavy metal ions.

<u>Hazardous Decomposition Products:</u> Carbon dioxide, carbon monoxide, acrylic decomposition products, depending on conditions of heating and burning.

11. Toxicological Information

Revision 3 *EU acc. To ISO 11014*Last revised: 09-May-2016
Approved for use: 09-May-2016



Acute oral toxicity:

<u>Irritation of Skin:</u> Dryness and Irritation possible upon prolonged exposure.

Allergic Effects: Individuals may exhibit an allergic reaction.

12. Ecological Information

Do not discharge into suvers or water supplies.

Environmental persistence and degradability: No data available.

<u>Ecotoxicity</u>: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

Also poisonous for fish and plankton in water bodies. Toxic for aquatic organisms

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

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	9 (M6)	RID	
	UN Number	3082	Kemler Number	90
	Packing Group	III		
	Proper shipping name	Miscellaneous Dangerous Substances and Articles		
14.2 Transport at sea	ADNR	9	IMDG	
	UN Number	3082		
	EMS		MFAG	
	Packing Group	III		
		Environmentally		
	Proper shipping name	Hazardous		
		Substance, Liquid		
14.3 Air transport	ICAO / IATA-DGR	9		
	UN Number	3082		
		Environmentally		
	Proper shipping name	Hazardous		
		Substance, Liquid		
	Subsidiary Risk			
	Labels	9		
	Packing Group	III		

<u>U.S. DOT</u> 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

Revision 3 *EU acc. To ISO 11014*Last revised: 09-May-2016
Approved for use: 09-May-2016



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

3082

15.2 National

regulations

15.3 EU number

15.4 Hazard symbols



15.5 Hazard designation 15.6 Risk phrases

Xi: Irritant. N: Dangerous for the environment.

Contains: Epoxy constituents.

R: 22, 36, 37/38, 43, 51/53

36 Irritating to eyes.

37/38 Irritating to respiratory system and skin. 43 May cause sensitization by skin contact.

51/53 Toxic to aquatic organisms may cause long-term

adverse effects in the aquatic environment.

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.

24 Avoid contact with skin.

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. 57 Use appropriate container to avoid environmental

contamination.

60 This material and its container must be disposed of as

hazardous waste.

<u>U.S. – O.S.H.A. Status:</u> 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 Irritating to eyes.

37/38 Irritating to respiratory system and skin.

43 May cause sensitisation by skin contact.

51/53 Toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.

Xi Irritant.

Revision 3 EU acc. To ISO 11014 Last revised: 09-May-2016 Approved for use: 09-May-2016

RCSA

Page 4 of 5



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

AN SI / NFPA 704 DATA Fire = 1 Health = 1 Reactivity = 1 Specific

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.