

SAFETY DATA SHEET Quick SEAL / Q-SEAL

1. Chemical Product and Company Identification

Product Name: Quick SEAL / Q-SEAL

Light curing pit & fissure sealant.

Restrictions on use: For use by dental professionals only.

Manufacturer: B.J.M. Laboratories Ltd.

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

Telephone: +972-74-7000111/ Fax: +972-3-7353020. Website: www.bjmlabs.com, Email: info@bjmlabs.com

EU Rep: **OBELIS S.A**.

Address: Bd. Général Wahis, 53 1030 Brussels, Belgium Telephone: +32.2.732.59.54 / Fax: +32.2.732.60.03 Website: www.obelis.net, Email: Regulatory@obelis.net

2. Hazards Identification Xi Irritant.

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.

3. Composition / Information on Ingredients

Hazardous Ingredients	% by Wt.*	CAS#	Hazard Identification & Risk Phrases
Urethandimethacrylate	<40%	72869-86-4	Xi, H319/335/315
Triethyleneglycoldimethacrylate	<40%	109-16-0	Xi, H319/335/315
4-methacryloxyethyltrimellitic anhydride	<5%	70293-55-9	Xi, H319/335/315
Glass Filler	<4%	65997-18-4	H360
Co-initiator	<1%	10287-53-3	Xi, H319/335/315

Non-Hazardous Ingredients

Bis-GMA	<30%	1565-94-2	N/A
Fumed Silica	<1%	67762-90-7	N/A
Photoinitiators	<1%	10373-78-1	N/A

*The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

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

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.

5. Fire-Fighting Measures

Flashpoint: N/A

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

chemical.

Special Fire Fighting Procedures: 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: White 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

Hazardous Polymerization: May occur.

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Conditions to Avoid: Heat; UV-light.

<u>Incompatibility:</u> 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

Acute oral toxicity: LD50 (rat) > 5000 mg/kg

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

<u>Allergic Effects:</u> 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>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

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This product requires classification according to the criteria of EC. The product is a medical device according to the Council Directive 93/42/EEC and EU Regulation 2017/745 for Medical Devices.

15.1 UN Number 15.2 National regulations 15.3 EU number 15.4 Hazard symbols



15.5 Hazard designation 15.6 Risk phrases

Xi: Irritant. Contains 4-Methacryloxyethyltrimellitic anhydride.

R: 302, 319, 335/315, 317 302 Harmful if swallowed. 319 Irritating to eyes.

335/315 Irritating to respiratory system and skin. 317 May cause sensitization by skin contact.

15.7 Safety phrases

SP: 102, 403, 210, 260, 305+351+338, 303+361+353, 262, 280

102 Keep out of the reach of children.

403 Keep container in a well-ventilated place.

210 Keep away from sources of ignition - No smoking.

260 Do not breathe vapor.

305+351+338 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

303+361+353 After contact with skin, wash immediately with plenty of water and soap. 262 Avoid contact with skin and eyes..

280 Wear suitable gloves and eye/face protection

<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 H-phrases

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302 Harmful if swallowed.

319 Irritating to eyes.

335/315 Irritating to respiratory system and skin.

317 May cause sensitisation by skin contact.

Xi Irritant

Xn Harmful.

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

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This information is based on data considered accurate. However, no warranty is expressed or implied regarding the accuracy of this data, or the results to be obtained from use thereof. In no event will the manufacturer or distributor be responsible for damage 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.

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