

SAFETY DATA SHEET**High-Q-Bond™ Orthodontic Bracket Primer****1. Chemical Product and Company Identification**

Product Name: **High-Q-Bond™ Orthodontic Bracket Primer**

Description: Light-cure bracket adhesive system for direct bonding of metal and ceramic orthodontic brackets to tooth surfaces.

Restrictions on use: For use only by dental professionals.

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

European Representative: **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.

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 of Ingredients

Hazardous Ingredients	% by Wt	CAS #	Hazard Identification & Risk Phrases
Urethane Dimethacrylate	<70%*	72869-86-4	Xi, H317, H411
Triethylenglycoldimethacrylate	<30%*	109-16-0	Xi, R36/37/38, R43
Ethanol	<20%*	64-17-5	H225, H319,
Co-initiator	<1%*	10287-53-3	Xi, H319/335/315
Non-Hazardous Ingredients			
Photoinitiators	<1%*	10337-78-1	N/A
Polymerization accelerators	<1%*	60506-81-2	N/A

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

✓ Additional information: 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.

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, away from light, open flames, contamination. Keep material in original packaging.

8. Exposure Controls/ Personal Protection

Exposure Controls: Use only in well ventilated areas.

Hand and Skin Protection: Avoid unnecessary skin contact. Wear latex gloves 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: Yellowish transparent liquid.

Odour: Specific odor.

Boiling Point/ Range: N/E

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, carbon monoxide, acrylic decomposition products, depending on conditions of heating and burning.

11. Toxicological Information

Acute oral toxicity: LD50 (rat) > 5000 mg/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	RID Kemler Number
14.2 Transport at sea	ADNR UN Number EMS Packing Group	IMDG MFAG
14.3 Air transport	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 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



Xi,

15.5 Hazard designation

Xi: Irritant.

15.6 Risk phrases

H: 302, 319, 335/315, 317
302 Harmful if swallowed
319 Irritating to eyes.
335/315Irritating to respiratory system and skin.
317May cause sensitization by skin contact.

15.7 Safety phrases

P: 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.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 H-phrases

- 319/335/315 Irritating to eyes, respiratory system and skin.
- 317 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

Revision **4.1** *EU acc. to ISO 11014, REACH*
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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.
