

# HIGH-Q-BOND ORTHODONTIC BRACKET ADHESIVE

## 1. Chemical Product and Company Identification

Product Name: High-Q-Bond Orthodontic Bracket Adhesive, Light Cure Adhesive Paste
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<br>& Risk Phrases |
|--------------------------------|-------------|---|
| Urethane Diacrylate Oligomer   | 72869-86-4  | Xi, R36/37/38                           |
| Polymerization accelerators    | 60506-81-2  | N/E                                     |
| Triethylenglycoldimethacrylate | 109-16-0    | Xi, R36/37/38, R43                      |
| 2-Hydroxyethylmethacrylate     | 868-77-9    | Xi, R36/38-43                           |
| Photoinitiators                | 10373-78-1  | N/E                                     |
|                                | 10287-53-3  | Xi, R36/37/38                           |
| Fumed Silica                   | 112945-52-5 | R36/37/38                               |

#### 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.

<u>Primary Routes of Exposure:</u> 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. <u>In case of skin contact:</u> wash with soap and water. <u>In case of eye contact:</u> Flush with large quantities of water for 15 minutes. Consult a physician. <u>In case of ingestion:</u> Consult a physician.

## 5. Fire-Fighting Measures

<u>Flash Point:</u> N/E <u>Extinguishing Media:</u> Carbon dioxide, water spray, dry chemical.

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

## 6. Accidental Release Measures

<u>Environmental Precautions:</u> Avoid seepage into sewers 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, 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. <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: Light yellow paste. Odour: Specific odor. Boling Point/ Range: N/E Evaporation Rate (water = 1): N/A Vapor Density (Air = 1): N/A Solubility in Water: Insoluble

# **10.** Stability and Reactivity

<u>Stability:</u> This material is stable. <u>Hazardous Reactions:</u> None if handled according to directions <u>Hazardous Polymerization:</u> May occur. <u>Conditions to Avoid:</u> 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.

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## 11. Toxicological Information

<u>Acute oral toxicity:</u> 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 suvers 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

| ADR<br>UN Number                                     | RID<br>Kemler<br>Number  |
|--|--|
| Packing Group  | 1 (01110-01  |
| Proper shipping name<br>ADNR<br>UN Number            | IMDG   |
| EMS<br>Packing Group                                 | MFAG   |
| Proper shipping name<br>ICAO / IATA-DGR<br>UN Number |  |
| Proper shipping name<br>Subcidiory Pick              |  |
| Labels   |  |
| Packing Group  |  |
|  | UN Number<br>Packing Group<br>Proper shipping name<br>ADNR<br>UN Number<br>EMS<br>Packing Group<br>Proper shipping name<br>ICAO / IATA-DGR<br>UN Number<br>Proper shipping name<br>Subsidiary Risk<br>Labels |

<u>U.S. DOT</u> Shipping Name: Not Regulated <u>U.S. DOT</u> Hazard Class: None U.N/ N.A. <u>Number:</u> None <u>U.S. Dot Packing Group:</u> None <u>Other:</u> 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

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Revision 5 *EU acc. To ISO 11014* Last revised: 30-July-2014 Approved for use: 30-July-2014



| 2.0.                    |   |
|-------------------------|---|
| 15.3 EU number          |   |
| 15.4 Hazard symbols     |   |
| -                       |   |
|                         |   |
|                         | Xi,   |
| 15.5 Hazard designation | ,   |
|                         | Xi: Irritant.   |
| 15.6 Risk phrases       |   |
| r inte                  | R: 36, 37/38, 43  |
|                         | 22 Harmful if swallowed                                 |
|                         | 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>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**

36/37/38 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.

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