

Safety Data Sheet

Q-CROWN, TEMPORARY CROWN & BRIDGE MATERIAL, CATALYST

1. Chemical Product and Company Identification

Product Name: **Q-CROWN**

Temporary self-cure crown & bridge material, Catalyst

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 Hazardous Ingredients

| Hazardous Ingredients | % by Wt* | CAS# | Hazard Identification & Risk Phrases |
|----------------------------------|----------|------------|--------------------------------------|
| Triethylenglycoldimethacrylate | <20% | 109-16-0 | Xi, H319/335/315, H317 |
| Polymerization activators | <10% | 10287-53-3 | Xi, H319/335/315 |
| Non-Hazardous Ingredients | | | |
| Bis GMA | <35% | 1565-94-2 | N/A |
| Fumed Silica | <5% | 67762-90-7 | N/A |
| Glass filler | <40% | 65997-17-3 | 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 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 | RID |
| | UN Number | Kemle r Number |
| | Packing Group Proper shipping name | |
| 14.2 Transport | ADNR | IMDG |

at sea

UN Number

EMS

MFA

G

Packing Group

Proper shipping

name

ICAO / IATA-

DGR

**14.3 Air
transport**

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****15.5****Hazard
designation**

Xi: Irritant.

15.6 Risk**phrases**

H: 319, 335/315, 317
319 Irritating to eyes.
335/315 Irritating to respiratory system and skin.
317 May 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
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

This 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.

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 2.1 EU acc. to ISO 11014, REACH

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.
