

SAFETY DATA SHEET

Q-Temp™ Base

1. Chemical Product and Company Identification

Product Name: Q-Temp™ Base

<u>Description:</u> Non-Eugenol, self-cure resin-based cement used for the temporary cementation of crowns and bridges, inlays and onlays.

Restrictions on use: For use only by dental professionals.

Manufacturer: B.J.M. Laboratories Ltd.

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

Telephone: +972-74-7000111 / Fax. +972-3-7353020

Email: <u>info@bjmlabs.com</u>
Website: <u>www.bjmlabs.com</u>

European Representative: Obelis S.A.

Bd. General Wahis 53, 1030 Brussels, Belgium Telephone: +32 2 732 59 54 Email: <u>regulatory@obelis.net</u>

2. Hazards Identification

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
Urethane Dimethacrylate	<40%*	Proprietary*	Xi, H317, 411
Polymerization activators	<5%*	10287-53-3	Xi, H319/335/315

Non-Hazardous Ingredients

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Titanium dioxide	<1%*	13463-67-7	N/A
Fumed Silica	<5%*	112945-52-5	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.

Store 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: Gold-Yellow paste

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Last revised: 30-Oct-2023

Approved for use: 31-Oct-2023



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 ADR RID

land

UN Number Kemler

Number

Packing Group

Proper shipping name

14.2 Transport at ADNR IMDG

sea

UN Number

EMS MFAG

Packing Group

Proper shipping name

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14.3 Air transport

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 EC-directive 93/42.

15.1 UN Number

15.2 National

regulations

15.3 EU number

15.4 Hazard

symbols

Xi,

15.5 Hazard

designation Xi: Irritant.

N: Dangerous for the environment.

15.6 Risk phrases

R: 319, 335/315.

319 Irritating to eyes.

335/315 Irritating to respiratory system and skin.

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.

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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

302 Harmful if swallowed.

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



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

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Last revised: 30-Oct-2023

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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SAFETY DATA SHEET

Q-Temp™ Catalyst

1. Chemical Product and Company Identification

Product Name: Q-Temp™ Catalyst

<u>Description:</u> Non-Eugenol, self-cure resin-based cement used for the temporary cementation of crowns and bridges, inlays and onlays.

Restrictions on use: For use only by dental professionals.

Manufacturer: B.J.M. Laboratories Ltd.

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

Telephone: +972-74-7000111 / Fax. +972-3-7353020

Email: <u>info@bjmlabs.com</u>
Website: <u>www.bjmlabs.com</u>

European Representative: Obelis S.A.

Bd. General Wahis 53, 1030 Brussels, Belgium Telephone: +32 2 732 59 54

Email: regulatory@obelis.net, Website: www.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			
Urethane Dimethacrylate	<50%*	Proprietary*	Xi, H317, 411			
Benzoyl Peroxide	<5%*	94-36-0	E, Xi, H242, 319, 317			
Non-Hazardous Ingredients						
Fumed Silica	<5%*	112945-52-5	N/A			
Titanium Oxide	<1%*	13463-67-7	N/A			

^{*} The specific chemical identity and/or exact percentage (concentration) of this composition has

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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,

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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

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OTP



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	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.S. DOT Shipping Name: Not Regulated

U.S. DOT Hazard Class: None

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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

15.6 Risk phrases

H: 319, 335/315

Xi: Irritant

319 Irritating to eyes.

335/315 Irritating to respiratory system and skin.

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

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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.



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 5.1 EU acc. to ISO 11014, REACH

Last revised: 30-Oct-2023

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