

Q-Glass Ortho[™] Powder

1. Chemical Product and Company Identification

Product Name: Q-Glass Ortho[™] Powder

<u>Description:</u> Glass ionomer band cement for bonding orthodontic bands. <u>Restrictions on use:</u> For use only by dental professionals.

Manufacturer: B.J.M. Laboratories Ltd.

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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 and skin irritation in high concentrations.



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		
Poly-acrylic acid	<10%*	9003-01-04	H315, H319		
Non-Hazardous Ingredients					
Strontium Aluminosilicate glass powder	<90%*	Proprietary*	N/A		

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

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

4. First Aid Measures

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B.J.M. Laboratories Ltd.

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/E Extinguishing Media: Carbon dioxide, water spray, dry chemical. Special Fire Fighting Procedures: Use extinguishing method & media suitable to surround fire. 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. Keep material in original packaging.

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: Blue fine powder Odor: Specific odor Boiling Point/Range: N/A Evaporation Rate (Water = 1): N/A Vapor Density (Air = 1): N/A Solubility in Water: 10WT% (dry acid content)

10. Stability and Reactivity

Stability: This material is stable.
Hazardous Reactions: None if handled according to directions.
Hazardous Polymerization: May occur.
Conditions to Avoid: Water.
Incompatibility: Eugenol products
Hazardous 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	ICÃO / 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



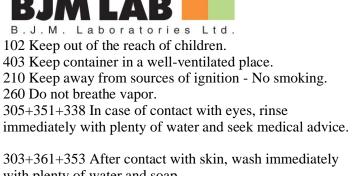
15.5 Hazard designation 15.6 Risk phrases

H: 319, 315319 Irritating to eyes.315 Irritating to respiratory system and skin.

15.7 Safety phrases

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

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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

319/315 Irritating to eyes and skin.



Material should be maintained in original containers. Empty containers should not be re-used.

ANSI/NFPA 704 Data:

Fire = 0 Health = 0 Reactivity = 0 Specific Hazard = None

Revision **3.1** *EU acc. to ISO 11014, REACH* Last revised: **30-Oct-2023**

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