

SAFETY DATA SHEET
Prima 2000 / Prima Quick**1. Chemical Product and Company Identification**Product Name: **Prima 2000 / Prima Quick***Single step bonding agent*Restrictions on use: For use by dental professionals only.Manufacturer: **B.J.M. Laboratories Ltd.**

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Website: www.bjmlabs.com, Email: info@bjmlabs.com.EU Rep: **OBELIS S.A.**

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Website: www.obelis.net, Email: Regulatory@obelis.net**2. Hazards Identification**

Xi, Irritant

H, Highly Flammable

Acute Health Hazards: May cause eye, respiratory and skin irritation.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
Acetone	<50%	67-64-1	H-Flammable, Xi, H319/EUH066/336
Urethane dimethacrylate	<10%	72869-86-4 126646-17-1	Xi, H319/335/315
Triethyleneglycoldimethacrylate	<15%	109-16-0	Xi, H319/335/315, H317
2-Hydroxyethylmethacrylate	<10%	868-77-9	Xi, H319/315-317
Multifunctional dimethacrylates	<10%	24448-20-2	Xi, H319/335/315
4-methacryloxyethyltrimellitic anhydride	<5%	70293-55-9	Xn; H302-319/315-317
Co-initiator	<1%	10287-53-3	Xi, H319/335/315/302/334
Ethanol	<10%	64-17-5	H-Flammable, H225
Non-Hazardous Ingredients			
Filler	<1%	68953-58-2	N/A
Photoinitiator	<1%	10337-78-1	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: $\geq 23^{\circ}\text{C}$ - ≤ 60 (Ethanol solution)

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. 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: Light yellow liquid.

Odour: Specific odour.

Boiling Point: N/A

Flash Point: $\geq 23^{\circ}\text{C}$ - ≤ 60 (Ethanol solution)

Solubility in Water: Insoluble

Vapor Density (Air = 1): N/E

Vapor Pressure (mm Hg): N/E

10. Stability and Reactivity

Stability: Stable if handled according to directions.

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) > 500 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	3	RID	
		Flash Point:		3
		≥ 23°C - ≤ 60		
	UN Number	1170	Kemler Number	---
	Packing Group	III		
	Proper shipping name	Ethanol Solution		
14.2 Transport at sea	ADNR	3	IMDG	3
	UN Number	1170		
	EMS	F-E, S-D	MFAG	
	Packing Group	III		
	Proper shipping name	Ethanol Solution		
14.3 Air transport	ICAO / IATA-DGR	---		
	UN Number	1170		
	Proper shipping name	Ethanol Solution		
	Subsidiary Risk	---		
	Labels	Ethanol Solution		
	Packing Group	III		

U.S. DOT Shipping Name: Ethanol Solution

U.S. DOT Hazard Class: 3

Number: UN1170

U.S. Dot Packing Group: III

Other: Class 3 Flammable Liquids.

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 1170

15.2 National regulations

15.3 EU number

15.4 Hazard symbols

Xi,



H



15.5 Hazard designation Xi: Irritant. H: Highly Flammable. Contains Ethyl Alcohol, HEMA, 4-Methacryloxyethyltrimellitic anhydride, Acetone

15.6 Risk phrases

H: 225, 319, 335/315, 317

225 Harmful if swallowed

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 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 Xi: Irritant.

H-Flammable under the criteria 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

225 Highly flammable.

302 Harmful if swallowed.

319 Irritating to eyes.

335/315 Irritating to respiratory system and skin.

317 May cause sensitisation by skin contact.

H, Flammable.

Xi Irritant.

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

AN SI / NFPA 704 DATA

Fire = 3

Health = 1

Reactivity = 1 Specific

Revision 4.1 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 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.
