

#### SAFETY DATA SHEET

#### PRIMA 1

### 1. Chemical Product and Company Identification

Product Name: PRIMA 1 Universal Cross Generation Dental Adhesive

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 & Risk Phrases	
Acetone	67-64-1	F, Xi, R11/36/66/67	
Ethanol	64-17-5	F, R11	
Triethyleneglycoldimethacrylate	109-16-0	Xi, R36/37/38, R43	
2-Hydroxyethylmethacrylate	868-77-9	Xi, R36/38-43	
4-methacryloxyethyltrimellitic anhydrid	70293-55-9	Xn, R22-36/38-43	
Multifunctional dimethacrylates	24448-20-2	Xi, R36/37/38	
Urethandimethacrylate	72869-86-4	Xi, R36/37/38	
Photoinitiators	10287-53-3	Xi, R36/37/38	
	10373-78-1	N/E	
Fumed Silica	112945-52-5	R36/37/38	

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

# **3. Hazards Identification.** Xi Irritant; 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.

### 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.

<u>In case of ingestion:</u> Consult a physician.

## 5. Fire-Fighting Measures

Flash Point: N/E

Revision 4.2 EU acc. To ISO 11014

Last revised: 30-July-2014 Approved for use: 30-July-2014



Extinguishing Media: Carbon dioxide, water spray, dry chemical. Special Fire Fighting Procedures: Avoid a direct jet of water. Unusial Fire and Explosion Hazards: None.

#### 6. Accidental Release Measures

Environmental Precautions: Avoid seepage into suvers 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

<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. Keep material in original packaging.

## 8. Exposure Controls/ Personal Protection

Exposure Controls: Use only in well ventilated areas.

<u>Hand and Skin Protection:</u> 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 liquid.

Odour: Specific odour. Boling Point: N/A Flash Point: N/E

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.

<u>Hazardous Reactions</u>: None if handled according to directions

<u>Hazardous Polymerization:</u> May occur. <u>Conditions to Avoid:</u> Heat; UV-light.

Incompatibility: 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.

Revision 4.2 EU acc. To ISO 11014 Last revised: 30-July-2014 Approved for use: 30-July-2014



## 11. Toxicological Information

Acute oral toxicity: LD50 (rat) > 500 mg/kg

Irritation of Skin: 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

14.1 Transport at land	ADR	3	RID	3
•	UN Number	1170	Kemler Number	
	Packing Group	III		
	Proper shipping name	Ethanol Solution,		
		Acetone		
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, Acetone		
14.3 Air transport	ICAO / IATA-DGR			
1	UN Number	1170		
	Proper shipping name	Ethanol Solution, Acetone		
	Subsidiary Risk			
	Labels	Ethanol Solution, Acetone		
	Packing Group	III		

<u>U.S. DOT</u> Shipping Name: Ethanol Solution

<u>U.S. DOT</u> Hazard Class: 3

Number: UN1170

U.S. Dot Packing Group: III

Other: Class 3 Flammable Liquids.

Page 3 of 5

Revision 4.2 EU acc. To ISO 11014 Last revised: 30-July-2014

Last revised: 30-July-2014 Approved for use: 30-July-2014



## 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

1170

15.2 National regulations

15.3 EU number

15.4 Hazard symbols



15.5 Hazard designation

Xi, F Xi: Irritant. F: Highly Flammable. Contains Ethyl Alcohol, HEMA, 4-Methacryloxyethyltrimellitic anhydride, Acetone

15.6 Risk phrases

**R:** 11, 36, 37/38, 43 11 Highly flammable. 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.

 $24/25 \ \mbox{Avoid}$  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 Xi: Irritant. F: 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 R-phrases**

11 Highly flammable.

22 Harmful if swallowed.

36 Irritating to eyes.

37/38 Irritating to respiratory system and skin.

43 May cause sensitisation by skin contact.

Xn Harmful. 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

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.

Revision 4.2 *EU acc. To ISO 11014*Last revised: 30-July-2014
Approved for use: 30-July-2014