

Material Safety Data Sheet

ITENA, TotalCem , Catalyst

1. Chemical product and company identification:

Product Name: TotalCem, Adhesive Resin Cement, catalyst

Manufacturer:

ITENA CLINICAL

83, Avenue Foch

75116 Paris –France

Tel: +33 1 45 91 30 06 – Fax: + 33 1 45 91 61 31

2. Composition / Information on Ingredients:

Hazardous Ingredients	CAS #	Hazard Identification & Risk Phrases
Urethandimethacrylate Oligomer	72869-86-4	Xi, R36-38
Triethylenglycoldimethacrylate	109-16-0 Xi	R36/37/38, R43
4-Methacryloxyethyltrimellitic acid	70293-55-9	Xn; R22-36/38-43
Benzoyl Peroxide	94-36-0	Explosive, Xi
Barium aluminoborosilicate glass	65997-17-3	N/E

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

3. Hazards Identification:

Acute Health Hazards:

May cause eye, respiratory 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.

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/E

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.

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:

<u>Solubility in Water:</u>	Insoluble
<u>Appearance:</u>	White / Natural / Yellow paste
<u>Odor:</u>	Specific odor
<u>Boiling Point/Range:</u>	N/A
<u>Evaporation Rate (Water = 1):</u>	N/A
<u>Vapor Density (Air = 1):</u>	N/A

10. Stability and Reactivity:

<u>Stability:</u>	This material is stable.
<u>Hazardous Reactions:</u>	None if handled according to directions
<u>Hazardous Polymerization:</u>	May occur.
<u>Conditions to Avoid:</u>	Heat, UV light and contamination.
<u>Incompatibility:</u>	Free radicals, reducing agents, heavy metal ions
<u>Hazardous Decomposition Products:</u>	Carbon dioxide, water, carbon monoxide, acrylic decomposition products, depending on conditions of heating and burning.

11. Toxicological Information:

<u>Acute oral toxicity:</u>	LD50 (rat) > 5000mg/KG
<u>Irritation of Skin:</u>	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 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
14.3 Air transport	Packing Group Proper shipping name	
	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
- 15.5 Hazard designation
- 15.6 Risk phrases
- 15.7 Safety phrases

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 R-phrases

- | | |
|----------|--|
| 22 | Harmful if swallowed. |
| 36/37/38 | Irritating to eyes, respiratory system and skin. |
| 43 | May cause sensitization by skin contact. |

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

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.
