



Material Safety Data Sheet

ITENA, PreventSeal

1. Chemical product and company identification

Product Name: PreventSeal, Self –etching light cured pit & fissures sealant

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 of Hazardous Ingredients

Hazardous Ingredients	CAS#	Hazard Identification & Risk Phrases
Urethandimethacrylate oligomer	72869-86-4	Xi, R36/37/38
Triethyleneglycoldimethacrylate	109-16-0	Xi
Methacrylated phosphoric acid esters	32435-46-4	Xi, R/36/38-43
4-methacryloxyethyltrimellitic acid	70293-55-9	Xn; Xi; R22-36/38-43
Photoinitiators	10373-78-1	Xi, R36/37/38
	10287-53-3	N/E
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

Xi Irritant

Acute Health Hazards: May cause eye, respiratory and skin irritation.

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 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

Flashpoint: N/A

Extinguishing Media: Carbon dioxide, water spray, foam or 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 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

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: White paste.

Odor: Specific odor.

Boiling Point/ Range: 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, carbon monoxide, acrylic decomposition products, depending on conditions of heating and burning.

11. Toxicological Information

Acute oral toxicity: LD50 (rat) > 5000 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	RID
	UN Number	Kemler Number
	Packing Group	
	Proper shipping name	
14.2 Transport at sea	ADNR	IMDG
	UN Number	



EMS
Packing Group

MFAG

14.3 Air transport

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

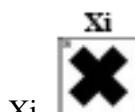
This product requires classification according to the criteria of EC.
The product is a medical device according to the EC-directive 93/42.

15.1 UN Number

15.2 National regulations

15.3 EU number

15.4 Hazard symbols



Xi

15.5 Hazard designation

Xi: Irritant. Contains 4-Methacryloxyethyltrimellitic acid.

15.6 Risk phrases

R: 22, 36, 37/38, 43

22 Harmful if swallowed.

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 advice.

28 After contact with skin, wash immediately with plenty of water and soap.

24/25 Avoid contact with skin and eyes.

37/39 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 R-phrases

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.

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

AN SI / NFPA 704 DATA

Fire = 1

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.
