

Safety Data Sheet according to 1907/2006/EC, Article 31

Silmet Adhesives

Date of revision: 03/2018

Rev. 7

SECTION 1: Identification

1.1 Product Identifier: Dental Adhesives

Trade Names: ProLink, ProLink SE, ProLink Ethanol, ProVeneer Bond

1.2 Relevant identified uses of the substances or mixture

Product Use:

Indications: Intended for the use as a dental restorative material.

Limitations on Use: For use only by dental professionals

1.3 Details of the supplier of the safety data sheet

Manufacturer: Silmet Ltd

Address: 12 Hassadna St. Industrial Park. Or Yehuda 6022011. Israel

Telephone: + 972 3 7353000 (Use for emergency also)

Fax: +972 3 5331581 **e-mail:** info@silmet.co.il

SECTION 2: Hazards Identification

The information below is provided with regard to the toxicity and hazards of the pure components present in this product.

2.1. Classification of the substance or mixture

Hazard-determining components of labeling

Contains Ethyl Alcohol, HEMA, 4-Methacryloxyethyltrimellitic anhydride, Acetone

2.2 Label elements

The product is classified in accordance with 67/548/EEC.

2.3 Other Hazards

Other Hazards: No Significant Hazard

Further information

Labeling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

Classification according to Regulation (EC) No 1272/2008: void

Information concerning particular hazards for human and environment:

The product does not have to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

Label elements

Hazard pictograms



Signal word

Warning

Hazard statements

H226 - Flammable liquid and vapour.

Precautionary statements

Prevention

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Disposal

P501 - Dispose of contents In accordance with local/regional & international regulations

Storage

P403 - Store in a well-ventilated place. Keep container tightly closed.

Other

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.

SECTION 3: Ingredients

Hazardous Ingredients	CAS#
Acetone	67-64-1
Urethandimethacrylate	72869-86-4
Triethyleneglycoldimethacrylate	109-16-0
2-Hydroxyethylmethacrylate	868-77-9
Multifunctional dimethacrylates	24448-20-2
Bisphenol diglycidylmethacrylate	1565-94-2
4-methacryloxyethyltrimellitic anhydrid	70293-55-9
Fumed Silica	7631-86-9
Photoinitiators	10287-53-3 10334-26-6
Ethanol	64-17-5

SECTION 4: First Aid Measures

4.1 First Aid Procedures

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.

SECTION 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.

SECTION 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.

SECTION 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.

SECTION 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.

SECTION 9: Physical and Chemical Properties

Appearance: Light yellow liquid.

Odour: Specific odour.

Boiling Point: N/A

Flash Point: N/E

(Ethanol Solution) $\geq 23^{\circ}\text{C} - \leq 60$

Solubility in Water: Insoluble

Vapor Density (Air = 1): N/E

Vapor Pressure (mm Hg): N/E

SECTION 10: Stability and Reactivity

Stability:	Stable if stored and handled as instructed.
Conditions to avoid	Heat, UV - light
Incompatibility:	Free radicals, reducing agents, heavy metal ions
Hazardous Polymerization:	May occur
Hazardous Decomposition:	Carbon dioxide, carbon monoxide acrylic decomposition products, depending on conditions of heating and burning.

SECTION 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.

SECTION 12: Ecological Information

Do not discharge into sewers or water supplies.

Environmental persistence and degradability: No data available.

Ecotoxicity: No data available.

SECTION 13: Disposable considerations

May be disposed of in landfill or incinerator In accordance with local, state and federal regulations.

SECTION 14: Transport Information

14.1 Transport at land	ADR	3	RID	3
	UN Number	1170	Kemler No.	---
	Packing Group	III		
14.2 Transport at sea	Proper shipping name	Ethanol Solution		
	ADNR	3	IMDG	3
	UN Number	1170		
	EMS	F-E, S-D	MFAG	
	Packing Group	III		
14.3 Air transport	Proper shipping name	Ethanol Solution, Acetone		
	ICAO / IATA-DGR	---		
	UN Number	1170		
	Proper shipping name	Ethanol Solution, Acetone		
	Subsidiary Risk	---		
	Labels	Ethanol Solution, Acetone		
	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.

SECTION 15: Regulatory Information

This product is classified as a medical device under EC Directives, US and Canadian regulations

SECTION 16: Other Information

CAUTION: PRODUCT FOR PROFESSIONAL USE

The information on this safety sheet is based on presently available data and to our best knowledge for the correct handling of the product under normal conditions. Any use of this product in any way not indicated on this sheet or use of this product together with any other process/procedure will be exclusively under the user's responsibility.