

**Safety Data Sheet****Silmet Composites - ProFil Bulk (Classification according to Directive 790/2009/EC)****Date of issue: 13.09.17****SECTION 1: Identification****Product name:** ProFil Bulk - Base**Manufacturer:** Silmet Ltd.**Address:** 12 Hassadna St.  
Industrial Zone, Or Yehuda  
6022011 Israel**Telephone:** + 972 3 7353000**Product use:****Intended Use:** Dental product**Limitations on use:** For use by dental professionals**Specific Use:** Composite restorative material**SECTION 2: Composition/Information on ingredients**

<b>Ingredient</b>	<b>C.A.S. No.</b>
Treated Fumed Silica	67762-90-7
Co-initiator	10287-53-3
Photo initiator	10373-78-1
Triethylenglycoldimethacrylate	109-16-0

**SECTION 3: Hazards Identification**

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

U.S.-O.S.H.A. Status: This material is not hazardous under the criteria of the U.S Federal Hazard Communication Standard.

**Label elements****Hazard pictograms****Signal word**

Warning

**Hazard statements**

H317 - May cause an allergic skin reaction

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

**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.

P102 - Keep out of reach of children.

P352 - Wash with plenty of soap and water.

**Disposal**

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

**Safety Data Sheet****Silmet Composites - ProFil Bulk (Classification according to Directive 790/2009/EC)****Date of issue: 13.09.17****Storage**

P403 - Store in a well-ventilated place.

**Overview****Acute Health Hazards:** May cause eye, respiratory and skin irritation in high concentration.**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.**SECTION 4: First Aid Measures**

The following first aid recommendations are based on assumption that appropriate personal and industrial hygiene practices are followed.

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.

**SECTION 5: Fire Fighting Measures**

Flash point: N/A

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.

**SECTION 7: Handling and Storage**

Handling: No special measures necessary if handled according to instruction

Storage: Keep container tightly closed when not in use. Store in a cool, dry location. Keep material in original packaging.

Storage away from light, open flames, contamination and prolonged storage above 24°C (75°F).

**SECTION 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)

**SECTION 9: Physical and Chemical Properties**

Appearance: White paste / Light-Yellow paste/ Blue paste.

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Odor: Specific odor  
Boiling Point: N/A  
Evaporation Rate (Water = 1): N/A  
Vapor Density (Air = 1): N/A  
Solubility in Water: Insoluble

**SECTION 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, water, carbon monoxide, acrylic decomposition products, depending on conditions of heating and burning.

**SECTION 11: Toxicological Information**

Acute oral toxicity: LD50 (rat) > 5000mg/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**

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

**SECTION 15: Regulatory information**

This product is classified as a medical device under US and Canadian & regulations. This product requires classification according to the criteria of EC.

The product is a medical device according to the EC-directive 93/42

**This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.**

**SECTION 16: Other Information**

ANSI/NFPA 704 Data  
Fire = 1  
Health = 0  
Reactivity = 0  
Specific Hazard = None

**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

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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.

**Safety Data Sheet****Silmet Composites - ProFil Bulk (Classification according to Directive 790/2009/EC)****Date of issue: 13.09.17****SECTION 1: Identification**

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Industrial Zone, Or Yehuda  
6022011 Israel  
**Telephone:** + 972 3 7353000

**Product use:**  
**Intended Use:** Dental product  
**Limitations on use:** For use by dental professionals  
**Specific Use:** Composite restorative material

**SECTION 2: Composition/Information on ingredients**

<b>Ingredient</b>	<b>C.A.S. No.</b>
Treated Fumed Silica	67762-90-7
Benzoyl Peroxide	94-36-0
Triethylenglycoldimethacrylate	109-16-0

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