 <b>SILMET</b>	
<b>Technical File</b>	<b>DMR2-TF2-PackagSDS</b>
<b>Safety Data Sheet</b>	<b>Rev.1</b>
<b>Title: TF2 Packaging- SDS- Composites - ProFil Bulk -Base</b>	<b>Page: 2 of 5</b>
<b>Classification according to Directive 790/2009/EC</b>	<b>Date: 11/11/2019</b>

## 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

Ingredient	C.A.S. No.
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.

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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 & international regulations

#### **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).

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## 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.  
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

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#### 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 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.

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## SECTION 1: Identification

**Product name:** ProFil Bulk - Catalyst

**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	
Benzoyl Peroxide	94-36-0	
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 & international regulations

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#### 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-grey paste

Odor: Specific odor

Boiling Point: N/A

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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 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.