

Safety Data Sheet
Silmet Composites (Classification according to Directive 790/2009/EC)
Date of issue: 25.6.15
Supersedes version of : 07.11.13
Rev. 4
SECTION 1: PRODUCT AND COMPANY IDENTIFICATION
Product name: ProFil

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: HAZARDS IDENTIFICATION
3.1 Emergency Overview
Specific Physical Form: Paste

Odor, Color, Grade: Slightly acrylate odor, tooth colored various shades

General Physical Form: Solid

Immediate health, physical and environmental hazards: May cause allergic skin reaction.

This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredient regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.

3.2 Potential Health Effects
Eye Contact: Moderate Eye Irritation: Signs/symptoms may include localized redness, swelling, pain, tearing and blurred or hazy vision.

Skin Contact: Moderate Skin Irritation: Signs/symptoms may include localized redness, swelling, itching and dryness.

Allergic Skin Reaction (non photo induced): Signs/symptoms may include redness, swelling, blistering and itching

Inhalation: Respiratory Tract Irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, nose and throat pain.

Ingestion: Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

SECTION 3: INGREDIENTS

| Ingredient | C.A.S. No. | % by Wt |
|--|--------------|-----------|
| Barium aluminosilicate | 65997-18-4 | 60-70 |
| Fumed Silica | 1129545-52-5 | 5-15 |
| Bisphenol A Diglycidyl Ether Dimethacrylate (Bis -GMA) | 1565-94-2 | 5-15 |
| Triethylene Glycol Dimethacrylate (TEGDMA) | 109-16-0 | 3-7 |
| Urethanedimethacrylate | 72869-86-4 | 1-5 |
| Camphorquinone | 10373-78-1 | 0.01-0.3 |
| Ethyl-4-dimethylaminobenzoate | 10287-53-3 | 0.01-0.3 |
| Butylated Hydroxytoluene (BHT) | 128-37-0 | 0.001-0.1 |
| Titanium Oxide | 1317-70-0 | 0.1-0.5 |
| Iron Oxide | 1317-61-9 | Trace |
| | | |

SECTION 4: FIRST AID MEASURES

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

Eye Contact: Flush eyes with large amounts of water. If signs/symptoms persist, get medical attention.

Skin contact: Remove contaminated clothing and shoes. Immediately flush skin with large amounts of water. Get medical attention. Wash contaminated clothing and clean shoes before reuse.

Inhalation: Remove person to fresh air. If signs/symptoms persist, get medical attention.

If swallowed: Do not induce vomiting unless instructed to do so by medical personnel.

Give victim 2 glasses of water. Never give anything by mouth to unconscious person. Get medical attention.

SECTION 5: FIRE FIGHTING MEASURES**5.1 Flammable properties**

| | |
|----------------------------------|--------------------|
| Auto ignition temperature | Not data available |
| Flash point | Not applicable |
| Flammable Limits – LEL | Not applicable |
| Flammable Limits – UEL | Not applicable |

5.2 Extinguishing media

Ordinary combustible material. Use fire extinguishers with class A extinguishing agents (e.g. water, foam)

5.3 Protection of fire fighters

Special Fire Fighting Procedures: Wear full protective equipment (Bunker Gear) and a self contained breathing apparatus (SCBA)

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards anticipated.

Note: See **STABILITY AND REACTIVITY (SECTION 10)** for hazardous combustion and thermal decomposition information.

SECTION 6: ACCIDENTAL RELEASE MEASURES**Accidental Release Measures:**

Evacuate unprotected and untrained personnel from hazard area. The spill should be cleaned up by qualified personnel. Ventilate the area with fresh air. Place in a closed container approved for transportation by appropriate authorities. Dispose of collected material as soon as possible. Observe precautions from other sections. Collect as much of the spilled material as possible. Clean up residue.

In the event of a release of this material, the user should determine if the release qualifies as reportable according to local, state and federal regulation.

SECTION 7: HANDLING AND STORAGE**7.1 Handling**

Avoid eye contact. Avoid skin contact. A no touch technique is recommended. If skin contact occurs, wash skin with soap and water.

7.2 Storage

Store in a cool, dry place. Store away from heat. Store away from oxidizing agents.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Engineering controls**

Use in a well-ventilated area.

8.2 Personal Protective Equipment (PPE)**8.2.1 Eye/Face Protection**

Avoid eye contact.

The following eye protection(s) are recommended: Safety Glasses with side shields.

8.2.2 Skin Protection

Avoid skin contact. See Section 7.1 for additional information on skin protection.

8.2.3 Respiratory Protection

Under normal use conditions, airborne exposures are not expected to be significant enough to require respiratory protection.

8.2.4 Prevention of Swallowing

Do not ingest. Wash hands after handling and before eating.

8.3 Exposure Guidelines

| Ingredient | Authority | Type | Limit | Additional Information |
|-------------------------------|-----------|---------------------------------------|---------------------|------------------------|
| Butylated Hydroxytoluene(BHT) | ACGIH | TWA, inhalable, fraction and vapor | 2 mg/m ³ | |

SOURCE OF EXPOSURE LIMIT DATA:

ACGIH: American Conference of Governmental Industrial Hygienists

CMRG: Chemical Manufacturer Recommended Guideline

OSHA: Occupational Safety and Health Administration

AIHA: American Industrial Hygiene Association Workplace Environmental Exposure Level (WEEL)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---------------------------------------|---|
| Specific Physical Form: | Paste |
| Odor, Color, Grade: | Slight acrylate odor, tooth-colored various shade |
| General Physical Form: | Solid |
| Autoignition temperature | No Data Available |
| Flash Point | Not Applicable |
| Flammable Limits - LEL | Not Applicable |
| Flammable Limits - UEL | Not Applicable |
| Boiling point | Not Applicable |
| Density | 1.9 g/cm ³ |
| Vapor Density | Not Applicable |
| Vapor Pressure | Not Applicable |
| Specific Gravity | 1.9 [Ref Std: WATER=1] |
| pH | Not Applicable |
| Melting point | No Data Available |
| Solubility in Water | Negligible |
| Evaporation rate | Not Applicable |
| Kow - Oct/Water partition coef | Not Applicable |
| Viscosity | No Data Available |

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable.

Materials and Conditions to Avoid:

10.1 Conditions to avoid: Heat

10.2 Incompatible Materials: Strong oxidizing agents

Hazardous Polymerization: Hazardous polymerization will not occur.

Hazardous Decomposition or By-Products

| Substance | Condition |
|-----------------|-------------------|
| Carbon monoxide | During Combustion |
| Carbon dioxide | During Combustion |

SECTION 11: TOXICOLOGICAL INFORMATION

Non toxic and high biocompatibility. Please contact the address listed on the 1st page of the MSDS for the Toxicological information on this material and/or its components

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION: Not determined.

CHEMICAL FATE INFORMATION: Not determined.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Method:

Dispose of completely cured (or polymerized) wastes in a sanitary landfill.

As a disposal alternative, incinerate uncured product in an industrial or commercial incinerator in the presence of a combustible material.

EPA Hazardous Waste Number (RCRA): Not regulated

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Since regulations vary, consult applicable regulations or authorities before disposal.

SECTION 14: TRANSPORTATION INFORMATION

Please contact the number listed on the 1st page of this MSDS for Transport Information of this material

SECTION 15: Regulatory information

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada

US FEDERAL REGULATIONS

Hazard Categories:

Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No Immediate Hazard - Yes Delayed Hazard - No

CHEMICAL INVENTORIES

Commercial use of this material is regulated by the FDA

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

SECTION 16: OTHER INFORMATION

Safety Data Sheet

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NFPA Hazard Classification

Health: 2 Flammability: 1 Reactivity: 0 Special Hazards: None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

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.