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Trade name: ProFil, ProFil Flow, ProVeneer, ProFil Posterior

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

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

Main Hazards: No Significant Hazard

2.2 Label elements

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

Risk Phrases: No Significant Hazard

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.


SECTION 3: INGREDIENTS

Chemical characterization: Mixture

Hazardous components:

None

SECTION 4: FIRST AID MEASURES

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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: Note: Uncured material contact to skin directly may cause irritation or skin rash especially in sensitive individuals

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 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

Water fog, CO2, foam, dry chemical

Unusual Fire and Explosion Hazards: Upon combustion irritating gases may form.

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.

Wipe up small spills with paper towels or dry cloth. Clean remainder with alcohol.

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

Only by qualified staff in dental offices or laboratories

7.2 Storage

Avoid exposure to intense light and elevated heat, store in room temperature..

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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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. Wear lab coat.

8.2.3 Respiratory Protection

N/A

8.2.4 Prevention of Swallowing

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

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
Specific Gravity	>1
pH	N/A
Solubility in Water	Insoluble

SECTION 10: STABILITY AND REACTIVITY

Stability: Unstable > 40°C

Materials and Conditions to Avoid:


10.1 Conditions to avoid: Heat and light

10.2 Incompatible Materials: Peroxide and Amines

Hazardous Polymerization: Heat and light.

Hazardous Decomposition: None

SECTION 11: TOXICOLOGICAL INFORMATION

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No data available

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION: Not determined.

CHEMICAL FATE INFORMATION: Not determined.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Method:

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

Land transport ADR/RID

Not classified as dangerous goods in the meaning of transport regulations

Sea transport IMDG

Not classified as dangerous goods in the meaning of transport regulations

Air transport ICAO-TI and IATA-DGR

Not classified as dangerous goods in the meaning of transport regulations

SECTION 15: Regulatory information

Classification according to EC-guidelines:

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

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

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

SECTION 16: OTHER INFORMATION

Changes compared with the previous version:

Adaptation according to REACH-regulation (EC) No. 1907/2006, Article 31

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.