

Safety Data Sheet**Silmet Composites - ProFil Flow SE (Classification according to Directive 790/2009/EC)****Date of issue: 13.11.17****SECTION 1: Identification**

Product name: ProFil Flow SE
Category: Dental Composites
Manufacturer: Silmet Ltd.
Address: 12 Hassadna St. Industrial Zone, Or Yehuda
6022011 Israel
Telephone: + 972 3 7353000 e-mail: info@silmet.co.il URL: www.silmetdental.com

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**Mixtures****Chemical characterization** (preparation): Acrylate.-resin.**Hazardous components**

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH No		
	Dimethacrylate Resin	< 45 %
41637-38-1	Xi - Irritant R36/37/38-43	
	Bis-GMA	15 - 35 %
1565-94-2	Xi - Irritant R41-43	

Full text of R-, H- and EUH-phrases: see section 16.

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.

Classification according to Regulation (EC) No. 1272/2008 [CLP]**Label elements****Hazard pictograms****Signal word:** Danger**Hazard statements**

H335 May cause respiratory irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

Safety Data Sheet

Silmet Composites - ProFil Flow SE (Classification according to Directive 790/2009/EC)

Date of issue: 13.11.17

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.

Precautionary statements

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P501 - Dispose of contents In accordance with local/regional & international regulations

SECTION 4: First Aid Measures

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

4.1. Description of first aid measures

After inhalation

Move victim to fresh air. Put victim at rest and keep warm.

After contact with skin

After contact with skin, wash immediately with: Water and soap.

After contact with eyes

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

After Ingestion

Immediately get medical attention.

SECTION 5: Fire Fighting Measures

5.1. Extinguishing media

Water fog. Extinguishing powder. Sand. Foam. Carbon dioxide (CO₂).

Suitable extinguishing media

High power water jet.

Unsuitable extinguishing media

5.2. Special hazards arising from the substance or mixture

CO_x, NO_x

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear suitable protective clothing. Provide adequate ventilation.

6.2. Environmental precautions

Do not empty into drains or the aquatic environment.

6.3. Methods and material for containment and cleaning up

Collect mechanically.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Advice on safe handling

Keep container tightly closed. Wear suitable protective clothing and gloves. Avoid contact with eyes.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels: Keep container tightly closed in a cool, well-ventilated place. Store only in original container.

SECTION 8: Exposure controls/Personal Protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls:

Ensure adequate ventilation of the storage area.

Safety Data Sheet**Silmet Composites - ProFil Flow SE (Classification according to Directive 790/2009/EC)****Date of issue: 13.11.17****Protective and hygiene measures:** When using do not eat or drink.**Eye/face protection:** Tightly sealed safety glasses.**Hand protection:** Tested protective gloves are to be worn: Suitable material: NBR (Nitrile rubber).**Respiratory protection:** The following must be prevented: inhalation.**SECTION 9: Physical and Chemical Properties****9.1. Information on basic physical and chemical properties**

Physical state: Paste
Colour: Yellow
Odour: like: ester

Test method

not applicable

pH-Value (at 20 °C):

Changes in the physical state

point of decomposition: > 200 °C
Flash point: > 150 °C
Density: 1.8 g/cm³
Water solubility: 1 g/L
(at 20 °C)
Vapour density: > 1

SECTION 10: Stability and Reactivity**Conditions to avoid**

Light. Heat.

Decomposition takes place from temperatures above: 200 °C

Decomposition under formation of: Acrylate

SECTION 11: Toxicological Information**11.1. Information on toxicological effects****Acute toxicity**

LD50: Rat. 5000 mg/kg

Irritation and corrosivity

Frequently or prolonged contact with skin may cause dermal irritation.

Irritant effect on the eye:

Sensitising effects

May cause sensitization by skin contact.

Additional information on tests

Contains Methacrylic esters.: May produce an allergic reaction.

SECTION 12: Ecological Information**12.2. Persistence and degradability**

Preparation not tested.

Further information

Do not empty into drains or the aquatic environment. Leakage into the environment must be prevented.

SECTION 13: Disposable considerations**13.1. Waste treatment methods****Advice on disposal**

Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

Paste: Carry out a burning of hazardous waste according to official regulations .

Waste disposal number of waste from residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except

Safety Data Sheet

Silmet Composites - ProFil Flow SE (Classification according to Directive 790/2009/EC)

Date of issue: 13.11.17

kitchen and restaurant wastes not arising from immediate health care); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing dangerous substances

Classified as hazardous waste.

SECTION 14: Transport Information

Other applicable information

Not a hazardous material with respect to these transportation regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulatory information

Water contaminating class (D): 2 - water contaminating

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

Relevant R-phrases (Number and full text)

36/37/38 Irritating to eyes, respiratory system and skin.

41 Risk of serious damage to eyes.

43 May cause sensitization by skin contact.

Relevant H- and EUH-phrases (Number and full text)

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

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.