

Safety Data Sheet

Silmet GICs – ProGlass Plus, ProBase
(according to 1907/2006/EC, Article 31)

Date of revision: 07.02.16 Rev. 4

Glass Ionomer Cement - Liquid

SECTION 1: Identification

1.1 Product Identifier: Silmet Glass Ionomer Cement – liquid component

Trade Names: ProGlass Plus, ProBase

1.2 Relevant identified uses of the substances or mixture

Product Use:

Indications: Intended for the use as a dental restorative material.

Limitations on Use: For use only by dental professionals

1.3 Details of the supplier of the safety data sheet

Manufacturer: Silmet Ltd

Address: 12 Hassadna St. Industrial Park. Or Yehuda 6022011. Israel

Telephone: + 972 3 7353000 (Use for emergency also)

Fax: +972 3 5331581 **e-mail:** info@silmet.co.il

SECTION 2: Hazards Identification

The information below is provided with regard to the toxicity and hazards of the pure components present in this portion of the unmixed powder/liquid system.

Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008:

Skin Irrit. 2, H315 Causes skin irritation

Eye Irrit. 2, H319 Causes serious eye irritation

Sens Skin 1; H317 May cause an allergic skin reaction

Information concerning particular hazards for human and environment:

The product has to be labeled due to calculation procedure for the “General Classification guideline for preparations of the EU” in the latest version.

Label elements

Labeling according to Regulation (EC) 1272/2008:

Hazard pictograms



Signal word

Warning

Hazard statements

H315 Causes skin irritation

H319 Causes serious eye irritation

H317 May cause an allergic skin reaction

Precautionary statements

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

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contact lenses, if present and easy to do. Continue rinsing.
P302+P352 IF ON SKIN: Wash with plenty of soap and water

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.

Other hazards**Results of PBT and vPvB assessment****PBT:** not applicable**vPvB:** not applicable**SECTION 3: Composition/Information on ingredients****Chemical characterization:** Mixture**Description of the mixture:** Aqueous solution of polyacids and methacrylates**Hazardous components:****CAS-Nr.** 868-77-9 2-Hydroxyethyl-methacrylate GHS07, H315, H319, H317**SECTION 4: First Aid Measures****General information:** Seek medical advice, if symptoms occur, which can be caused by the product.**after skin contact:** wash with plenty of water and soap**after inhalation:** supply with fresh air**after eye contact:** rinse opened eye for several minutes under running water and consult a doctor**after swallowing:** seek medical advice if problems persist.**SECTION 5: Fire Fighting Measures****Extinguishing media:**CO₂, powder, water spray.

Use extinguishing method and media suitable to surrounding fire

Special hazards arising from the substance or mixture No further relevant information available**Protective equipment** Wear self-contained respiratory protective equipment**SECTION 6: Accidental Release Measures****Personal precautions, protective equipment and emergency procedures:** not necessary**Environmental precautions:**

Do not allow to enter drains/surface water/ ground-water.

Methods for cleaning up:

Absorb with liquid binding material. Clean up affected area.

Reference to other sections:

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment

See Section 13 for disposal information

SECTION 7: Handling and Storage**Handling:**

This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Precautions for safe handling: Observe normal care for working with chemicals**Information about fire and explosion protection:** No special measures required**Storage:**

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Requirements at storerooms and containers: Store only in the original containers
Further information on storage conditions: Store at dry place, at room temperature (< 25°C, 78°F). Store away from food stuffs. Always store with lid on
Specific end uses: No further relevant information available

SECTION 8: Exposure Controls/Personal Protection

Components with limits of values to be supervised at the workplace:

The product contains no relevant quantities of components with limit values to be supervised at the workplace.

Additional information: The lists valid during the making were used as basis

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.
 Keep away from foodstuffs and beverages.

Hand protection

Protective gloves.

Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: safety glasses

Respiratory protection: Required, when aerosols are generated

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance

Form: liquid

Color: colorless

Odor: faint odor

	Value	Unit	Method
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Safety relevant basic data

Melting point/melting range:

n.a.

Boiling point/boiling range:

approx. 100 °C

Flash point:

> 100 °C

Ignition temperature:

Product is not self igniting

Danger of explosion:

None

Density:

1.20 g/cm³

Vapor pressure:

Not applicable (solute substance non volatile)

Viscosity:

liquid

pH

ca. 2.5

Solubility in/miscibility with:

Water: Very soluble

Content of solvents: none

Organic solvents: none

SECTION 10: Stability and Reactivity

Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications. Avoid heat, direct sunlight, reactive materials e.g. peroxides.

Possibility of hazardous reactions: No dangerous reaction known

Conditions to avoid: No further relevant information available

Incompatible materials: No further relevant information available

Hazardous decomposition products: No dangerous decomposition products known.

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SECTION 11: Toxicological Information

Acute toxicity:
Primary irritation:
skin: irritating effect
eye: irritating effect
Sensitization: risk of skin sensitization
Additional toxicological information:
 Allergic reaction by chronic exposure to product are possible.
 When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

SECTION 12: Ecological Information

Toxicity:
Aquatic toxicity: No further relevant information available
Persistence and degradability: No further relevant information available
Behavior in environmental systems:
Bioaccumulative potential No further relevant information available
Mobility in soil No further relevant information available
General information: Do not allow undiluted product or large quantities of it into surface water or sanitary sewer system

SECTION 13: Disposal Considerations

Product:
Recommendation: Use proper landfill disposal or incineration in accordance with local, state and federal regulations
Uncleaned packaging: Recommendation: Disposal must be made according to official regulations

SECTION 14: Transport Information

Land transport ADR/RID and GGVs/GGVE (Germany)
 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

This product is classified as a medical device under US and EU regulations. The product has been marked in accordance with EU Directives and has been reviewed by the US Food and Drug Administration.

US FEDERAL REGULATIONS

CHEMICAL INVENTORIES

Commercial use of this material is regulated by the FDA

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

Changes compared with the previous version:

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

SECTION 16: Other Information

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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Glass Ionomer Cement –Powder

SECTION 1: Identification

1.1 Product Identifier: Silmet Glass Ionomer Cement – Powder component

Trade Names: ProGlass Plus, ProBase

1.2 Relevant identified uses of the substances or mixture

Product Use:

Indications: Intended for the use as a dental restorative material.

Limitations on Use: For use only by dental professionals

1.3 Details of the supplier of the safety data sheet

Manufacturer: Silmet Ltd

Address: 12 Hassadna St. Industrial Park. Or Yehuda 6022011. Israel

Telephone: + 972 3 7353000 (Use for emergency also)

Fax: +972 3 5331581 **e-mail:** info@silmet.co.il

SECTION 2: Hazards Identification

Classification of the substance or mixture:

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.

Label elements

Labeling according to Regulation (EC) 1272/2008: void

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.

Other hazards

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

SECTION 3: Composition/Information on ingredients

Chemical characterization: Mixture

Description of the mixture: barium-fluoro-aluminosilicate glass powder, pigments, initiators

Hazardous components: none

SECTION 4: First Aid Measures

General information: no special measures required

after skin contact: wash with plenty of water and soap

after inhalation: supply with fresh air

after eye contact: rinse opened eye for several minutes under running water and consult a doctor

after swallowing: seek medical advice if problems persist

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SECTION 5: Fire Fighting Measures

Extinguishing media:

CO₂, powder, water spray.

Use extinguishing method and media suitable to surrounding fire

Special hazards arising from the substance or mixture No further relevant information available

Protective equipment Wear self-contained respiratory protective equipment

SECTION 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Environmental precautions: Do not allow to enter drains/surface water/ ground-water.

Methods for cleaning up: Take up mechanically. Clean up affected area.

Reference to other sections:

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment

See Section 13 for disposal information

SECTION 7: Handling and Storage

Handling:

This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Precautions for safe handling: Observe normal care for working with chemicals

Information about fire and explosion protection: No special measures required

Storage:

Requirements at storerooms and containers: Store only in the original containers

Further information on storage conditions: Store at dry place, at room temperature (< 25°C, 78°F). Store away from food stuffs. Always store with lid on

Specific end uses: No further relevant information available

SECTION 8: Exposure Controls/Personal Protection

Components with limits of values to be supervised at the workplace:

The product contains no relevant quantities of components with limit values to be supervised at the workplace.

Additional information: The lists valid during the making were used as basis

Personal protective equipment:

General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs and beverages.

Hand protection

Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: safety glasses

Respiratory protection: Required, when aerosols are generated

SECTION 9: Physical and Chemical Properties

Information on basic physical and chemical properties

Appearance

Form: Fine powder

Color: white

Odor: odorless

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	Value	Unit	Method
Safety relevant basic data			
Melting point/melting range:	n.a.		
Boiling point/boiling range:	n.a.		
Flash point:	n.a.		
Ignition temperature:	Product is not self igniting		
Danger of explosion:	None		
Density:	Not determined		
Vapor pressure:	Not applicable (non volatile)		
Solubility in/miscibility with:			
Water:	slightly		
Content of solvents:	none		
Organic solvents:	none		
10: Stability and Reactivity			
Thermal decomposition / conditions to be avoided			
No decomposition if used according to specifications. Avoid heat and direct sunlight.			
Possibility of hazardous reactions: No dangerous reaction known			
Conditions to avoid: No further relevant information available			
Incompatible materials: No further relevant information available			
Hazardous decomposition products: No dangerous decomposition products known.			
SECTION 11: Toxicological Information			
Acute toxicity:			
Primary irritation:			
skin: may cause skin irritation (aerosols)			
eye: irritating effect (aerosols)			
Sensitization: no sensitizing effect known			
Additional toxicological information:			
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.			
SECTION 12: Ecological Information			
Toxicity:			
Aquatic toxicity: No further relevant information available			
Persistence and degradability: No further relevant information available			
Behavior in environmental systems:			
Bioaccumulative potential No further relevant information available			
Mobility in soil No further relevant information available			
General information: Do not allow undiluted product or large quantities of it into surface water or sanitary sewer system			
SECTION 13: Disposal Considerations			
Product:			
Recommendation:			
Use proper landfill disposal or incineration in accordance with local, state and federal regulations			
Uncleaned packaging:			

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Recommendation: Disposal must be made according to official regulations

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Air transport ICAO-TI and IATA-DGR

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SECTION 16: Other Information

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