

Safety Data Sheet

Silmet GICs – ProGlass One, ProGlass Two, ProGlass Nine, ProGlass Silver
(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

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.

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: Composition/Information on ingredients

Safety Data Sheet**Silmet GICs – ProGlass One, ProGlass Two, ProGlass Nine, ProGlass Silver
(according to 1907/2006/EC, Article 31)****Date of revision: 07.02.16 Rev. 4****Substance/Mixture:** Mixture

Other means of identification: Not available

CAS number/other identifiers**CAS #**

Acrylic Acid Polymer 9003-01-4

Other Ingredients

Water

Hazardous components: None

SECTION 4: First Aid Measures

4.1. Description of first aid measures

Inhalation: Move the exposed person to fresh air.

Eye contact: Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist.

Skin contact: Wash off immediately with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist.

Ingestion : **DO NOT INDUCE VOMITING.** Seek medical attention if irritation or symptoms persist.

4.2. Most important symptoms and effects, both acute and delayed

Inhalation: May cause irritation to mucous membranes.

Eye contact: May cause irritation to eyes.

Skin contact: May cause irritation to skin.

Ingestion: May cause irritation to mucous membranes.

4.3. Indication of any immediate medical attention and special treatment needed

If you feel unwell, seek medical advice

SECTION 5: Fire Fighting Measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation of the working area.

6.2. Environmental precautions

Do not allow product to enter drains. Prevent further spillage if safe.

6.3. Methods and material for containment and cleaning up

Sweep up. Transfer to suitable, labeled containers for disposal. Clean spillage area thoroughly with plenty of water.

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6.4. Reference to other sections: SECTION 13: Disposal considerations.
Storage, handling and special precautions: Store in a cool dry place in tightly closed container.

SECTION 7: Handling and Storage

7.1 Handling: This product should only be supplied or handled to dentists or dental technicians or upon their Instructions.

7.2. Precautions for safe handling

Observe normal care for working with chemicals

Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing.

7.3. Conditions for safe storage, including any incompatibilities

Keep in a cool, dry, well ventilated area. Keep containers tightly closed. Store in correctly labeled containers.

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.

8.1 Engineering controls

Use in a well-ventilated area.

8.2 Personal Protective Equipment (PPE)

Eye/Face Protection

Avoid eye contact.

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

Skin protection – Hand protection

Chemical resistant gloves.

Prevention of Swallowing

Do not ingest. Wash hands after handling and before eating

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance: Viscous liquid.

Colour: Clear/Colourless

Odour: Slight/Odourless

pH: 3

Solubility: Soluble in water

9.2. Other information

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None.
SECTION 10: Stability and Reactivity
<p>10.1. Reactivity: Stable.</p> <p>10.2. Chemical stability: Stable under normal conditions.</p> <p>10.3. Possibility of hazardous reactions: No data available.</p> <p>10.4. Conditions to avoid: Heat.</p> <p>10.5. Incompatible materials: Strong acids. Strong bases.</p> <p>10.6. Hazardous decomposition products: Carbon dioxide (CO2).</p>
SECTION 11: Toxicological Information
No data available
SECTION 12: Ecological Information
<p>12.1. Toxicity No data available</p> <p>12.2. Persistence and degradability No data is available on this product.</p> <p>12.3. Bioaccumulative potential No data is available on this product.</p> <p>12.4. Mobility in soil No data available.</p> <p>12.5. Results of PBT and vPvB assessment None.</p> <p>12.6. Other adverse effects No data is available on this product.</p>
SECTION 13: Disposal Considerations
<p>13.1. Waste treatment methods Dispose of in compliance with all local and national regulations.</p> <p>Disposal methods For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.</p> <p>Disposal of packaging Do NOT reuse empty containers. Empty containers can be sent for disposal or recycling. Recommendation: Consult applicable regulations or authorities before disposal.</p>
SECTION 14: Transport Information
<p>Land transport ADR/RID Not classified as dangerous goods in the meaning of transport regulations</p> <p>Sea transport IMDG Not classified as dangerous goods in the meaning of transport regulations</p> <p>Air transport ICAO-TI and IATA-DGR Not classified as dangerous goods in the meaning of transport regulations</p> <p>Special precautions for user: Not applicable. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code The product is not classified as dangerous for carriage.</p>

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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

311/312 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 SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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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Silmet GICs – ProGlass One, ProGlass Two, ProGlass Nine, ProGlass Silver
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Glass Ionomer Cement –Powder

SECTION 1: Identification

1.1 Product Identifier: Silmet Glass Ionomer Cement – Powder component

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.

2.1. Classification of the substance or mixture

Main Hazards: No Significant Hazard

2.2 Label elements

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: Composition/Information on ingredients

Substance/Mixture: Mixture

Other means of identification: Not available

CAS number/other identifiers

CAS #

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Acrylic Acid Polymer 9003-01-4
 Glass Powder 65997-18-4

Other Ingredients

ProGlass Silver also contains silver

Hazardous components: None

SECTION 4: First Aid Measures

4.1. Description of first aid measures

Inhalation: Move the exposed person to fresh air.
 Eye contact: Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist.
 Skin contact: Wash off immediately with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist.
 Ingestion: DO NOT INDUCE VOMITING. Seek medical attention if irritation or symptoms persist.

4.2. Most important symptoms and effects, both acute and delayed

Inhalation: May cause irritation to mucous membranes.
 Eye contact: May cause irritation to eyes.
 Skin contact: May cause irritation to skin.
 Ingestion: May cause irritation to mucous membranes.

4.3. Indication of any immediate medical attention and special treatment needed

No data is available on this product.

SECTION 5: Fire Fighting Measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation of the working area.

6.2. Environmental precautions: Do not allow product to enter drains. Prevent further spillage if safe.

6.3. Methods and material for containment and cleaning up: Sweep up. Transfer to suitable, labeled containers for disposal.

Clean spillage area thoroughly with plenty of water.

6.4. Reference to other sections: SECTION 13: Disposal considerations

Storage, handling and special precautions: Store in a cool dry place in tightly closed container.

SECTION 7: Handling and Storage

Handling: This product should only be supplied or handled to dentists or dental technicians or upon their Instructions.

7.1. Precautions for safe handling

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Observe normal care for working with chemicals
Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing.

7.2. Conditions for safe storage, including any incompatibilities

Keep in a cool, dry, well ventilated area. Keep containers tightly closed. Store in correctly labeled containers.

7.3. Specific end use(s): None.

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.

8.1 Engineering controls

Use in a well-ventilated area.

8.2 Personal Protective Equipment (PPE)

Individual Protection Measures: Wear protective clothing.

Eye/Face Protection: Avoid eye contact.

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

Sink/Hand Protection: Chemical resistant gloves.

Prevention of Swallowing: Do not ingest. Wash hands after handling and before eating

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance: Powder

Color: White

Odor: Odorless

9.2. Other information

No data available.

10: Stability and Reactivity

10.1. Reactivity : Stable.

10.2. Chemical stability: Stable under normal conditions.

10.3. Possibility of hazardous reactions: No data available.

10.4. Conditions to avoid: Heat, open flames, sparks

10.5. Incompatible materials: oxidizing agents

10.6. Hazardous decomposition products

No data is available on this product.

SECTION 11: Toxicological Information

Acute toxicity:

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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

13.1. Waste treatment methods
 Dispose of in compliance with all local and national regulations.

Disposal methods

For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.

Recommendation:

Use proper landfill disposal or incineration in accordance with local, state and federal regulations

Disposal of packaging

Do NOT reuse empty containers.

Recommendation: Consult applicable regulations or authorities before disposal. Disposal must be made according to official regulations

SECTION 14: Transport 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

Special precautions for user: Not applicable.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

The product is not classified as dangerous for carriage.

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

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

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.