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Trade Names: Glass Ionomer Cements

Liquid Part (ProBase, Plus)

SECTION 1: Identification
<p>1.1 Product Identifier: Silmet Glass Ionomer Cement – liquid component Trade Names: ProGlass Plus, ProBase</p> <p>1.2 Relevant identified uses of the substances or mixture</p> <p>Product Use: Indications: Intended for the use as a dental restorative material. Limitations on Use: For use only by dental professionals</p> <p>1.3 Details of the supplier of the safety data sheet</p> <p>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</p>
SECTION 2: Hazards Identification
<p>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.</p> <p>Classification of the substance or mixture:</p> <p>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</p> <p>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.</p> <p>Label elements</p> <p>Labeling according to Regulation (EC) 1272/2008: Hazard pictograms</p> <div style="text-align: center;">  </div> <p>Signal word Warning</p> <p>Hazard statements H315 Causes skin irritation H319 Causes serious eye irritation H317 May cause an allergic skin reaction</p> <p>Precautionary statements P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P302+P352 IF ON SKIN: Wash with plenty of soap and water</p> <p>Labeling according to EU guidelines:</p>

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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:


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

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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
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: Toxilogical Information
<p>Acute toxicity:</p> <p>Primary irritation:</p> <p>skin: irritating effect</p> <p>eye: irritating effect</p> <p>Sensitization: risk of skin sensitization</p> <p>Additional toxicological information:</p> <p>Allergic reation by chronic exposure to product are possible.</p> <p>When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.</p>
SECTION 12: Ecological Information
<p>Toxicity:</p> <p>Aquatic toxicity: No further relevant information available</p> <p>Persistence and degradability: No further relevant information available</p> <p>Behavior in environmental systems:</p> <p>Bioaccumulative potential No further relevant information available</p> <p>Mobility in soil No further relevant information available</p> <p>General information: Do not allow undiluted product or large quantities of it into surface water or sanitary sewer system</p>
SECTION 13: Disposal Considerations
<p>Product:</p> <p>Recommendation: Use proper landfill disposal or incineration in accordance with local, state and federal regulations</p> <p>Uncleaned packaging: Recommendation: Disposal must be made according to official regulations</p>
SECTION 14: Transport Information
<p>Land transport ADR/RID and GGVs/GGVE (Germany)</p> <p>Not classified as dangerous goods in the meaning of transport regulations</p> <p>Sea transport IMDG</p> <p>Not classified as dangerous goods in the meaning of transport regulations</p> <p>Air transport ICAO-TI and IATA-DGR</p> <p>Not classified as dangerous goods in the meaning of transport regulations</p>
SECTION 15: Regulatory Information
<p>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.</p> <p>US FEDERAL REGULATIONS</p> <p>CHEMICAL INVENTORIES</p> <p>Commercial use of this material is regulated by the FDA</p> <p>This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.</p> <p>Changes compared with the previous version:</p> <p>Adaptation according to REACH-regulation (EC) No. 1907/2006, Article 31</p>
SECTION 16: Other Information
<p>CAUTION: PRODUCT FOR PROFESSIONAL USE</p> <p>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.</p>


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Powder Part (ProBase, Plus)

SECTION 1: Identification
<p>1.1 Product Identifier: Silmet Glass Ionomer Cement – Powder component Trade Names: ProGlass Plus, ProBase</p> <p>1.2 Relevant identified uses of the substances or mixture</p> <p>Product Use: Indications: Intended for the use as a dental restorative material. Limitations on Use: For use only by dental professionals</p> <p>1.3 Details of the supplier of the safety data sheet</p> <p>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</p>
SECTION 2: Hazards Identification
<p>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.</p> <p>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.</p> <p>Other hazards Results of PBT and vPvB assessment PBT: not applicable vPvB: not applicable</p>
SECTION 3: Composition/Information on ingredients
<p>Chemical characterization: Mixture Description of the mixture: barium-fluoro-aluminosilicate glass powder, pigments, initiators Hazardous components: none</p>
SECTION 4: First Aid Measures
<p>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</p>
SECTION 5: Fire Fighting Measures
<p>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</p>

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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			
	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.			

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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: 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 Changes compared with the previous version: Adaptation according to REACH-regulation (EC) No. 1907/2006, Article 31 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.