

Safety Data Sheet

Silmet GICs – ProBase (Classification according to Directive 790/2009/EC)

Date of issue: 07.11.13

Replaces version of : 30.05.2010

Rev. 2

ProBase –Liquid

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Manufacturer: Silmet Ltd.
 Address: 12 Hassadna St.
 Industrial Zone, Or Yehuda
 60200 Israel
 Telephone: + 972 3 5331474

Common name: ProBase – Liquid
 Chemical name: N.A

Product use:
 Intended Use: Dental product
 Limitations on use: For use by dental professionals
 Specific Use: Reinforced glass ionomer cement – liquid component

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.

SECTION 2: INGREDIENTS

Component	C.A.S	Exposure limits	LD50/LC50	%
Distilled water	7732-18-15	N.E	N.E	20-30
Polyacrylic acid	9003-01-4	TWA = 10ppm (ACGIH)	LD50=2500mg/kg (oral rat) LC50=N.E	20-30
2-Hydroxyethylmethacrylate	868-77-9	N.E	LD50=5888mg/kg (oral rat) LC50=N.E	25-35
Urethanedimethacrylate	72869-86-4	N.E	N.E	5-10

SECTION 3: HAZARDS IDENTIFICATION

	Yes	No	NE	NA	NTP	IARC	OSHA	Other
Mutagenic affects		X						
Teratogenic affects		X						
Reproductive toxin		X						
Carcinogenicity		X						
Sensitizer		X						

Routes of entry: Inhalation Skin Ingestion

Health hazard(acute & chronic): Acidic solution (pH=1.90), care should be taken to avoid contact with skin or eyes.

SECTION 4: FIRST AID MEASURES

After skin contact: Immediately wash with water and soap and rinse thoroughly.
After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, seek medical assistance
After swallowing: If symptoms persist, seek medical assistance

SECTION 5: FIRE FIGHTING MEASURES

Flash point	Not flammable	Hazardous combustion products: Emits acrid smoke when heated beyond boiling point. Special Fire Fighting Procedures: Full protective clothing and self contained breathing apparatus.
Flammable Limits	N.A	
Extinguishing media:	Alcohol foam	
Unusual fire & Exposure hazards	None	

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SECTION 6: ACCIDENTAL RELEASE MEASURES

In case of release or spill: Absorb with liquid binding material (sand, diatomite, acid binders, universal binders, sawdust).

Ensure adequate ventilation

Do not allow to enter sewers/ surface or ground water

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

SECTION 7: HANDLING AND STORAGE

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Store in a cool dry place in tightly closed container.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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.

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

Appearance & odour Colorless, slightly viscous and odorless liquid

Specific gravity (H₂O=1) 1.18

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

Flash point: Not applicable.

Self-igniting: Product is not self igniting.

Danger of explosion: Product does not present an explosion hazard.

Density: Not determined

SECTION 10: STABILITY AND REACTIVITY

Stability : Stable Unstable

Polymerization: Will Not Occur Will Occur

Conditions to avoid: High heat

Incompatibility (Materials to Avoid): Alkali will inactivate product

Hazardous decomposition or by-products: N.E.

SECTION 11: TOXICOLOGICAL INFORMATION

Please contact the address listed on the 1st page of the MSDS for the Toxicological information on this material and/or its components

SECTION 12: ECOLOGICAL INFORMATION

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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SECTION 13: DISPOSAL CONSIDERATIONS

Do not dispose together with household garbage. Do not allow product to reach sewage system.
Recommendation: Consult applicable regulations or authorities before disposal.

SECTION 14: TRANSPORTATION INFORMATION

Please contact the number listed on the 1st page of this MSDS for Transport Information of this material

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 MSDS 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.

Safety Data Sheet

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ProBase –Powder

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Manufacturer: Silmet Ltd.
 Address: 12 Hassadna St.
 Industrial Zone, Or Yehuda
 60200 Israel
 Telephone: + 972 3 5331474

Common name: ProBase – Powder
 Chemical name: N.A

Product use:
 Intended Use: Dental product
 Limitations on use: For use by dental professionals
 Specific Use: Reinforced glass ionomer cement – powder component

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.

SECTION 2: INGREDIENTS

Component	C.A.S	Exposure limits	LD50/LC50	%
Alumino-silicate glass	Not listed	TLV =10mg/m ³ PEL = 15mg/m ³ (ACGIH)	N.E	95 - 100

SECTION 3: HAZARDS IDENTIFICATION

	Yes	No	NE	NA	NTP	IARC	OSHA	Other
Mutagenic affects		X						
Teratogenic affects		X						
Reproductive toxin		X						
Carcinogenicity		X						
Sensitizer		X						

Routes of entry: Inhalation Skin Ingestion

Health hazard(acute & chronic): Contains silica glass which is considered a hazard by inhalation. IARC has classified it as a probable carcinogenic for humans. Dusts of silica glass is also a known cause of silicosis, a non-cancerous lung disease.

Signs & symptoms of overexposure: Irritation and soreness in throat and nose.

Conditions generally aggravated by exposure: May aggravate preexisting upper respiratory and lung disease.

Emergency first aid procedures:
Inhalation: Remove to fresh air, drink water to clear throat and blow nose to evacuate dust.
Ingestion: Do not induce vomiting – give large volumes of water. Seek medical attention.
Skin: Wash with soap and water. If irritation develops seek medical attention.
Eyes: Flush with water for 15 minutes . If irritation develops or persists seek medical attention.

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After skin contact: Immediately wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, seek medical assistance

After swallowing: If symptoms persist, seek medical assistance

SECTION 5: FIRE FIGHTING MEASURES

Flash point Not flammable

Flammable Limits N.A

Extinguishing media: Alcohol foam

Unusual fire & Exposure hazards None

Hazardous combustion products: Emits acrid smoke when heated beyond boiling point.

Special Fire Fighting Procedures: Full protective clothing and self contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

In case of release or spill: Absorb with liquid binding material (sand, diatomite, acid binders, universal binders, sawdust).

Ensure adequate ventilation

Do not allow to enter sewers/ surface or ground water

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

SECTION 7: HANDLING AND STORAGE

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

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8.1 Engineering controls

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8.2 Personal Protective Equipment (PPE)

Eye/Face Protection

Avoid eye contact.

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

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

Boiling Point N.E
Vapour pressure N.A
Vapour density N.A
Solubility in water Insoluble
Appearance & odour Very fine white powder

Specific gravity (H₂O=1) 2.56
Melting point > 1,350°C
Evaporation rate N.A
Odor threshold N.E
Coefficient of oil/water distribution N.E

10: STABILITY AND REACTIVITY

Stability : Stable Unstable

Polymerization: Will Not Occur Will Occur

Conditions to avoid: High heat

Incompatibility (Materials to Avoid): Alkali will inactivate product.

Hazardous decomposition or by-products: N.E.

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