

Safety Data SheetTrade Name: **GLASS IONOMER CEMENTS**

1.0 Commercial Product Name and Supplier																
1.1	Commercial product name / designation GlassFill™, GlassLine™, GlassLute™ OrthoChoice™ Glass Ionomer Band Cement															
1.2	Application / Use Dental material for use by dental professional only.															
1.2.2	SIC 851 Human health activity															
1.2.3	Use Category 55															
1.3	Manufacturer Pulpdent Corporation 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA Telephone: 1 617 926-6666 / Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com															
1.4	Emergency Telephone Number 1-800-535-5053 (24 Hour / USA)															
1.5	Authorized European Representative Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta															
	UK Responsible Person Advena Limited Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom															
	CH Authorized Representative MedEnvoy Switzerland Gotthardstrasse 28, 6302 Zug, Switzerland															
2.0 Hazards Identification																
2.1	Classification															
2.11	Classification according to Regulation (EC) No 1272/2008 [CLP]															
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<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>														
Eye irritation	2	H319														
STOT SE	3	H335														
Skin irritation	2	H315														
Skin sensitization	1	H317														
2.1.2	Classification according to Directive 67/548/EEC Irritant (Xi); R 36/37/38-43 (See SECTION 16 for full text of risk phrases)															
2.2	GHS Label Elements															
	Hazard Pictograms															
																
	Signal Word: WARNING															
	Restricted to use by dental professional only.															
	Hazard Statements															
	H319: Eye irritation. 2. May cause eye irritation.															
	H335: STOT SE. 3. May cause respiratory irritation.															
	H315: Skin irritation. 2. May cause skin irritation.															
	H317: Sensitization. 1. May cause an allergic skin reaction.															
	Precautionary Statements															
	P261: Avoid breathing powder/dust.															

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P280: Wear protective gloves and eye protection

P305+P351: If in eyes, rinse cautiously with water for several minutes.

P337+P313: If eye irritation persists, get medical advice/attention.

P302+P352: If on skin, wash with plenty of soap and water.

P304+340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P333+P313: If irritation or rash occurs, get medical advice/attention.

3.0 Composition

3.1 Chemical characterization of the preparation: Glass ionomer cements in two parts, powder and liquid, that are mixed together just before use.

3.2 Hazardous ingredients

	CAS Number	Name of the Ingredient	Concentration	Classification according to 67/548/EEC	Classification according to Regulation (EC) No.1272/2008 (CLP).
Powder	----	Alumino-fluorosilicate glass	92-100%	Xi (irritant); R: 36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
Liquid	9003-01-4	Polyacrylic acid	30-40%	Xi (irritant); R: 36/37/38-43	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317

4.0 First Aid Measures

4.1	Special Instructions	May be irritating to eyes, respiratory system, mucous membranes and skin. Liquid may cause sensitization by prolonged or repeated skin contact. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.
4.2	Inhalation	Move to fresh air. If necessary, administer oxygen and/or artificial respiration and seek medical attention.
4.3	Skin Contact	Wash skin thoroughly with soap and running water.
4.4	Eye Contact	Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention if irritation persists.
4.5	Ingestion	Rinse mouth and seek medical attention. Never give anything by mouth to an unconscious person.
4.6	Precautions for first responders	Wear safety glasses, gloves and lab coat. If powder has dispersed into the air, wear dust mask.
4.7	Information for physician	
	Symptoms	Red and/or irritated eyes, mucous membranes or skin.
	Hazards	May be irritating to eyes, respiratory system, mucous membranes, skin. Liquid may cause sensitization by prolonged or repeated skin contact.
	Treatment	Same as above under First Aid.

5.0 Fire Fighting Measures

5.1 Suitable extinguishing media Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.

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5.2	Extinguishing media to avoid	Do not use direct water stream	
5.3	Special exposure hazards in a fire	Heat may cause polymerization with rapid release of energy.	
5.4	Special protective equipment for fire-fighters	Self-contained breathing apparatus	
6.0	Accidental Release Measures		
6.1	Personal precautions.	Ventilate area. Wear gloves, lab coat and safety glasses.	
6.2	Environmental precautions	Contain spilled material. Follow all government regulations.	
6.3	Method for clean up	Absorb or wipe up spill with paper towels or cloths. Collect for disposal in a covered container. Wash area of spill with alcohol or soap / water.	
7.0	Handling and Storage		
7.1	Handling	Follow good hygiene practices. Cap product immediately after use. Avoid cross contamination and dispersion of powder into the air.	
7.2	Storage	Store product tightly capped in original container at cool room temperature (< 25°C). Avoid getting powder wet; avoid direct, strong light and extremes of temperature (>27°C/80°F, <5°C/40°F). Shelf life for unopened product is three years from date of manufacture, provided that the material has been stored properly.	
7.3	Specific uses	Dental material	
8.0	Exposure Controls / Personal Protection		
8.1	Exposure limit values	<u>Powder</u>	<u>Liquid</u>
		PEL:	Not established
		TLV:	Not established
			10 ppm
			10 ppm
8.2	Exposure controls		
8.2.1	Occupational exposure controls	No special equipment required under normal conditions of use.	
8.2.1.1	Respiratory protection	No special equipment required under normal conditions of use.	
8.2.1.2	Hand protection	Usual surgical gloves will limit contact with the glass ionomer liquid.	
8.2.1.3	Eye protection	No special requirements other than the usual safety glasses.	
8.2.1.4	Skin protection	Good personal hygiene and safety practices; wearing a lab coat.	
8.2.1.5	Other controls	Close emergency eye wash fountain. Wash hands after use.	
8.2.2	Environmental exposure controls	Powder is inert. Liquid should not be discharged into environment. Follow all government regulations.	
9.0	Physical and Chemical Properties		
9.1	Characteristics	<u>Powder</u>	<u>Liquid</u>
9.1.1	Appearance /Color	Depends on product	Colorless to pale yellow
9.1.2	Odor	None	Mild, characteristic
9.1.3	Physical state	Fine powder	Viscous liquid
9.2	Important health, safety and environmental information		
9.2.1	pH	Not applicable	5.50
9.2.2	Boiling point	Not applicable	100°C

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9.2.3	Flash point	Not applicable	> 110°C
9.2.4	Flammability (solid, gas)	Not applicable	Not applicable
9.2.5	Explosive properties	Not applicable	Not applicable
9.2.6	Oxidizing properties	Not determined	Not determined
9.2.7	Vapor pressure	<1 mm Hg / 133 Pa	17 mm Hg
9.2.8	Specific gravity	5.650	1.250 to 1.150 (depending on product)
9.2.9	Solubility in water	Nil	Dilutable
9.2.10	Partition coefficient	Not applicable	Not determined
9.2.11	Viscosity	Not applicable	Not determined
9.2.12	Vapor density	Not applicable	0.62
9.2.13	Evaporation rate	Not applicable	< 1
10.0	Stability and reactivity		
10.1	Conditions to avoid	Temperature > 38°C, cross-contamination.	
10.2	Materials to avoid	<i>Powder:</i> Strong acids. <i>Liquid:</i> acids, bases, ammonia, sodium hydroxide, potassium hydroxide and strongly basic amines	
10.3	Hazardous decomposition products	Carbon monoxide, carbon dioxide, acrylic monomers.	
10.4	Further information	Stable if stored and used as directed.	
11.0	Toxicological information		
11.1	Acute toxicity	Not toxic. Minimal health hazard in the quantities present in this product and under normal conditions of use.	
11.2	Irritation and corrosiveness	May be irritating to eyes, respiratory system, mucous membranes or skin on contact or with prolonged exposure.	
11.3	Sensitization	May be sensitizing. Prolonged/frequent skin contact with liquid may cause allergic skin reaction in those sensitive to acrylics.	
11.4	Sub-acute, sub-chronic and prolonged toxicity	Prolonged/frequent skin contact may cause eye, skin, mucous membrane and respiratory system irritation.	
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known	
11.6	Empirical data	Not available	
11.7	Clinical Experience	Glass Ionomer Cements have been used safely and effectively in the US and internationally for more than 25 years.	
12.0	Ecological Information		
12.1	Ecotoxicity	To the best of our knowledge, Glass Ionomer Powders are inert. Glass Ionomer Liquids should not be discharged into the environment. Follow all government regulations.	
13.0	Disposal Considerations		
13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.	

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14.0	Transport Information	
14.1	Restrictions	None. Not regulated by IATA.
15.0	Regulatory Information	
15.1	EU	Class IIa medical device under the MDD 93/42/EEC.
15.2	US FDA	Class II medical device
16.0	Other information	
16.1	List of relevant R phrases	R36/37/38, Irritating to eyes, respiratory system and skin R43, Sensitizing by skin contact
16.2	Hazard Statements	H261: Avoid breathing powder/dust. H319: Eye irritation. Hazard category 2. H335: Specific Target Organ Toxicity - Single exposure; hazard category. 3. Respiratory tract irritation. H315: Skin irritation. Hazard category 2. H317: Skin Sensitization. Hazard category 1.
16.3	Precautionary Statements	P280: Wear protective gloves and eye protection P304+340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351: If in eyes, rinse cautiously with water for several minutes. P337+P313: If eye irritation persists, get medical advice/attention. P302+P352: If on skin, wash with plenty of soap and water. P333+P313: If irritation or rash occurs, get medical advice / attention.
16.4	Restrictions on use	Glass Ionomer Cements are for use by dental professionals only.
16.5	Further information	The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.
16.6	Sources of key data	National Institute for Occupational Safety (NIOSH) US Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency
16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format and Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.