

**Safety Data Sheet**

According to Regulation (EC) No. 1907/2006 (REACH)

Trade Name: **GLASS IONOMER CEMENTS**

<b>1.0 Commercial Product Name and Supplier</b>			
1.1	Commercial product name / designation	<i>GlassBase™</i> <i>GlassCore™</i> <i>GlassFill™</i>	<i>GlassLine™</i> <i>GlassLute™</i> <i>OrthoChoice™ Glass Ionomer Band Cement</i>
1.2	Application / Use	Dental material for use only by dental professionals.	
1.2.2	SIC	851 Human health activity	
1.2.3	Use Category	55	
1.3	Manufacturer, Importer		
1.3.1	Manufacturer	<b><i>Pulpdent Corporation</i></b> 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA  Telephone: 1 617 926-6666 Fax: 1 617 926-6262 Email: <a href="mailto:Pulpdent@pulpdent.com">Pulpdent@pulpdent.com</a>	
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)	
1.5	Authorized European Representative	International Business Solutions Ltd. 54 Mayfield Ridge Hatch Warren, Basingstoke, RG22 4RS UK Tel: 07989 407479 / Fax: 01256 350330 Email: <a href="mailto:scwcqc@globalnet.co.uk">scwcqc@globalnet.co.uk</a>	
<b>2.0 Hazards Identification</b>			
2.1	Classification	Irritant.	
3.2	Adverse human health effects	May be irritating to eyes, respiratory system, mucous membranes and skin. Liquid may cause sensitization by prolonged or repeated skin contact.	
<b>3.0 Composition</b>			
3.1	Chemical characterization of the preparation	Glass ionomer cements in two parts, powder and liquid, that are mixed together just before use.	

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	CAS Number	EC Number	Name of the Ingredient	Concentration	Warning symbol, R phrases
Powder	----	----	Aluminofluorosilicate glass	92-100%	Xi (irritant); R: 36/37/38
Liquid	9003-01-4	Not available	Polyacrylic acid	30-40%	Xi (irritant); R: 36/37/38-43

**4.0 First Aid Measures**

4.1	General information	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 physicians	
	Symptoms	Red and/or irritated eyes, mucous membranes or skin.
	Hazards	May be irritating to eyes, respiratory system, mucous membranes and 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	Foam, carbon dioxide and ABC dry chemical. Water spray may be used to keep fire exposed containers cool.
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5.2	Extinguishing media to avoid	None
5.3	Special exposure hazards in a fire	Burning liberates carbon monoxide, carbon dioxide and acid fumes.
5.4	Special protective equipment for fire-fighters	A self-contained breathing apparatus should be worn by fire fighting personnel.

**6.0 Accidental Release Measures**

6.1	Personal precautions.	Wear safety glasses, gloves and lab coat. If powder has dispersed, wear dust mask.
6.2	Environmental precautions	Contain spilled material. Follow all government regulations.
6.3	Method for clean up	<p>Powder should be carefully swept into dry, covered container. Avoid raising dust. Rinse area with water.</p> <p>Absorb Liquid with inert absorbent material (paper towels, etc.). Collect for disposal in a covered container kept in a cool place. Wash area of spill with detergent and hot water. Rinse with hot water. Spills of Liquid are very slippery.</p>

**7.0 Handling and Storage**

7.1	Handling	For use only by dental professionals trained in their use. Follow good hygiene practices. Do not smoke, eat or drink while using. Cap product immediately after use. Avoid cross contamination between powder and liquid.
7.2	Storage	<p>Keep containers tightly closed. Store each part in original container at cool room temperature (&lt;25°C) and in a dry, well ventilated area. Avoid direct, strong light, sources of ignition, extremes of temperature and cross-contamination.</p> <p>Shelf life, three years from production date, is dependent on proper storage conditions.</p>
7.3	Specific uses	Dental material for use in various clinical situations.

**8.0 Exposure Controls / Personal Protection**

8.1	Exposure limit values	<u>Powder</u>	<u>Liquid</u>
	PEL:	Not established	10 ppm
	TLV:	Not established	10 ppm

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8.2	Exposure controls	
8.2.1	Occupational exposure controls	No special equipment required under normal conditions of use of this product in the quantity provided.
8.2.1.1	Respiratory protection	None required. Good general ventilation is sufficient to control any nuisance dust or airborne vapors during normal conditions of use.
8.2.1.2	Hand protection	No special requirements. The usual surgical gloves worn by dental staff will limit contact with uncured material.
8.2.1.3	Eye protection	No special requirements other than the usual safety glasses worn by dental staff.
8.2.1.4	Skin protection	No special requirements. Good personal hygiene and safety practices and wearing a lab coat should protect dental staff from unnecessary exposure.
8.2.1.5	Other controls	Emergency eye wash fountain should be available. 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	Appearance / Color	<u>Powder</u> Fine powder	<u>Liquid</u> Viscous liquid
9.1.1	Color	Depends on product	Colorless to pale yellow
9.1.2	Odor	None	Mild, characteristic
9.2	Important health, safety and environmental information		
9.2.1	pH	Not applicable	5.5
9.2.2	Boiling point	Not applicable	100° C
9.2.3	Flash point	Not applicable	> 110° C
9.2.4	Flammability (solid, gas)	Not determined	Not applicable
9.2.5	Explosive properties	Not applicable	Not applicable

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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	1.150-1.250
9.2.9	Solubility in water	Nil	Dilutable
9.2.10	Partition coefficient	Not determined	Not determined
9.2.11	Viscosity	Not determined	Not determined
9.2.12	Vapor density	Not determined	0.62
9.2.13	Evaporation rate	Not determined	<1

**10.0 Stability and reactivity**

10.1	Conditions to avoid	Heat (> 38°C).
10.2	Materials to avoid	Powder: Strong acids. Liquid: 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	Both powder and liquid may be irritating to eyes, respiratory system, mucous membranes or skin on contact or with prolonged exposure.
11.3	Sensitization	Individuals susceptible to acrylics may develop an allergic response with prolonged or frequent exposure to the liquid part of this product.
11.4	Sub-acute, sub-chronic and prolonged toxicity	Prolonged exposure to powder or liquid may cause eye, skin mucous membrane and respiratory system irritation.
11.5	Carcinogenicity, Mutagenicity,	None known

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## Reproductive Toxicity

11.6	Empirical data	Not available
11.7	Clinical Experience	According to the US National Institute of Health Technology Assessment Conference on <i>Effects and Side-Effects of Dental Restorative Materials</i> : "General usage of these materials over about 20 years indicates a high benefit-to-risk ratio...both composites and glass ionomers are relatively trouble-free. There is no evidence of short-term or long-term risk...There is no suspicion of any problems after virtually billions of procedures in the United States."

**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.
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**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.
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**15.0 Regulatory Information**

15.1	EU Regulations	Glass Ionomer Cements are Class IIA Medical Devices under the Medical Devices Directive 93/42/EEC.
15.2	Information on the warning label	
15.2.1	Hazard symbol	Xi
15.2.2	Hazardous ingredient	Polyacrylic acid; aluminofluorosilicate glass
15.2.3	Risk phrases	R36/37/38, Irritating to eyes, respiratory system and skin. R43: Sensitizing by skin contact.

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15.2.4 Safety phrases

S24/25: Avoid contact with skin and eyes.

S3/9/49: Keep only in the original container in a cool, well ventilated place.

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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	Training advice	Glass Ionomer Cements are for use only by dental professionals.
16.3	Restrictions on use	Glass Ionomer Cements are to be sold to and used only by dental professionals
16.4	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.
16.5	Sources of key data	National Institute for Occupational Safety (NIOSH) Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law
16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of Regulation (EC) No. 1907/2006 (REACH)

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