

Safety Data SheetTrade Name: **PolyCarb™ WaterSet Cement**

1.0 Commercial Product Name and Supplier																		
1.1	Commercial product name / designation	PolyCarb WaterSet Anhydrous Polycarboxylate 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]	<table border="1"> <thead> <tr> <th><u>Hazard Class</u></th> <th><u>Hazard Category</u></th> <th><u>Hazard Statement</u></th> </tr> </thead> <tbody> <tr> <td>Eye irritation</td> <td>2</td> <td>H319</td> </tr> <tr> <td>STOT SE</td> <td>3</td> <td>H335</td> </tr> <tr> <td>Skin irritation</td> <td>2</td> <td>H315</td> </tr> <tr> <td>Skin sensitization</td> <td>1</td> <td>H317</td> </tr> </tbody> </table>	<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	
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2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Irritant (Xi); R 36/37/38 - 43																
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.																	
	P280: Wear protective gloves and eye protection																	

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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: Anhydrous Polycarboxylate Cement																	
3.2	Hazardous ingredients																	
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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 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	Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.																
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.																

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5.4	Special protective equipment for fire-fighters	A self-contained breathing apparatus. Cool exposed containers with water spray to prevent polymerization under fire conditions.
6.0 Accidental Release Measures		
6.1	Personal precautions.	Ventilate area. Wear gloves, lab coat, dust mask and safety glasses.
6.2	Environmental precautions	Contain spilled material. Follow all government regulations.
6.3	Method for clean up	Sweep up spill without raising dust. Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water.
7.0 Handling and Storage		
7.1	Handling	For use only by dental professionals. Follow good hygiene practices. Cap immediately after use. Avoid moisture and dispersion of powder into the air.
7.2	Storage	Store tightly capped in original container at cool room temperature (<25°C). Avoid extremes of temperature (>27°C/80°F, <5°C/40°F) and moisture. 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	Not established.
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	No special requirements other than the usual surgical gloves.
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 should protect dental staff from unnecessary exposure to material.
8.2.1.5	Other controls	Emergency eye wash fountain close-by. Wash hands after use.
8.2.2	Environmental exposure controls	Not to be discharged into environment. Follow government regulations.
9.0 Physical and Chemical Properties		
9.1	Characteristics	
9.1.1	Appearance /Color	Off-white to light yellow
9.1.2	Odor	Acidic
9.1.3	Physical state	Fine powder
9.2	Important health, safety and environmental information	
9.2.1	pH	Not applicable
9.2.2	Boiling point	Not applicable
9.2.3	Flash point	Not applicable
9.2.4	Flammability (solid, gas)	Not applicable
9.2.5	Explosive properties	Not applicable

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9.2.6	Oxidizing properties	Not determined
9.2.7	Vapor pressure	<1 mm Hg / 133 Pa
9.2.8	Specific gravity	5.650
9.2.9	Solubility in water	Forms a paste with water
9.2.10	Partition coefficient	Not applicable
9.2.11	Viscosity	Not applicable
9.2.12	Vapor density	Not applicable
9.2.13	Evaporation rate	Not applicable
10.0 Stability and reactivity		
10.1	Conditions to avoid	Temperature > 38°C, moisture.
10.2	Materials to avoid	Strong acids.
10.3	Hazardous decomposition products	Oxides of carbon, acrylic monomers, acrylate vapor.
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 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	Similar cements have been safely and effectively in the US and internationally for more than 25 years.
12.0 Ecological Information		
12.1	Ecotoxicity	Not to 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.
14.0 Transport Information		
14.1	Restrictions	None. Not regulated.
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

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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	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	Dental 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.