

Safety Data Sheet**Dentin Conditioning Gel**

1.0 Commercial Product Name and Supplier																		
1.1	Commercial product name / designation	Dentin Conditioning Gel																
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 Emergency / 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																	
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<table border="1"> <thead> <tr> <th>Hazard Class</th> <th>Hazard Category</th> <th>Hazard Statement</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>	Hazard Class	Hazard Category	Hazard Statement	Eye irritation	2	H319	STOT SE	3	H335	Skin irritation	2	H315	Skin sensitization	1	H317	
Hazard Class	Hazard Category	Hazard Statement																
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 (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																	
	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.																	

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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.

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3.0 Composition				
3.1	Chemical characterization of the preparation			
3.2	Hazardous ingredients			
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC
	9003-01-4	Polyacrylic acid	22%	Xi (irritant); R: 36/37/38-43
				Classification per Regulation (EC) No.1272/2008 (CLP). Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317
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	Eye Contact	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	Ingestion	Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention if irritation persists.		
4.5	Inhalation	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.		
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. 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.		
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 suitable material (paper towels or cloths). Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water.		
7.0 Handling and Storage				

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7.1	Handling	For use by dental professionals only. Wear safety glasses and gloves; wash hands after use. Protect soft tissue during intraoral procedures.
7.2	Storage	Remove applicator tip after use. Keep tightly capped in original container. Store at cool room temperature. Avoid direct, strong light and extremes of temperature (>27°C/80°F, <5°C/40°F).
7.3	Specific uses	Dental conditioner
8.0	Exposure Controls / Personal Protection	
8.1	Exposure limit values	PEL: 10 ppm TLV: 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	Good general ventilation is sufficient to control airborne vapors.
8.2.1.2	Hand protection	No special requirements other than surgical gloves.
8.2.1.3	Eye protection	No special requirements other than the usual safety glasses.
8.2.1.4	Skin protection	No special requirements other than good personal hygiene, lab coat.
8.2.1.5	Other controls	Emergency eye wash fountain should be available. Protect soft tissue from material during intraoral procedures. Wash hands after use.
8.2.2	Environmental exposure controls	Do not discharge into environment. Follow all government regulations.
9.0	Physical and Chemical Properties	
9.1	Characteristics	
9.1.1	Appearance /Color / Physical state	Colorless to pale yellow liquid
9.1.2	Odor	Mild, characteristic
9.2	Important health, safety and environmental information	
9.2.1	pH	pH 5.5
9.2.2	Boiling point	100°C
9.2.3	Flash point	> 110°C
9.2.4	Flammability (solid, gas)	Not applicable
9.2.5	Explosive properties	Not applicable
9.2.6	Oxidizing properties	Not determined
9.2.7	Vapor pressure	17 mm Hg
9.2.8	Specific gravity	1.250 to 1.150
9.2.9	Solubility in water	Dilutable
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	0.62
9.2.13	Evaporation rate	< 1
10.0	Stability and reactivity	
10.1	Conditions to avoid	Temperature > 38°C

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10.2	Materials to avoid	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 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	Using polyacrylic acid to prepare dentin for bonding procedures is a well-established, industry-accepted, dental procedure.
12.0	Ecological Information	
12.1	Ecotoxicity	No specific information available. Use according to good working practices. Avoid release into the environment as it may cause pH variation. 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 devices under MDD 93/42/EEC.
15.2	US FDA	Class II medical devices
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	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.

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		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	To be sold to and used 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) 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
16.7	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.
