

Trade Name: *Pulpdent Dentin Desensitizer*

1.0 Commercial Product Name and Supplier	
1.1	Commercial product name / designation <i>Pulpdent Dentin Desensitizer</i> , 5% glutaraldehyde in water
1.2	Application / Use Dental material for use by dental professionals.
1.2.2	SIC 851 Human health activity
1.2.3	Use Category 55
1.3	Manufacturer <i>Pulpdent Corporation</i> 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		
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<u>Hazard Class</u>	<u>Hazard Category</u> <u>Hazard Statement</u>
		Acute toxicity	3 H331, H301
		Skin Irritation	2 H315
		Eye damage	1 H318
		Respiratory sensitizer	1 H334
		STOT SE	3 H335
		Skin sensitizer	1 H317
		Aquatic acute	1 H400
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Toxic; R20/22, R36/37/38, R41, R42/43	

2.2 **GHS Label Elements**
Hazard Pictogram



Signal Word: Danger

Restricted to use by dental professional only

Hazard Statements:

H331: Toxic if inhaled

H301: Toxic if swallowed

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- H315: Causes skin irritation.
- H318: Causes serious eye damage.
- H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H335: May cause respiratory irritation
- H317: May cause an allergic skin reaction
- H400: Very toxic to aquatic life.

Precautionary Statements

- P260: Do not breathe dust / fumes / gas / mist / vapors / spray.
- P264: Wash hands thoroughly after handling.
- P273: Avoid release to the environment.
- P280: Wear protective gloves, lab coat and eye/face protection.
- P284: Wear respiratory protection.
- P305+P351+P338: IF IN EYES, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P301+P312: IF SWALLOWED, immediately call a Poison Control Center or doctor/physician.
- 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.

3.0 Composition					
3.1	Chemical characterization of the preparation		5% aqueous solution of glutaraldehyde		
3.2	Hazardous ingredients				
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).
	111-30-8	Glutaraldehyde	5 %	Toxic R20/22, R36/37/38, R41, R42/43,	Acute toxicity, 3 Skin Irritation, 2 Eye damage, 1 Respiratory sensitizer, 1 STOT SE, 3 Skin sensitizer, 1 Aquatic acute, 1
	7681-49-4	Sodium fluoride	1%	Harmful (Xn) R22-36/38	Acute toxicity, 4 Skin irritation, 2 Eye irritation, 2

4.0 First Aid Measures		
4.1	Special Instructions	Consult a physician and/or call a Poison Control Center. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
4.2	Eye Contact	Move eyelids apart and flush with running water for 15+ minutes. Get medical attention. Continue rinsing eyes during transport to hospital.
4.3	Skin Contact	Remove any contaminated clothing. Wash off with soap and water. Immediately transport victim to hospital for medical care.
4.4	Ingestion	Rinse mouth with water. Do not induce vomiting unless directed by medical personnel. Give large amounts of water to dilute. Get immediate medical attention for ingestion of large amount. Never give anything by mouth to an unconscious person.

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4.5	Inhalation	Move to fresh air. If necessary, administer artificial respiration and/or oxygen and seek immediate medical attention.
4.6	Precautions for first responders	Wear safety glasses and gloves to prevent contact.
4.7	Information for physician	
	Symptoms	Irritation, pain or redness in eyes, on skin, on mucous membranes. Difficulty breathing.
	Hazards	May be irritating / destructive to eyes, skin, upper respiratory tract, or mucous membranes. May cause an allergic reaction by inhalation or skin contact. There is a risk of serious damage to eyes. Toxic if swallowed
	Treatment	Same as First Aid above.

5.0 Fire Fighting Measures

5.1	Suitable extinguishing media	Not a fire hazard. Extinguish fire with water spray, alcohol-resistant foam, dry chemical or carbon dioxide
5.2	Extinguishing media to avoid	None
5.3	Special exposure hazards in a fire	Toxic gases and vapors and carbon oxides may be released under fire conditions.
5.4	Special protective equipment for fire-fighters	Self-contained breathing apparatus; full, protective clothing.

6.0 Accidental Release Measures

6.1	Personal precautions.	Wear respiratory protection, chemical splash goggles, impervious gloves, lab coat with long sleeves and shoe covers. Ensure adequate ventilation. Evacuate personnel to safe areas.
6.2	Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not let material enter drains. Discharge into the environment is to be avoided.
6.3	Method for clean up	Soak up with inert material; place spilled material and absorbent into covered container. Dispose as hazardous waste. Wash area of spill with detergent and water.

7.0 Handling and Storage

7.1	Handling	For use by dental professionals only. Wear gloves, safety glasses; wash hands after use. Avoid contact with skin and eyes. Avoid inhalation of vapors or mist. Follow good hygiene practices.
7.2	Storage	Keep tightly capped in original container. Store at cool room temperature (<25°C) in a well-ventilated area. Avoid extremes of temperature (>27°C/80°F, <5°C/40°F).
7.3	Specific uses	Dental preparation

8.0 Exposure Controls / Personal Protection

8.1	Exposure limit values	Glutaraldehyde: 0.05 ppm TLV (Threshold Limit Value) Sodium fluoride: 2.5 mg/m ³ TLV
8.2	Exposure controls	Wear safety goggles, lab coat and impervious gloves. For the amount of glutaraldehyde in this product (5%), no other safety equipment is required under normal conditions of use in the dental operatory.

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8.2.1	Occupational exposure controls	Wear safety goggles, lab coat and gloves. For the amount of glutaraldehyde in this product (5%), no other safety equipment is required under normal conditions of use in the dental operatory.
8.2.1.1	Respiratory protection	Good general ventilation is sufficient to control any airborne vapors for the concentration of glutaraldehyde in this product (5%).
8.2.1.2	Hand protection	Impervious gloves
8.2.1.3	Eye protection	Safety goggles / face shield
8.2.1.4	Skin protection	Wear a lab coat. Good personal hygiene and safety practices should protect from exposure.
8.2.1.5	Other controls	Wash hands immediately after handling the product. Emergency eye wash fountain should be close by.
8.2.2	Environmental exposure controls	Avoid release into environment.

9.0 Physical and Chemical Properties

9.1	Characteristics	
9.1.1	Appearance /Color / Physical state	Clear, colorless liquid
9.1.2	Odor	Characteristic pungent odor
9.2	Important health, safety and environmental information	
9.2.1	pH	No data available
9.2.2	Boiling point	No data available
9.2.3	Flash point	Not combustible
9.2.4	Flammability (solid, gas)	Not applicable
9.2.5	Explosive properties	Not applicable
9.2.6	Oxidizing properties	No data available
9.2.7	Vapor pressure	15 mmHg at 20°C
9.2.8	Specific gravity	1.106 g/ml
9.2.9	Solubility in water	Soluble
9.2.10	Partition coefficient	No data available
9.2.11	Viscosity	No data available
9.2.12	Vapor density	3.46
9.2.13	Evaporation rate	No data available

10.0 Stability and reactivity

10.1	Conditions to avoid	No data available
10.2	Materials to avoid	Strong acids, strong bases, strong oxidizing agents
10.3	Hazardous decomposition products	Under fire conditions: carbon oxides
10.4	Further information	Stable under recommended storage conditions

11.0 Toxicological information

11.1	Acute toxicity	Glutaraldehyde: LD ₅₀ oral - rat: 246 mg/kg (m), 154 mg/kg (f)
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11.2	Irritation and corrosiveness	Sodium fluoride: LD ₅₀ oral – rat: 31 mg/kg 5% Glutaraldehyde may be irritating to the skin.
11.3	Sensitization	May be sensitizing by inhalation or skin contact
11.4	Sub-acute, sub-chronic and prolonged toxicity	No data available
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	Not considered a carcinogen, mutagen, teratogen or a cause of reproductive toxicity.
11.6	Empirical data	Not available
11.7	Clinical Experience	Similar preparations have been marketed to and used by dental professionals for many years.
12.0	Ecological Information	
12.1	Ecotoxicity	Toxic to aquatic life. Follow 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.
14.2	UN Number	None
14.3	Technical name	Not applicable
14.4	Packing group	Not applicable
	IATA class	Not applicable
15.0	Regulatory Information	
15.1	EU	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device
15.3	Health Canada	Not applicable
16.0	Other information	
16.1	List of relevant R phrases	R20/22: Harmful by inhalation and if swallowed. R36/37/38: Irritating to eyes, respiratory system and skin. R41: Risk of serious damage to eyes R42/43: May cause sensitization by inhalation or skin contact
16.2	Hazard Statements	H331: Toxic if inhaled H301: Toxic if swallowed H315: Causes skin irritation. H318: Causes serious eye damage. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335: May cause respiratory irritation H317: May cause an allergic skin reaction

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		H400: Very toxic to aquatic life.
16.3	Precautionary Statements	P260: Do not breathe dust / fumes / gas / mist / vapors / spray. P264: Wash hands thoroughly after handling. P273: Avoid release to the environment. P280: Wear protective gloves, lab coat and eye/face protection. P284: Wear respiratory protection. P305+P351+P338: IF IN EYES, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P301+P312: IF SWALLOWED, immediately call a Poison Control Center or doctor/physician. 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.
16.4	Restrictions on use	Dentin Desensitizer is to be used only by trained dental professionals.
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, 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.
