

Trade Name: **Ethanol-based Materials: DRY-RITE / SILANE BOND ENHANCER**

1.0 Commercial Product Name and Supplier	
1.1	Commercial product name / designation <i>Dry-Rite Drying Agent</i> <i>Silane Bond Enhancer</i>
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 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	European Authorized 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		Hazard Class	Hazard Category	Hazard Statement
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Flammable liquid	2	H225
		Eye irritation	2	H319
		STOT SE	3	H335
		Skin irritation	2	H315
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Flammable (F) R 11		
		Irritant (Xi) R 36/37/38		

2.2 GHS Label Elements

Hazard Pictograms



Signal Word: **DANGER**

Restricted to use by dental professional only

Hazard Statements:

H225: Highly flammable liquid and vapor. Category 2.

H319: Causes serious eye irritation. Category 2.

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H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation.

H315: Causes skin irritation. Category 2.

Precautionary Statements:

P210: Keep away from heat, sparks, open flame, hot surfaces. No smoking.

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P261: Avoid breathing fumes.

P280: Wear protective gloves/ clothing and eye protection.

P304+P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water.

P370+P378: In case of fire, use dry chemical, alcohol foam, or carbon dioxide for extinction.

3.0 Composition

3.1 Chemical characterization of the preparation: Denatured ethyl alcohol preparation.

3.2 Hazardous ingredients

CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).
64-17-5	Ethyl alcohol	92%	Flammable (F); Irritant (Xi). R11- 36/ 37/38-66	Flammable liquid, Category 2 Eye irritation, Category 2 STOT SE, Category 3 Skin irritation Category 2.
67-64-1	Acetone (denaturant)	7%	Flammable (F); Irritant (Xi). R11- 36/ 37/38-66	Flammable liquid, Category 2 Eye irritation, Category 2 STOT SE, Category 3 Skin irritation Category 2.

4.0 First Aid Measures

4.1	General Information	May cause irritation of eyes or skin on contact. May cause irritation of respiratory tract if inhaled. Exposure to ethanol >1000 ppm may cause headache, drowsiness, lassitude, appetite loss. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.
4.2	Eye Contact	Keep eyelids apart, flush with running water for 15+ minutes. Get medical attention.
4.3	Skin Contact	Remove contaminated clothing. Immediately wash with soap, running water. Use hand cream. Get medical attention if irritation persists.
4.4	Ingestion	Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. Never give anything by mouth to an unconscious person.
4.5	Inhalation	Move to fresh air. If necessary, administer oxygen and/or artificial respiration; seek medical attention.
4.6	Precautions for first responders	Ventilate the area. Wear safety glasses and gloves.
4.7	Information for physicians	

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Symptoms	Contact with material may cause irritation or redness in eyes or on skin. Inhalation may cause irritation of respiratory tract.
Hazards	Exposure to ethanol >1000 ppm may cause headache, drowsiness, lassitude, appetite loss. Persons with chronic respiratory or skin disease are at increased risk with prolonged and/or repeated contact.
Treatment	Same as above under First Aid

5.0 Fire Fighting Measures

5.1	Suitable extinguishing media	Use dry chemical, alcohol foam, or carbon dioxide. Water may be ineffective, but should be used to keep fire-exposed containers cool.
5.2	Extinguishing media to avoid	Water may be ineffective, but will keep fire-exposed containers cool.
5.3	Special exposure hazards in a fire	Carbon monoxide, carbon dioxide from incomplete combustion
5.4	Special protective equipment for fire-fighters	Self-contained breathing apparatus.

6.0 Accidental Release Measures

6.1	Personal precautions.	Wear chemical splash goggles and gloves.
6.2	Environmental precautions	Avoid releasing large quantities into environment.
6.3	Method for clean up	For small quantities: Ventilate area. Wear safety glasses, lab coat, gloves. Wipe up with absorbent material (paper or cloth towels). Rinse area of spill with water. Place all material in closed container away from heat, sparks, sun and oxidizers.

7.0 Handling and Storage

7.1	Handling	For use by dental professionals only. Remove applicator tip and recap immediately after use. Keep material tightly capped in original container. Do not use in presence of ignition sources. Take same precautions when container is emptied, as residual product is hazardous.
7.2	Storage	Remove applicator tip after use. Keep tightly capped in original container. Store at cool room temperature in a well-ventilated area. Avoid extreme temperatures (>27°C/80°F, <5°C/40°F), sparks, direct sunlight, oxidizing agents. Vapor may form flammable mixtures with air.
7.3	Specific uses	<i>Dry-Rite</i> : Dental drying agent; <i>Silane</i> : Material used to enhance bonding of porcelain to resin composites and luting agents.

8.0 Exposure Controls / Personal Protection

8.1	Exposure limit values	Ethanol: 1000 ppm; Acetone: 750 ppm
8.2	Exposure controls	
8.2.1	Occupational exposure controls	No special equipment or ventilation required under normal conditions of use. For large quantities/prolonged exposure, use enclosure, local ventilation, dilution to reduce concentration below TLV.
8.2.1.1	Respiratory protection	Good general ventilation is sufficient to control any 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 safety glasses.
8.2.1.4	Skin protection	No special requirements other than good hygiene and safety practices.

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8.2.1.5	Other controls	Emergency eye wash fountain should be close by. Wash hands after use. Do not eat, drink or smoke.
8.2.2	Environmental exposure controls	Follow all government regulations.

9.0 Physical and Chemical Properties

9.1	Characteristics	
9.1.1	Color / Physical state	Dry-Rite: Pink liquid Silane: Clear liquid
9.1.2	Odor	Characteristic, sweet, ethanol odor
9.2	Important health, safety and environmental information	
9.2.1	pH	Not applicable
9.2.2	Boiling point	Boiling Point: 173°F / 78.3°C
9.2.3	Flash point	43°F / 6°C (Tag closed cup)
9.2.4	Ignition temperature	423°C
9.2.5	Explosive properties	LEL: 3.3; UEL: 19
9.2.6	Odor threshold	159 ppm
9.2.7	Vapor pressure	44.6 mm Hg / 59 mbar / Id: E
9.2.8	Specific gravity	0.795
9.2.9	Solubility in water	Dry-Rite: Complete Silane: Slight
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	1.59
9.2.13	Evaporation rate	Not determined

10.0 Stability and reactivity

10.1	Conditions to avoid	Heat, sparks, open flame, any ignition source.
10.2	Materials to avoid	Acetyl chloride and a wide range of oxidizing agents.
10.3	Hazardous decomposition products	Carbon monoxide, carbon dioxide from incomplete combustion.
10.4	Further information	Stable if stored and used as directed.

11.0 Toxicological information

11.1	Acute toxicity	Minimal health hazard under normal conditions of use. Ethanol: LD ₅₀ in young rats: 10.6 g/kg orally; LD ₅₀ in old rats: 7.06 g/kg orally. Acetone: LD ₅₀ in rats : 10.7 ml/kg orally
11.2	Irritation and corrosiveness	May cause irritation/redness of eyes or skin on contact. May cause irritation of respiratory tract if inhaled.
11.3	Sensitization	Not applicable.

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11.4	Sub-acute, sub-chronic and prolonged toxicity	No chronic health hazard under normal conditions of use.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	Not a carcinogen under normal conditions of use. Large quantities of ethanol, ingested over time, may be carcinogenic or a cause of Fetal Alcohol Syndrome. IARC has reported a relationship between habitual drinking of significant quantities of alcoholic beverages and cancer of oral cavity, pharynx, esophagus, liver.
11.6	Empirical data	None available
11.7	Clinical experience	<i>Dry-Rite, Silane</i> and similar products have been used in dentistry for decades with no reported problems.

12.0 Ecological Information

12.1	Ecotoxicity	Follow good work practices and government regulations. Avoid release into environment.
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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	UN Number	1170
14.2	Technical name	Ethyl alcohol
14.3	Packing group	II
14.4	IATA class	3

15.0 Regulatory Information

15.1	EU	Dry-Rite is a Class I medical device under the Medical Devices Regulation (EU) 2017/745. Silane is a Class II medical device under the Medical Devices Directive 93/42/EEC
15.2	US FDA	Dry-Rite and Silane are Class II medical devices
15.3	Health Canada	Dry-Rite (Class I) and Silane (Class III) medical devices


16.0 Other information

16.1	List of relevant R phrases	R11: Highly flammable R36/37/38: Irritating to eyes, respiratory system and skin.
16.2	Hazard Statements	H225: Highly flammable liquid and vapor. Category 2. H319: Causes serious eye irritation. Category 2. H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation. H315: Causes skin irritation. Category 2.

Trade Name: **Ethanol-based Materials: DRY-RITE / SILANE BOND ENHANCER**

16.3	Precautionary Statements	<p>P210: Keep away from heat, sparks, open flame, hot surfaces. No smoking.</p> <p>P403+P233: Store in a well-ventilated place. Keep container tightly closed.</p> <p>P261: Avoid breathing fumes.</p> <p>P280: Wear protective gloves/ clothing and eye protection.</p> <p>P304+P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.</p> <p>P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water.</p> <p>P370+P378: In case of fire, use dry chemical, alcohol foam, or carbon dioxide for extinction.</p>
16.4	Restrictions on use	<p>Pulpdent dental materials, such as Dry-Rite and Silane, are to be sold to and used by dental professionals only.</p>
16.5	Further information	<p>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.</p>
16.6	Sources of key data	<p>National Institute for Occupational Safety (NIOSH)</p> <p>US Occupational Safety and Health Administration (OSHA)</p> <p>Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH).</p> <p>Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency</p>
16.7	Information which has been added, deleted or revised.	<p>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.</p>

Safety Data SheetTrade Name: **PULPDENT KOOL-DAM**

1.0 Commercial Product Name and Supplier																
1.1	Commercial product name / designation Kool-Dam Heatless Liquid Dam & Block Out Resin															
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: 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 Irritant.															
2.1.1	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
<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 (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 vapor. 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.															

Safety Data SheetTrade Name: **PULPDENT KOOL-DAM**

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

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

P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.

3.0 Composition				
3.1	Chemical characterization of the preparation	Aliphatic and Polyurethane Dimethacrylate Oligomer / Monomer in a light-cured, glass-filled paste.		
3.2	Hazardous ingredients			
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC
	Proprietary	Aliphatic and Polyurethane Dimethacrylate Oligomer / Monomer	55-65%	Xi (Irritant) R36/37/38, R43
	112945-52-5	Amorphous silica	5 %	Xi (Irritant), R36/37/38
				Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317
				Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
4.0 First Aid Measures				
4.1	General Information	Minimal health hazard under normal conditions of use. May be irritating to eyes, respiratory system and skin on contact. Prolonged or repeated contact with Oligomer / Monomer may cause sensitization. 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 / artificial respiration; seek medical attention.		
4.3	Skin Contact	Take off contaminated clothing. Wash skin thoroughly with soap and water for 15 minutes.		
4.4	Eye Contact	Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention.		
4.5	Ingestion	Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person.		
4.6	Precautions for first responders	Ventilate the area. Wear eye and skin protection.		
4.7	Information for physicians			
	Symptoms	Irritation or redness in eyes, throat or on skin.		
	Hazards	May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact.		
	Treatment	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.		

Safety Data SheetTrade Name: **PULPDENT KOOL-DAM**

5.4	Special protective equipment for fire-fighters	A self-contained breathing apparatus should be worn by fire fighting personnel.
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6.0 Accidental Release Measures

6.1	Personal precautions	Ventilate area. Wear safety glasses, gloves, and lab coat.
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

7.1	Handling	For use only by dental professionals. Follow good hygiene practices. Remove applicator tip from syringe and recap immediately after use. Keep light-cured materials shaded from intense light sources.
7.2	Storage	Store tightly capped in original container at cool room temperature (<25°C). Avoid direct light, sources of ignition, extremes of temperature (>27°C/80°F, <5°C/40°F). Shelf life for unopened product is two 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	PEL: Not established. TLV: 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	Good general ventilation is sufficient to control any airborne vapors..
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; lab coat.
8.2.1.5	Other controls	Emergency eye wash fountain should be available. Wash hands after use.
8.2.2	Environmental exposure controls	Follow all government regulations. Cure material before disposing.

9.0 Physical and Chemical Properties

9.1	Characteristics	
9.1.1	Appearance /Color / Physical state	Light blue gel
9.1.2	Odor	Faint, characteristic
9.2	Important health, safety and environmental information	
9.2.1	pH	Not determined
9.2.2	Boiling point	Not determined
9.2.3	Flash point	Not determined
9.2.4	Flammability (solid, gas)	Not applicable
9.2.5	Explosive properties	Not applicable



Safety Data SheetTrade Name: **PULPDENT KOOL-DAM**

9.2.6	Oxidizing properties	Not determined
9.2.7	Vapor pressure	< 1 mm Hg / 133 Pa / Id: B
9.2.8	Specific gravity	1.290
9.2.9	Solubility in water	Nil
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	Not determined
9.2.13	Evaporation rate	Not determined
10.0	Stability and reactivity	
10.1	Conditions to avoid	Temperature extremes (>80°F / 27°C, <40°F / 5°C), intense light, contamination.
10.2	Materials to avoid	Reducing and oxidizing agents, peroxides, amines.
10.3	Hazardous decomposition products	Under fire conditions and with amounts far greater than that supplied in this product, hazardous polymerization may occur with heat build-up, release of carbon monoxide, carbon dioxide, oxides of nitrogen.
10.4	Further information	Polymerization will occur when exposed to direct light.
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, mucous membranes or skin on contact or with prolonged exposure.
11.3	Sensitization	May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.
11.4	Sub-acute, sub-chronic and prolonged toxicity	Prolonged and/or frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to large amounts (more than in this product) of this material may cause eye and respiratory irritation.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available
11.7	Clinical experience	Kool-Dam has been used safely and effectively in the US and internationally for about 10 years with no reports of adverse events.
12.0	Ecological Information	
12.1	Ecotoxicity	To the best of our knowledge, polymerized material is inert. No other information is available. 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 by IATA.

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15.0 Regulatory Information		
15.1	EU	Class I medical devices under the Medical Devices Regulation (EU) 2017/745
15.2	US FDA	Class I medical device
15.3	Health Canada	Class III 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	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	P261: Avoid breathing vapor. 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. P333 + P313: If irritation or rash occurs, get medical advice / attention. P410 + P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.
16.4	Restrictions on use	Pulpdent products are 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) 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
16.7	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.

Safety Data SheetTrade Name: **Porcelain Etch Gel**

1.0 Commercial Product Name and Supplier										
1.1	Commercial product name / designation Porcelain Etch Gel, 9.6% Hydrofluoric Acid Gel									
1.2	Application / Use Dental material used to etch porcelain.									
1.2.2	SIC 851 Human health activity									
1.3	Manufacturer Pulpdent Corporation 80 Oakland Street, PO 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									
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Hazard Class	Hazard Category	Hazard Statement								
Acute Toxicity	2	H300, H330, H310								
Skin Corrosion / Serious eye damage	1A	H314								
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases) T; R26/27/28 C; R35									
2.2	GHS Label Elements									
	Hazard Pictograms									
	 									
	Signal Word: DANGER									
	Restricted to use by dental professional only.									
	Hazard Statements									
	H300: Fatal if swallowed									
	H330: Fatal if inhaled.									
	H310: Fatal in contact with skin.									
	H314: Causes severe skin burns and eye damage.									
	Precautionary Statements									
	P260: Do not breathe dust/fume/gas/mist/vapors/spray									
	P262: Do not get in eyes, on skin or on clothing.									

Safety Data SheetTrade Name: **Porcelain Etch Gel**

P264: Wash hands thoroughly after handling.

P280: Wear protective gloves, lab coat and eye/face protection.

P301+P310: If swallowed, IMMEDIATELY call a Poison Center or doctor/physician.

P302+P350: If on skin, gently wash with soap and water.

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

P305 + P351 + P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing until pH of tears is 7.

3.0 Composition

3.1 Chemical Characterization 9.6% Hydrofluoric Acid in a proprietary gel base

3.2 Hazardous Ingredients

CAS Number	Name of the ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).
7664-39-3	Hydrofluoric acid	9.6%	T; R 26/27/28 C; R 35	Acute Toxicity; 2 Skin Corrosion / Serious eye damage, 1A
64-17-5	Ethyl alcohol	5.3 %	Xi: R 10-36/37/38	Flammable liquid,2 Eye irritation, 2 STOT SE, 3 Skin irritation, 2

4.0 First Aid Measures

- 4.1 General Information **VERY CORROSIVE! Toxic!** Although Porcelain Etch Gel is buffered, diluted (9.6%) hydrofluoric acid that has been incorporated into a gel, this product is still very corrosive. **AVOID ALL CONTACT WITH PRODUCT.** May be fatal if inhaled, swallowed or absorbed through skin. Causes severe burns.
Acute effects may be delayed.
- 4.2 Eye Contact **Call for emergency medical care.** Immediately (within 1 minute) flush eyes and surrounding skin with running water for 30-60 minutes, holding lids apart to ensure flushing of the entire surface. Get emergency medical attention only after the flushing is complete unless it can be continued during transport.
- 4.3 Skin Contact **Call for emergency medical care.** Immediately flush skin with running water for 30-60 minutes while removing contaminated clothing and shoes. Get emergency medical attention only after the flushing is complete unless it can be continued during transport. Apply 2.5% calcium gluconate gel to the exposed area (rubbing it in well) every 15 minutes; if calcium gluconate is not available, apply benzethonium chloride or benzalkonium chloride to the exposed area.
- 4.4 Ingestion **Call for emergency medical care.** Do not induce vomiting. If conscious, have patient rinse mouth and drink a large amount of water to dilute. Never give anything by mouth to an unconscious person
- 4.5 Inhalation Remove patient to fresh air. Administer oxygen, artificial respiration and/or CPR as necessary. Seek immediate medical care. Have patient lie down; keep quiet, warm.
- 4.6 Precautions for first responders Avoid all contact with material. Wear face shield, gloves, lab coat. **Awareness of burns may be delayed.** Begin first aid as soon as possible. Have someone else call for emergency medical care and ventilate area.
- 4.7 Information for physicians
- Symptoms Pain and redness at site of contact. Victim may not initially be aware of burn.

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Hazards	May be fatal if inhaled, swallowed, absorbed through skin. Causes severe burns.
Treatment	Same as above (4.1 to 4.4). Also, skin burns may be treated by immersing the area in iced magnesium sulfate solution (25 to 50%) or iced water, taking care to prevent frostbite by moving from iced solution every 10 to 15 minutes.

5.0	Fire Fighting Measures	
5.1	Suitable extinguishing media	Carbon dioxide. Dry chemical.
5.2	Extinguishing media to avoid	Water.
5.3	Special exposure hazards in a fire	Porcelain Etch Gel: None likely in this product. Bulk Hydrofluoric acid in closed containers: Pressure will build to dangerous levels when exposed to high temperatures. Flammable when heated.
5.4	Special protective equipment for firefighters	Firefighters should wear self-contained breathing apparatus with full face-piece operated in pressure demand or other positive pressure mode.
6.0	Accidental Release Measures	
6.1	Personal precautions	Wear face shield or goggles, chemically resistant gloves, and buttoned up lab coat. Avoid all contact with material. Ventilate the area.
6.2	Environmental precautions	Not indicated for the quantity of HF in this product and under normal conditions of use in a dental practice. Large amounts should not be flushed into sewer.
6.3	Method for clean up	For a small spill (this product): Absorb or wipe up spill with inert material, such as paper towels, and transfer to container for disposal. Wash spill site.
7.0	Handling and Storage	
7.1	Handling	<i>For use by dental professionals only.</i> Keep tightly capped in original container. Do not add any other material to container. Empty container may contain explosive or flammable residue.
7.2	Industrial Hygiene	Do not allow food or drink consumption or smoking while handling. Wear protective gloves and goggles. Do not get in eyes, on skin, or on clothing. Wash hands well after use.
7.3	Storage	Recap immediately after use. Store tightly capped in original container at cool room temperature (<25°C) and in a dry, well-ventilated area. Avoid water, heat, sparks, flame, organic substances, and direct sunlight.
8.0	Exposure Controls / Personal Protection	
8.1	Exposure limit values	PEL/TLV (HF): 3 ppm; TWA (Alcohol): 1000 ppm
8.2	Exposure controls	
8.2.1	Occupational exposure controls	Eye protection and chemically impervious gloves are recommended for dental personnel under anticipated conditions of normal use.
8.2.1.1	Respiratory protection	For the small quantity provided in this product, no special respiratory protection is required. Local mechanical exhaust ventilation should be used to maintain exposure below 3 ppm. For large amounts of hydrofluoric acid, when threshold limits are exceeded (greater than 3 ppm), use self-contained breathing apparatus. Guard against aspiration into lungs.
8.2.1.2	Hand protection	Neoprene or polyethylene gloves are recommended.

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8.2.1.3	Eye protection	Safety glasses or face shield worn by dental staff is adequate under normal conditions of use. For large quantities, safety goggles are required.
8.2.1.4	Skin Protection	Wear buttoned lab coat, long sleeves and/or apron over clothing to protect skin.
8.2.1.5	Other Controls	If used <i>in vivo</i> , use rubber dam around tooth to be etched and high speed evacuator tip or other protective devices for patient. Mask all surrounding tissue. Patient should wear safety glasses. Emergency eye wash fountain should be close by. Wash hands thoroughly after handling. Clean protective equipment before reuse
8.2.2	Environmental exposure controls	Do not wash large amounts of any acid into sewer system.

9.0 Physical and Chemical Properties

9.1	Characteristics	
9.1.1	Appearance /Color / Physical state	Transparent yellow gel
9.1.2	Odor	Characteristic
9.2	Important health, safety and environmental information	
9.2.1	pH value	pH <1.5
9.2.2	Boiling Point (Hydrofluoric acid)	108.33°C
9.2.3	Flash point	Not determined
9.2.4	Flammability	Not applicable for Porcelain Etch Gel.
9.2.5	Explosive properties	Not applicable for Porcelain Etch Gel. For bulk hydrofluoric acid in closed containers: Pressure will build to dangerous levels when exposed to high temperatures. Flammable when heated.
9.2.6	Oxidizing properties	Not determined
9.2.7	Vapor Pressure	10.00 mm Hg / 13.33 mbar / Id: E
9.2.8	Specific Gravity	1.18
9.2.9	Solubility in water	100%
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	0.7
9.2.13	Evaporation rate	Not determined
9.2.14	Ignition temperature	Not applicable
9.2.15	Further information	Odor Threshold: 0.04 ppm

10.0 Stability and reactivity

10.1	Conditions to avoid	Extremes of temperature (>27°C/80°F, <5°C/40°F), sparks, open flame, all other sources of ignition, contamination
10.2	Materials to avoid	Water, glass, concrete, materials containing silicon, carbonates, sulfides, cyanides, alkalis, bases, reducing agents, nitric acid, organic materials, metals.
10.3	Hazardous decomposition products	Not available

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10.4 Hazardous reactions Strong exothermic reaction when exposed to incompatible substances. Pressure will build to dangerous levels when closed containers of hydrofluoric acid are exposed to high temperatures. Flammable when heated.

11.0 Toxicological information		
11.1	Acute toxicity of Hydrofluoric acid (as F)	PEL/TLV: 3 ppm. Dermal LD ₅₀ mouse: 500 mg/kg. Vapor LC ₅₀ human: 50 ppm, 30 min. Causes severe burns. Destructive to tissue. Sensation may be delayed.
11.2	Irritation and corrosiveness	Causes severe burns. Destructive to tissue. Sensation of burn may be delayed.
11.3	Sensitization	Not a sensitizer
11.4	Sub-acute, sub-chronic and prolonged toxicity	Not likely in the quantity and concentration available in this product.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known.
11.6	Empirical data	None available.
11.7	Clinical experience	Pulpdent Porcelain Etch Gel has been used safely and effectively for almost twenty years to successfully prepare porcelain surfaces for bonding. There have been no reports of serious injury during that time. Many of these preparations have taken place in a dental lab where there is less danger. Sometimes, however, it is necessary to use Porcelain Etch Gel intraorally. For these cases, it is most important to have a well-trained, experienced dentist perform the procedure and to use adequate shielding of soft tissue.

12.0 Ecological Information		
12.1	Ecotoxicity	Strong acid. Large amounts of HF may damage wildlife or aquatic ecosystems. Do not flush large amounts to sewer; do not allow large amounts to flow into bodies of water.

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	UN Number	UN 1790
14.2	Technical name	Hydrofluoric Acid Preparation
14.3	IATA Class / Packing group	Class 8, 6.1, Packing Group II
14.4	Transport over land	US DOT/ IATA: Excepted Small Quantities. Maximum unit quantity: 0.5L
14.4.1	Transport Class	Class 8, 6.1, Packing Group II
14.4.2	Label	Hydrofluoric Acid Preparation. Corrosive! Toxic!
14.5	Transport at sea	US DOT/IATA: Excepted Small Quantities. On deck, under deck, passenger and cargo vessels Maximum unit quantity: 0.5L
14.5.1	Transport Class	Class 8, 6.1, Packing Group II
14.5.2	Label	Hydrofluoric Acid Preparation; Corrosive! Toxic!
14.6	Air transport	US DOT/ IATA: Excepted Small Quantities. Maximum unit quantity: 30 ml
14.6.1	Transport Class	Class 8, 6.1, Packing Group II

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14.6.2	Label	Hydrofluoric Acid Preparation. Corrosive! Toxic!
14.7	Further information	No aluminum or glass containers. Packaging must be very secure to prevent leaks and breakage.

15.0 Regulatory Information

15.1	EU	Class I medical device under the Medical Devices Regulation (EU) 2017/745
15.2	US FDA	Class II medical device
15.3	Health Canada	Class III medical device

16.0 Other information

16.1	List of the relevant R phrases	R 35: Causes severe burns R 26/27/28: Very toxic by inhalation, in contact with skin and if swallowed.
16.2	Hazard Statements	H300: Fatal if swallowed H330: Fatal if inhaled. H310: Fatal in contact with skin. H314: Causes severe skin burns and eye damage.
16.3	Precautionary Statements	P260: Do not breathe dust/fume/gas/mist/vapours/spray. P262: Do not get in eyes, on skin or on clothing. P264: Wash hands thoroughly after handling. P280: Wear protective gloves, lab coat and eye/face protection. P301 + P310: If swallowed, immediately call Poison Center or doctor/physician. P302 + P350: If on skin, gently wash with soap and water. P304 + 340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing. P305 + P351 + P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing until pH of tears is 7.
16.4	Restrictions on use	Porcelain Etch Gel is 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, Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.