## **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

075901988

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

075901905

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

075901913

#### Safety Data Sheet

Trade Name: Porcelain Etch Gel

1.0	Commercial Product Name and Supplier				
1.1	Commercial product name / designation	Porcelain Etch Gel,	<b>Gel</b> , 9.6% Hydrofluoric Acid Gel		
1.2	Application / Use	Dental material used	Dental material used to etch porcelain.		
1.2.2	SIC	851 Human health ac	tivity		
1.3	Manufacturer <b>Pulpdent Corporation</b> 80 Oakland Street, PO Box 780 Watertown, MA 02472 USA	•	Telephone: 1 617 926-6666 / Fax: 1 617 926-6262 Email: <u>Pulpdent@pulpdent.com</u>		
1.4	Emergency Telephone Number	1-800-535-5053 (24 H	Hour / USA)		
1.5	Authorized European Representative Advena Ltd. Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom				
2.0	Hazards Identification				
2.1	Classification				
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<u>Hazard Class</u> Acute Toxicity Skin Corrosion / Serious eye damage	Hazard Category 2 1A	<u>Hazard Statement</u> H300, H330, H310 H314	
2.1.2	2 Classification according to Directive 67/548/EEC T; R26/27/28 (See SECTION 16 for full text of risk phrases) C; R35				
2.2	GHS Label Elements				
	Hazard Pictograms Very Very Very Very Very Very Very Very				
	Precautionary Statements				
	P260: Do not breathe dust/fume/gas/mist/vapors/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 a Poison Center or doctor/physician.				
	LIVE LIZED IF ON OKIN CONTRACT WOOD with or	oon and water			

P301+P310: If swallowed, IMMEDIATELY call a Poison Center or do 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 Chara	acterization	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 Mea	sures			
4.1	General Inform	nation	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		<b>Call for emergency medical care</b> . 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	<b>Call for emergency medical care.</b> Immediately flush skin with running water for 30-60 minutes while removing contaminated clothing and shoes. Get emergence medical attention only after the flushing is complete unless it can be continue during transport. Apply 2.5% calcium gluconate gel to the exposed area (rubbing in well) every 15 minutes; if calcium gluconate is not available, apply benzethonium chloride or benzalkonium chloride to the exposed area.			
4.4	Ingestion		<b>Call for emergency medical care.</b> 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 C necessary. Seek immediate medical care. Have patient lie down; keep quiet,				
4.6	Precautions for first responders Avoid all contact with material. Wear face shield, gloves, lab coat. Awareness burns may be delayed. Begin first aid as soon as possible. Have someone call for emergency medical care and ventilate area.		d as soon as possible. Have someone else		
4.7 Information for physicians					
	Symptoms		Pain and rednes	ss at site of contact. Vic	tim may not initially be aware of burn.
	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 preven frostbite by moving from iced solution every 10 to 15 minutes.		
5.0	Fire Fighting Measures				
5.1	Suitable exting	guishing media	Carbon dioxide.	Dry chemical.	

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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 o 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	For use by dental professionals only. Keep tightly capped in original container. Do not add any other material to container. Empty container may contain explosive o 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 we after use.	
7.3	Storage	Recap immediately after use. Store tightly capped in original container at cool roon 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 denta 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 (greate 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.	
8.2.1.3	Eye protection	Safety glasses or face shield worn by dental staff is adequate under norma 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 spee evacuator tip or other protective devices for patient. Mask all surrounding tissue Patient should wear safety glasses. Emergency eye wash fountain should be clos by. Wash hands thoroughly after handling. Clean protective equipment before reus	

#### Trade Name: Porcelain Etch Gel

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 environ	mental 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 / ld: 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
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 <sub>50</sub> mouse: 500 mg/kg. Vapor LC <sub>50</sub> 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
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 MDD 93/42/EEC.
15.2	US FDA	Class II medical device
10.2		

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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	<ul> <li>P260: Do not breathe dust/fume/gas/mist/vapours/spray.</li> <li>P262: Do not get in eyes, on skin or on clothing.</li> <li>P264: Wash hands thoroughly after handling.</li> <li>P280: Wear protective gloves, lab coat and eye/face protection.</li> <li>P301 + P310: If swallowed, immediately call Poison Center or doctor/physician.</li> <li>P302 + P350: If on skin, gently wash with soap and water.</li> <li>P304 + 340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.</li> <li>P305 + P351 + P338: If in eyes, rinse cautiously with water for several minutes.</li> <li>Remove contact lenses, if present and easy to do. Continue rinsing until pH of tears is 7.</li> </ul>
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.