

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

075901913

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

075896592 075896659 075901905 075901988

**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).**

075896519 075896527 075896543 075896550 075896584 075914445

Trade Name: **Etch-Rite 38% Phosphoric Acid Etching Gel**

<b>1.0</b>	<b>Commercial Product Name and Supplier</b>	
1.1	Commercial product name / designation	<b>Etch-Rite, 38% Phosphoric Acid Etching Gel</b>
1.2	Application / Use	Dental etching gel for use by dental professional only.
1.2.2	SIC	851 Human health activity
1.2.3	Use Category	55
1.3	Manufacturer	<b>Pulpdent Corporation</b> 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA Telephone: 1 617 926-6666; Fax: 1 617 926-6262 Email: <a href="mailto:Pulpdent@pulpdent.com">Pulpdent@pulpdent.com</a>
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

**2.0 Hazards Identification**

<b>2.1</b>	<b>Classification</b>			
2.1.1	<b>Classification according to Regulation (EC) No. 1272/2008 [CLP]</b>	<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>
		Skin corrosion	1B	H314
		Serious eye damage	1	H318
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Corrosive (C); R 34; R 36 / 37 / 38		

**2.2 GHS Label Elements**  
 Hazard Pictograms



Signal Word: **DANGER**

**Restricted to use by dental professional only.**

**Hazard Statements**

H314: Causes severe skin burns and eye damage.

H318: Causes serious eye damage.

**Precautionary Statements**

P264: Wash hands thoroughly after handling.

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

P301 + P330 + P331: If swallowed, rinse mouth. Do NOT induce vomiting.

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

P363: Wash contaminated clothing before reuse.

P310: Immediately call a Poison Center or doctor/physician.

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.

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<b>3.0 Composition</b>				
3.1	Chemical characterization of the preparation		Phosphoric acid in a gel matrix.	
3.2	Hazardous ingredients			
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC
	7664-38-2	Phosphoric Acid	38%	Corrosive (C) R34; R36/ 37/38
				Classification per Regulation (EC) No.1272/2008 (CLP).
				Skin corrosion; 1B Eye damage, 1
<b>4.0 First Aid Measures</b>				
4.1	General Information		May cause burns or irritation to eyes, skin or mucous membranes. Acute effects may be delayed. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.	
4.2	Eye Contact		Remove contact lenses. Keep eyelids apart and flush with running water for 15+ minutes or until pH of tears is 7. Get medical attention.	
4.3	Skin Contact		Immediately flush skin with running water for 15 minutes. Get medical attention for persistent irritation or burns.	
4.4	Ingestion		Rinse mouth with water. Do not induce vomiting. Give water to dilute. 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 and seek medical attention.	
4.6	Precautions for first responders		Ventilate the area. Wear safety glasses, gloves and lab coat.	
4.7	Information for physicians			
	Symptoms		Irritation, pain or redness in eyes, mucous membranes or skin. Acute effects may be delayed so continued monitoring of the patient is indicated.	
	Hazards		May cause burns or irritation to eyes, skin or mucous membranes. Acute effects may be delayed.	
	Treatment		Same as above under First Aid.	
<b>5.0 Fire Fighting Measures</b>				
5.1	Suitable extinguishing media		Not a fire hazard. Use water spray to keep fire-exposed containers cool. Extinguish fire with agent suitable for surrounding fire.	
5.2	Extinguishing media to avoid		None	
5.3	Special exposure hazards in a fire		Phosphoric acid can react with metals to liberate hydrogen, a flammable gas. Combustion by-products include oxides of phosphorus.	
5.4	Special protective equipment for fire-fighters		A self-contained breathing apparatus.	
<b>6.0 Accidental Release Measures</b>				
6.1	Personal precautions.		Wear chemical splash goggles and gloves.	
6.2	Environmental precautions		Avoid releasing large quantities into the environment as phosphoric acid may affect pH of water or soil.	
6.3	Method for clean up		For small quantities (as in this product): Wear safety glasses, lab coat and gloves. Absorb or wipe up spill with dry paper towels. Place all material in covered chemical waste container for disposal. Flush spill area with water.	
<b>7.0 Handling and Storage</b>				

Trade Name: **Etch-Rite 38% Phosphoric Acid Etching Gel**

7.1	Handling	For use by dental professionals only. Wear safety glasses and gloves; wash hands after use. Avoid unnecessary exposure. Follow good hygiene practices. Protect soft tissue from etchant during intraoral procedures.
7.2	Storage	Remove applicator tip after use. Keep tightly capped in original container. Store at cool room temperature. Avoid extremes of temperature (>27°C/80°F, <5°C/40°F), alkalis, sulfites, sulfides and most metals.
7.3	Specific uses	Dental etchant
<b>8.0</b>	<b>Exposure Controls / Personal Protection</b>	
8.1	Exposure limit values	TWA: 1 mg/m <sup>3</sup> TLV: 3 mg/m <sup>3</sup>
8.2	Exposure controls	
8.2.1	Occupational exposure controls	No special equipment required under normal conditions of use of this product in the quantity provided.
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 safety glasses.
8.2.1.4	Skin protection	No special requirements. Good personal hygiene and safety practices, wearing a lab coat will protect from unnecessary exposure to etchant.
8.2.1.5	Other controls	Emergency eye wash fountain should be available. Protect soft tissue from etchant during intraoral procedures. Wash hands after use.
8.2.2	Environmental exposure controls	Avoid releasing large quantities of phosphoric acid into the environment as phosphoric acid may affect pH of water or soil.
<b>9.0</b>	<b>Physical and Chemical Properties</b>	
9.1	Appearance / Color	
9.1.1	Color / Physical state	Medium blue, thixotropic gel.
9.1.2	Odor	Mild, characteristic
9.2	Important health, safety and environmental information	
9.2.1	pH	pH 1
9.2.2	Boiling point	135°C
9.2.3	Flash point	Not combustible
9.2.4	Flammability (solid, gas)	Not combustible
9.2.5	Explosive properties	Not applicable
9.2.6	Oxidizing properties	Not determined
9.2.7	Vapor pressure	2.933 mbar / Id: C
9.2.8	Specific gravity	1.380
9.2.9	Solubility in water	Complete
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
<b>10.0</b>	<b>Stability and reactivity</b>	
10.1	Conditions to avoid	Not applicable

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10.2	Materials to avoid	Avoid contact with materials such as sulfides and sulfites that could release toxic gases. Avoid strong alkalis because high heat of reaction can generate steam. Avoid most metals because phosphoric acid can react to liberate hydrogen, a flammable gas.
10.3	Hazardous decomposition products	Avoid contact with materials such as sulfides and sulfites that could release toxic gases. Avoid strong alkalis because high heat of reaction can generate steam. Avoid most metals because phosphoric acid can react to liberate hydrogen, a flammable gas.
10.4	Further information	Stable under normal conditions of use and storage.

**11.0 Toxicological information**

11.1	Acute toxicity	Not toxic
11.2	Irritation and corrosiveness	Corrosive. May cause burns or irritation to eyes, skin, mouth, throat or gastrointestinal tract. Not expected to be an inhalation hazard unless product is misted or heated at high temperatures.
11.3	Sensitization	Not applicable.
11.4	Sub-acute, sub-chronic, prolonged toxicity	None known.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	Not considered a carcinogen, mutagen, teratogen or reproductive toxin.
11.6	Empirical data	Not available
11.7	Clinical Experience	Using phosphoric acid etchants to prepare teeth for bonding procedures is a well-established (more than 20 years), industry-accepted, dental procedure. Etching enamel with phosphoric acid is safe and effective treatment in the hands of a dental professional.

**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.
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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	1805
14.2	Technical name	Phosphoric acid
14.3	Packing group	Packing Group III
14.4	IATA class	Class 8, Corrosive

**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	Class II medical device

**16.0 Other information**


16.1	List of relevant R phrases	R 34: Causes burns R 36 / 37 / 38: Irritating to eyes, respiratory system and skin.
16.2	Hazard Statements	H314: Causes severe skin burns and eye damage.

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		H318: Causes serious eye damage.
16.3	Precautionary Statements	P264: Wash hands thoroughly after handling. P280: Wear protective gloves, clothing and eye/face protection. P301 + P330 + P331: If swallowed, rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: If on skin (or hair), remove all contaminated clothing. Rinse skin with water. P363: Wash contaminated clothing before reuse. P310: Immediately call a Poison Center or doctor/physician. 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	Dental etchants are to be sold to/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.

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**Safety Data Sheet**Trade Name: **Porcelain Etch Gel**

1.0 Commercial Product Name and Supplier			
1.1	Commercial product name / designation	<b>Porcelain Etch Gel, 9.6% Hydrofluoric Acid Gel</b>	
1.2	Application / Use	Dental material used to etch porcelain.	
1.2.2	SIC	851 Human health activity	
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: <a href="mailto:Pulpdent@pulpdent.com">Pulpdent@pulpdent.com</a>	
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	
2.0 Hazards Identification			
2.1	<b>Classification</b>		
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<u>Hazard Class</u> Acute Toxicity Skin Corrosion / Serious eye damage	<u>Hazard Category</u> 2 1A <u>Hazard Statement</u> H300, H330, H310 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	<b>GHS Label Elements</b>		
	Hazard Pictograms		
			
	Signal Word: <b>DANGER</b>		
	<b>Restricted to use by dental professional only.</b>		
	<b>Hazard Statements</b>		
	H300: Fatal if swallowed		
	H330: Fatal if inhaled.		
	H310: Fatal in contact with skin.		
	H314: Causes severe skin burns and eye damage.		
	<b>Precautionary Statements</b>		
	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.		

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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	<b>VERY CORROSIVE! Toxic!</b> Although Porcelain Etch Gel is buffered, diluted (9.6%) hydrofluoric acid that has been incorporated into a gel, this product is still very corrosive. <b>AVOID ALL CONTACT WITH PRODUCT.</b> May be fatal if inhaled, swallowed or absorbed through skin. Causes severe burns. <b>Acute effects may be delayed.</b>
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 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	<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 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. <b>Awareness of burns may be delayed.</b> 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.
	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



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frostbite by moving from iced solution every 10 to 15 minutes.

<b>5.0 Fire Fighting Measures</b>		
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.
<b>6.0 Accidental Release Measures</b>		
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.
<b>7.0 Handling and Storage</b>		
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.
<b>8.0 Exposure Controls / Personal Protection</b>		
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.
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.

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- 8.2.1.5 Other Controls If used *in vivo*, 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
- 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 PEL/TLV: 3 ppm. Dermal LD<sub>50</sub> mouse: 500 mg/kg. Vapor LC<sub>50</sub> human: 50 ppm,

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	(as F)	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**

<b>12.1</b>	<b>Ecotoxicity</b>	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.
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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	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 MDR 93/42/EEC.
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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.