

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH)

Trade Name: **Porcelain Etch Gel**

1.0 Commercial Product Name and Supplier		
1.1	Commercial product name / designation	<i>Pulpdent Porcelain Etch Gel</i>
1.2	Application / Use	Dental material used to etch porcelain.
1.2.2	SIC	851 Human health activity
1.3	Producer	<i>Pulpdent Corporation</i> 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	International Business Solutions Ltd. 54 Mayfield Ridge Hatch Warren, Basingstoke, RG22 4RS UK Tel: 07989 407479 / Fax: 01256 350330 Email: scwcgc@globalnet.co.uk
2.0 Hazards Identification		
2.1	Classification	Corrosive. Toxic
2.2	Adverse human health effects	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.
3.0 Composition		
3.1	Chemical Characterization	9.6% Hydrofluoric Acid in a proprietary gel base

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3.2 Hazardous Ingredients

2.2.1 CAS Number	2.2.2 Name of the ingredient	2.2.3 Concentration	2.2.4 Warning symbol/ R phrase
7664-39-3	Hydrofluoric acid	9.6%	T, C, R 35 - 23 / 24 / 25
64-17-5	Ethyl alcohol	5.3 %	R 10 - 25 - 36 / 37 / 38

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 attention. Keep patient lying down, quiet and warm.

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4.6	Precautions for first responders	Avoid all contact with material. Wear face shield, gloves and 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.
	Hazards	May be fatal if inhaled, swallowed or 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 a full facepiece operated in a pressure demand or other positive pressure mode. Use extinguishing media appropriate to the surrounding fire conditions. Do not use water.
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 provided 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 (as in this product): Absorb or wipe up spill with inert material, such as paper towels, and transfer to

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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	Keep containers tightly closed. Recap immediately after use. Store product in original containers 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	<p>For the small quantity provided in this product, the surgical mask worn by dental staff and the high speed evacuation tip used <i>in vivo</i> are adequate protection. Local mechanical exhaust ventilation should be used to maintain exposure below 3 ppm.</p> <p>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.</p>
8.2.1.2	Hand protection	For the small quantity of this product used in a dental procedure, the usual surgical gloves worn by staff are adequate. For larger quantities, neoprene or polyethylene gloves are recommended.
8.2.1.3	Eye protection	For the small quantity of this product used in a dental procedure, the usual safety glasses or face shield worn by dental staff is adequate. For large quantities, safety goggles are required.

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| 8.2.1.4 | Skin Protection | Wear a buttoned-up 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 available. 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

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| 9.1 | Appearance / Color | |
| 9.1.1 | 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 |
| 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.

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 |

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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	High temperatures, 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 ₅₀ mouse: 500 mg/kg. Vapor LC ₅₀ human: 50 ppm, 30 minutes. Causes severe burns. Destructive to tissue. Sensation of burn 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.

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Trade Name: **Porcelain Etch Gel****11.7 Clinical experience**

Pulpdent Porcelain Etch Gel has been used 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.

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 and 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 and 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!

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14.6	Air transport	US DOT and 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 Regulations	Pulpdent Porcelain Etch Gel is a Class I Medical Device under the Medical Devices Directive 93/42/EEC.
15.2	Information on the warning label	
15.2.1	Hazard symbol	C, T
15.2.2	Technical name	Hydrofluoric Acid Preparation
15.2.3	R phrases	R35: Causes severe burns. R23/24/25: Toxic by inhalation, in contact with skin and if swallowed.
15.2.4	S phrases	S24/25: Avoid contact with skin and eyes. S36/37/39: Wear suitable protective clothing, gloves and eye/face protection S3/9/49: Keep only in the original container in a cool, well-ventilated place away from water, glass, concrete, materials containing silicon, carbonates, sulfides, cyanides, alkalis, bases, reducing agents, nitric acid, organic materials, metals.
15.3	National regulations	US DOT and IATA: Excepted Small Quantities
16.0 Other information		
16.1	List of the relevant R phrases	R 35: Causes severe burns R 23 / 24 / 25: Toxic by inhalation, in contact with skin and if swallowed.

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| 16.2 | Training advice | Porcelain Etch Gel is to be used only by dental professionals who have been trained in their use. |
| 16.3 | Restrictions on use | Porcelain Etch Gel is to be sold to and used by dental professionals only. |
| 16.4 | 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. |
| 16.5 | Sources of key data | National Institute for Occupational Safety (NIOSH)
Occupational Safety and Health Administration (OSHA)
Eur-Lex European Union Law |
| 16.6 | Information which has been added, deleted or revised. | This Safety Data Sheet has been revised to meet the requirements of Commission Regulation (EC) No. 1907/2006 (REACH). |
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