Safety Data Sheet
Trade Name: *Porcelain Etch Gel*

### 1.0 Commercial Product Name and Supplier

<table>
<thead>
<tr>
<th>1.1</th>
<th>Commercial product name / designation</th>
<th><em>Pulpdent Porcelain Etch Gel, 9.6% Hydrofluoric Acid Gel</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>Application / Use</td>
<td>Dental material used to etch porcelain.</td>
</tr>
<tr>
<td>1.2.2</td>
<td>SIC</td>
<td>851 Human health activity</td>
</tr>
<tr>
<td>1.3</td>
<td>Producer</td>
<td><em>Pulpdent Corporation</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>80 Oakland Street, PO Box 780</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Watertown, MA 02472 USA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Telephone: 1 617 926-6666</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fax: 1 617 926-6262</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Email: <a href="mailto:Pulpdent@pulpdent.com">Pulpdent@pulpdent.com</a></td>
</tr>
<tr>
<td>1.4</td>
<td>Emergency Telephone Number</td>
<td>1-800-535-5053 (24 Hour / USA)</td>
</tr>
<tr>
<td>1.5</td>
<td>Authorized European Representative</td>
<td><em>International Business Solutions Ltd.</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>54 Mayfield Ridge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hatch Warren, Basingstoke, RG22 4RS UK</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tel: 07989 407479 / Fax: 01256 350330</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Email: <a href="mailto:s.williams5@btconnect.co.uk">s.williams5@btconnect.co.uk</a></td>
</tr>
</tbody>
</table>

### 2.0 Hazards Identification

#### 2.1 Classification

<table>
<thead>
<tr>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Toxicity</td>
<td>2</td>
<td>2</td>
<td>H300, H330, H310</td>
</tr>
<tr>
<td>Skin Corrosion</td>
<td>1A</td>
<td></td>
<td>H314</td>
</tr>
<tr>
<td>Serious eye damage</td>
<td>1</td>
<td></td>
<td>H318</td>
</tr>
</tbody>
</table>

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

- **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.
- H318: Causes serious eye damage.
Precautionary Statements
P261: Avoid breathing vapors.
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: 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.

3.0 Composition

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

3.2 Hazardous Ingredients

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Name of the ingredient</th>
<th>Concentration</th>
<th>Classification per 67/548/EEC</th>
<th>Classification per Regulation (EC) No.1278/2008 (CLP).</th>
</tr>
</thead>
<tbody>
<tr>
<td>7664-39-3</td>
<td>Hydrofluoric acid</td>
<td>9.6%</td>
<td>T; R 26 / 27 / 28 C; R 35</td>
<td>Acute Toxicity; 2</td>
</tr>
<tr>
<td>64-17-5</td>
<td>Ethyl alcohol</td>
<td>5.3 %</td>
<td>Xi: R 36 / 37 / 38</td>
<td>Skin Corrosion; 1A; Serious eye damage; 1; Eye irritation, 2; STOT SE 3; Skin irritation, 2</td>
</tr>
</tbody>
</table>

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.
Hazard: 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 facepiece operated in pressure demand or other positive pressure mode. Use extinguishing media appropriate to surrounding fire conditions, but no 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 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: 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 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 container at cool room temperature (<25°C) and in a dry, well-ventilated area. Avoid water, heat, sparks, flame, organic substances, 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.
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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.
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 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 <1.5
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
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10.2 Materials to avoid
Water, glass, concrete, materials containing silicon, carbonates, sulfides, cyanides, alkalies, 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 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 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
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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

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.
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16.3 Precautionary Statements
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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.

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)
## Safety Data Sheet

**Trade Name:** *Porcelain Etch Gel*

<table>
<thead>
<tr>
<th>16.7</th>
<th>Information which has been added, deleted or revised.</th>
</tr>
</thead>
</table>

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.