Safety Data Sheet

Trade Name: ***Etch Royale,* 37% Phosphoric Acid Etching Gel**

1.0 Commercial Product Name and Supplier

1.1	Commercial product name / designation	***Etch Royale,* 37% Phosphoric Acid Etching Gel**
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	
	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 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

2.1 **Classification**

2.1.1 **Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard Class	Hazard Category	Hazard Statement
Skin corrosion	1B	H314
Eye irritation	2	H319

2.1.2 Classification according to Directive 67/548/EEC — Corrosive (C); R 34; R 36 / 37 / 38
(See SECTION 16 for full text of risk phrases)

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.

H319: Causes serious eye irritation.

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.

3.0 Composition

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	Classification per Regulation (EC) No.1272/2008 (CLP).
7664-38-2	Phosphoric Acid	37%	Corrosive (C) R34; R36/ 37/38	Skin corrosion; 1B Eye irritant, 2

4.0 First Aid Measures

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.

5.0 Fire Fighting Measures

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 should be worn by firefighting personnel.

6.0 Accidental Release Measures

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.

7.0	**Handling and Storage**	
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
8.0	**Exposure Controls / Personal Protection**	
8.1	Exposure limit values	TWA: 1 mg/m^3 TLV: 3 mg/m^3
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.
9.0	**Physical and Chemical Properties**	
9.1	Appearance / Color	
9.1.1	Color / Physical state	Dark blue 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	1.300
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

10.0	**Stability and reactivity**	
10.1	Conditions to avoid	Not applicable
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.
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	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. H319: Causes serious eye irritation.
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.