

SAFETY DATA SHEETS

This SDS packet was issued with item:

075897863

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

074089140 075897848 076665343 076665491 076665517 076665525 076665541

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).

072801017 073270824 073650017 075897806 075897814 075897822 075897830 075897855

View Section : 12345678910111213141516
EC Directive Pictograms

Personal Protective Pictograms

Gloves
Dust
Respirator
Faceshield
Full
Suit
Splash
Goggles

SECTION 1: CHEMICAL PRODUCT and COMPANY IDENTIFICATION AD31001MS

Product Name:Patterson Topical Benzocaine Anesthetic

Manufacturer MSDS.:AD31001MS

Manufacturer Name:Patterson Companies, Inc.

Address: 1031 Mendota Heights Road
St. Paul, MN 55120

General Use: Recommended Use: Topical anesthetic
Restrictions on Use: Use only as directed

Business Phone:651-686-1600

Business Fax:651-686-9331

CHEMTREC Numbers:

For emergencies in the US, call CHEMTREC: 800-424-9300

Revision Date:1/28/11

Supersedes: 6/22/09

Revision Number: 2

Trade Names:Topex« Topical Anesthetic Gel/Liquid

Chemical Name/Classification: Mixture

U.N. Number: None

U.N. Dangerous Goods Classification: Not Regulated

Product Codes: AD31001, AD31002, AD31003, AD31004, AD31005, AD31006,
AD31007, AD31064, AD31065, AD31067, AD31068, AD31011, AD31012,
AD31014

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SECTION 2 : COMPOSITION, INFORMATION ON INGREDIENTSAD31001MS

Ingredient NameCAS#Ingredient Percent

Polyethylene Glycol25322-68-330-50% by Weight
EC Number:Not available
EC Index Number:1
IUPAC Name: Poly(ethylene oxide)

Substance Classification: Not applicable

Benzocaine94-09-720% by Weight
EC Number:202-303-5
EC Index Number:1
Hazard Symbols:Xi
Risk Phrases:R43
IUPAC Name: Ethyl p-aminobenzoate

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

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SECTION 3 : HAZARDS IDENTIFICATIONAD31001MS

EU Classification: Irritant (Xi)

EU Labelling: X Irritant

Contains benzocaine:
R43 May cause sensitization by skin contact.
S24/25 Avoid contact with skin and eyes.
S37 Wear suitable gloves

US Hazard Classification: Hazardous

Applies to all ingredients:

Route of Exposure: Eye, Skin, Inhalation, Ingestion

Signs/Symptoms: Contact with skin, eyes or mucous membranes may cause numbness. Repeated skin contact may cause burning and itching of the skin with dermatitis or rash.

Aggravation of Pre-Existing Conditions: Employees with pre-existing skin disorders may be at increased risk from exposure.

Polyethylene Glycol :

Target Organs: Specific Target Organ Toxicity (STOT):

Repeated Exposure: Propylene glycol: In 2 week inhalation study, rats were administered whole body exposure for 6 hr/day for 9 days. No exposure related clinical signs or ophthalmic changes were noted and no mortality was recorded during the study.

Benzocaine :

Target Organs: Specific Target Organ Toxicity (STOT):

Single Exposure: Benzocaine: When applied topically as recommended, benzocaine has been shown to be relatively nontoxic, however, sensitization may occur.

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SECTION 4 : FIRST AID MEASURESAD31001MS

Eye Contact: Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation or other symptoms persist.

Skin Contact: Wash skin thoroughly with soap and water. Get medical attention if symptoms develop and persist.

Inhalation: None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.

Ingestion: If swallowed, call a poison control center. Only induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.

Note to Physicians: (Treatment, Testing, and Monitoring):

Treatment of overexposure should be directed at the control of symptoms and clinical conditions.

Most important symptoms of exposure:

Contact with skin, eyes or mucous membranes may cause numbness. Repeated skin contact may cause burning and itching of the skin with dermatitis or rash.

Other: None known.

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SECTION 5 : FIRE FIGHTING MEASURESAD31001MS

Fire: Flammability: Not flammable

Explosion: Explosive limits: Not applicable

Flash Point: > 300 deg F / > 149 deg C

Auto Ignition Temperature: Not available

Extinguishing Media: Suitable: Use media appropriate for

surrounding fire.

Fire Fighting Instructions: Fire Fighting Procedures: Cool fire exposed containers and structures with water.

Specific Hazards Arising from the Chemical: None known.

Precautions for Fire Fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

Protective Equipment: Recommended Protective Equipment for Fire Fighters:

EYES/FACE, SKIN, RESPIRATORY, THERMAL

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SECTION 6 : ACCIDENTAL RELEASE MEASURESAD31001MS

Personal Precautions: PPE and Emergency Procedures: For large spills, wear gloves and eye protection. Small spills do not require special precautions.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE, SKIN

Spill Cleanup Measures: Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

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SECTION 7 : HANDLING and STORAGEAD31001MS

Handling: Precautions for Safe Handling: Avoid contact with the eyes and skin. Wash thoroughly after handling. Use in accordance with package instructions.

Storage: Conditions for Safe Storage: Avoid prolonged storage at elevated temperatures as product degradation may occur.

Work Practices: Wash thoroughly after handling. Remove and launder contaminated clothing before reuse.

Hygiene Practices: Wash thoroughly after handling. Remove and launder contaminated clothing before reuse.

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SECTION 8 : EXPOSURE CONTROLS, PERSONAL PROTECTIONAD31001MS

Engineering Controls:Appropriate Engineering Controls: No special controls required.
Personal Protective Equipment
Routine Handling:Specific Thermal Hazards: Not applicable

Recommended Personal Protective Equipment:

EYES/FACE, SKIN

Skin Protection Description:Avoid skin contact. Wear plastic or rubber gloves to avoid contact.

Eye/Face Protection:Avoid eye contact. Safety glasses should be worn if contact is likely.

Respiratory Protection:None required under normal use conditions.

Exposure Limits:Occupational Exposure Limits:

Polyethylene Glycol:

10 mg/m3 TWA AIHA WEEL (aerosol)

1000 mg/m3 (inhalable) DFG MAK

Benzocaine: None Established

Biological Exposure Limits: None Established

Environmental Exposure Controls: None required for normal use.

General Hygiene Considerations and Work Practices: Wash thoroughly after handling. Remove and launder contaminated clothing before reuse.

Protective Measures During Repair and Maintenance of Contaminated Equipment: Not applicable for product.

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SECTION 9 : PHYSICAL and CHEMICAL PROPERTIESAD31001MS

Physical State/Appearance:Gel

Odor:Characteristic of flavor

pH:6.05

Decomposition Temperature:Not available

Vapor Pressure:Negligible

Vapor Density:Not available

Flash Point:> 300 deg F/> 149 deg C

Auto Ignition Temperature:Not available

Boiling Point:Initial: > 482 deg F/> 250 deg C

Freezing Point:Not available

Melting Point:Not available

Solubility:Disperses

Density:Relative: 1.091 @ 25 deg C

Evaporation Point:Not available

Viscosity:164,000 centipose

Odor Threshold:Not available

Coefficient of Water/Oil Distribution:Partition coefficient:

n-octanol/water: Not available

Flammability: Not flammable

Explosive Properties: None

Explosive limits: Not applicable

Oxidizing Properties: None

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SECTION 10 : STABILITY and REACTIVITYAD31001MS

Chemical Stability:Stable.
Conditions to Avoid:None known.
Incompatibilities with Other Materials:Avoid oxidizing agents.
Reactivity:Will not polymerize.

Possibility of Hazardous Reactions: Hazardous reactions are unlikely.
Hazardous Decomposition Products:Thermal decomposition may produce carbon and nitrogen oxides.

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SECTION 11 : TOXICOLOGICAL INFORMATIONAD31001MS

Applies to all ingredients:
Eye Effect:Direct contact may cause irritation with redness and tearing. Numbness may occur.
Skin Effects:Direct contact may cause numbness. Prolonged or repeated skin contact may cause contact dermatitis or hypersensitivity to benzocaine with burning, stinging, tenderness and edema.
Ingestion Effects:Swallowing may cause nausea, vomiting and diarrhea. In rare cases benzocaine has been shown to cause methemoglobinemia.
Inhalation Effects:None expected from normal use. Inhalation of mists may cause respiratory irritation.
Chronic Effects:None expected.
Carcinogenicity:None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.
Mutagenicity:No data available
Reproductive Toxicity:No data available.
Other Toxicological Information:Medical Conditions Aggravated by Exposure: Employees with pre-existing skin disorders may be at increased risk from exposure.
Polyethylene Glycol :
Ingestion Effects:Oral mouse LD50: 28,900 mg/kg
Other Toxicological Information:Specific Target Organ Toxicity (STOT) :
Repeated Exposure: Propylene glycol: In 2 week inhalation study, rats were administered whole body exposure for 6 hr/day for 9 days. No exposure related clinical signs or ophthalmic changes were noted and no mortality was recorded during the study.
Benzocaine :
Ingestion Effects:LD50 oral rat: 3042 mg/kg

Other Toxicological Information: Specific Target Organ Toxicity (STOT):

Single Exposure: Benzocaine: When applied topically as recommended, benzocaine has been shown to be relatively nontoxic, however, sensitization may occur.

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SECTION 12 : ECOLOGICAL INFORMATIONAD31001MS

Ecological Paragraph: Toxicity:

Propylene glycol: Salmo salar (Atlantic salmon) > 1000 mg/L

Biodegradation: Benzocaine: Readily biodegradable

Other: Other Adverse Effects: None known.

Bio-accumulative Potential: Benzocaine: Estimated BCF is 5.
Potential for bioaccumulation is low.

Mobility in Soil: Benzocaine: Moderate mobility based upon an estimated Koc of 250.

Results of PBT/vPvB Assessment: Not required.

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SECTION 13 : DISPOSAL CONSIDERATIONSAD31001MS

Waste Disposal: Regulations: Dispose in accordance with local and national environmental regulations.

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: None needed for normal anticipated use.

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SECTION 14 : TRANSPORT INFORMATIONAD31001MS

UN Proper Shipping Name: Not Regulated

UN Class: None

UN Number: None

UN Packaging Group: None

Special precautions for user: Not applicable

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SECTION 15 : REGULATORY INFORMATIONAD31001MS

Applies to all ingredients:

TSCA 8(b): Inventory Status:Toxic Substances Control Act (TSCA): This product is a drug and not subject to chemical notification requirements.

SARA:Superfund Amendments and Reauthorization Act (SARA) Title III Information:

Section 304:Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):

This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Section 312 Hazard Category:SARA Section 311/312 (40 CFR 370) Hazard Categories:

Acute:Yes

Chronic:No

Fire:No

Reactive:No

Pressure:No

Section 313 Toxic Release Form:This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components: None

Section 112(r): Clean Air ActClean Air Act (CAA): Not Listed
Section 116.4 part 117: Clean Water ActClean Water Act (CWA):
Not Listed

OSHA 29 CFR 1200:OSHA Hazard Classification: Sensitizer

State:California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components: None

Canada WHMIS:Canadian Workplace Hazardous Materials

Information System (WHMIS): Drugs are not subject to WHMIS

European Community Chemical Inventory Status:EU REACH: This product is a medicinal product and not subject to registration requirements.

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SECTION 16 : ADDITIONAL INFORMATIONAD31001MS

MSDS Revision Date:1/28/11

Supersedes: 6/22/09

Revision Number: 2

Full text of Classification abbreviations used in Section 2 and 3:

Xi Irritant

R43 May cause sensitization by skin contact.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for

components, IUCLID Dataset EU Chemical Bureau, ESIS, Country
websites for occupational exposure limits.

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MATERIAL SAFETY DATA SHEET: *Pulpdent Etch Royale™*

IDENTITY: Trade Name: Pulpdent *Etch Royale™*
Codes: ER, ER6, ER12G, ER24, ER50, ER50R
Chemical Description: 37% Phosphoric acid in a soft gel base.
Product Use: Dental etching material

SECTION I*Pulpdent Corporation*

80 Oakland Street

Watertown, MA 02472 USA

Date Prepared: September 1, 2008

Phone Numbers:

24 Hour Emergency: (800) 535-5053

Customer Service: (800) 343-4342/ (617) 926-6666

SECTION II - HAZARDOUS INGREDIENTS

Ingredients	CAS RN	PEL/TLV	UN Number
Phosphoric Acid	7664-38-2	1 mg/m ³ / 3 mg/m ³	UN 1805
Amorphous, fumed silica	112945-52-5	6 mg/m ³ / 10 mg/m ³	----

DOT HAZARD CLASS/ID No: Class 8, III
WHMIS CLASSIFICATION: Class E - Corrosive
NFPA HMIS RATING: HEALTH: 2 FLAMMABILITY: 0 REACTIVITY: 0

SECTION III - PHYSICAL / CHEMICAL CHARACTERISTICS

Boiling Point: 135°C Specific Gravity: 1.30 Vapor Pressure: 0.0285
Melting Point: 42°C Solubility in water: Complete Odor Threshold: Not available
Appearance and Odor: Dark blue gel with characteristic odor.

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

Flash Point: Not combustible Flammable limits: LEL N/A UEL N/A
Extinguishing Media: Extinguish fire using agent suitable for surrounding fire. Use water spray to keep fire-exposed containers cool.
Special Fire Fighting Procedures: Protective clothing; positive-pressure, self-contained breathing apparatus.
Hazardous Combustion Products: Phosphoric acid may react with metals to liberate hydrogen, a flammable gas. Combustion by-products include oxides of phosphorus.

SECTION V - REACTIVITY DATA

Stability: Stable Conditions to avoid: None
Incompatibility: Avoid contact with materials such as sulfides and sulfites, which 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.
Hazardous Decomposition Products: Toxic gases, steam, hydrogen (flammable), oxides of phosphorus.
Hazardous Polymerization: Does not occur. Conditions to avoid: None

SECTION VI - HEALTH HAZARD DATA

Summary of Acute Hazards: Corrosive material. Causes eye and skin burns. Acute effects may be delayed. Contact with material may not produce an immediate burning sensation.

Route of Exposure

Inhalation

Signs & Symptoms

None expected under normal conditions of use of this product. However, if inhaled as a mist or vaporized, it can be irritating to the respiratory tract.

Eye Contact

Corrosive. May cause burns or irritation.

Skin Absorption

Slightly toxic.

Skin Contact

Corrosive. May cause burns or irritation. Acute effects may be delayed. Contact with material may not produce an immediate burning sensation.

Ingestion

Corrosive. Slightly toxic. May cause burns or irritation to the mouth, throat or gastrointestinal tract.

Summary of Chronic Hazards: None known.

Carcinogenicity, Not known to be a carcinogen.

Teratogenicity, Mutagenicity, Reproductive Toxicity: None known

Emergency First Aid Procedures:

Inhalation

Remove to fresh air. Seek medical attention if symptoms persist.

Eye contact

Immediately flush with running water for 15+ minutes until pH of tears is 7. Seek medical care.

Ingestion

Dilute with water/milk. Do not induce vomiting. Seek medical attention.

Skin contact

Immediately flush with running water for 15+ minutes. Seek medical attention. Remove contaminated clothing and wash before reuse.

SECTION VII - PRECAUTIONS FOR SAFE HANDLING & USE

Handling and Storage Precautions: Store tightly closed in original container, in a cool, dry well-ventilated location away from heat sources and out of direct sunlight. Separate from alkalies and most metals.

Release or Spill: Wear gloves and chemical splash goggles. For small quantities: absorb or wipe up spill with dry paper towels. Place all material in chemical waste container for disposal. Flush spill area with water.

Waste Disposal Method: Follow all government regulations.

Other Precautions: Wash thoroughly after handling. Use with adequate ventilation. Keep container closed. Empty container retains vapor and product residue; observe all safeguards.

SECTION VIII - CONTROL MEASURES

Respiratory Protection: None needed under normal conditions of use of this product. If used *in vivo*, a high speed evacuation tip should be used to protect patient. When airborne limits are exceeded, a NIOSH-approved respirator with full face piece is recommended.

Ventilation: No special ventilation required under normal conditions of use of this product. For larger quantities, local mechanical exhaust ventilation to keep TLV < 3 mg/m³.

Protective Gloves: Chemically resistant gloves. Eye Protection: Chemically resistant splash goggles.

Other Protective Clothing or Equipment: Wear long sleeves, apron and lab coat over clothing to protect skin. If used *in vivo*, use rubber dam around tooth to be etched and high speed evacuator tip or other protective devices for patient. Emergency eye wash fountain should be close by and maintained.

Work/Hygienic Practices: Wash thoroughly after handling. Clean protective equipment before reuse.

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.

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 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]	Hazard Class	Hazard Category
		Skin corrosion	1B
		Eye irritation	2
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.		
	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.	

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

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.		

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

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

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

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

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

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.