

# SAFETY DATA SHEET

## Premier® Etch and Spot-On™ Etch

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### 1. Chemical Product and Company Identification

**Product Name: Premier Etch and Spot-On™ Etch**

An etching gel consisting of 37% phosphoric acid in aqueous solution

**Premier® Dental Products Company**

1710 Romano Drive

Plymouth Meeting, PA 19462

Phone: 610-239-6000 Fax: 610-239-6171

**Emergency Phone: 610-239-6000**

**Indications for Use:**

Premier® Etch and Spot-On™ etch are prescription-only, 37% phosphoric acid etchant in a gel form that is used by the dental professional for etching dentin or enamel prior to tooth restoration.

**Contraindications and Cautions**

- If accidental contact occurs, rinse with a copious amount of water and seek medical attention immediately. Avoid contact with skin, oral soft tissue and eyes.
- Do not use Premier etch products if the patient is allergic to phosphoric acid based ingredients. If an allergic reaction occurs, seek medical attention immediately.

### 2. Hazards Identification

**Acute Health Hazards:** May cause eye, respiratory and skin irritation in high concentration.

**Chronic Health Hazards:** Material is not known to cause significant health problems

**Signs and Symptoms of Exposure:** High concentrations can cause eye and respiratory irritation. Prolonged skin exposure can cause dryness

**Primary routes of exposure:** Inhalation, skin contact, eye contact.

**Carcinogenicity:** NTP - no, OSHA - no, IARC – no.

**Hazard symbols:** 

### 3. Composition / Information on Hazardous Ingredients

Hazardous Ingredients	CAS #	Hazard Identification & Risk Phrases
Phosphoric acid	7664-38-2	C, R34
Fumed Silica	112945-52-5	R36/37/38

✓ **Additional information:** For the wording of the listed risk phrases refer to section 16.

### 4. First Aid Measures

**In case of inhalation:** If irritation occurs, take victim to open air. Get medical attention.

**In case of skin contact:** Wash with soap and water.

**In case of eye contact:** Flush with large quantities of water for 15 minutes. Consult a physician.

**In case of ingestion:** Drink two glasses of water or milk. Seek medical attention if a substantial amount has been ingested. Do not induce vomiting.

### 5. Fire-Fighting Measures

**Flash point:** Non flammable

**Extinguishing Media:** Carbon dioxide, foam or dry chemical

**Unusual Fire and Explosion Hazards:** Upon combustion, irritating gases may form.

## 6. Accidental Release Measures

**Personal Precautions:** Prevent skin / eye contact.

**Environmental Precautions:** Avoid ground water contamination.

**Clean-Up Procedure:** Wipe with damp paper towel. Discard properly.

## 7. Handling and Storage

**Handling:** No special measures necessary if handled according to instruction

**Storage:** Keep container tightly closed when not in use. Store at room temperature. Keep material in original packaging.

Avoid unnecessary exposure to the product. At high temperatures toxic fumes of phosphoric acid and phosphorous oxides can be generated.

## 8. Exposure Controls / Personal Protection

**Exposure Controls:** Use only in well-ventilated areas

**Eye Protection:** Use protective eyewear.

**Hand and Skin Protection:** Avoid unnecessary skin contact. Wear latex gloves when handling

**Hygiene Measures:** Remove spilled material from skin and clothing. Do not eat or drink when handling this material

## 9. Physical and Chemical Properties

**Appearance:** Blue semi-gel

**Odor:** Odorless

**Boiling Point:** > 100° C / 212°F

**Evaporation Rate** (Water = 1): N/A

**Vapor Density** (Air = 1): N/A

**Solubility in Water:** Miscible

## 10. Stability and Reactivity

**Stability:** This material is stable.

**Hazardous Reactions:** None if handled according to directions

**Conditions to Avoid:** Heat

**Incompatibility:** Strong caustics, metals, sulfides and sulfites

## 11. Toxicological Information

**Acute oral toxicity:** LD50 (rat) > 5000mg/kg

**Irritation to Eyes:** Irritates the eyes.

**Irritation of Skin:** May irritate the skin.

**Allergic Effects:** May cause allergic reaction on contact with skin.

**Other:** If swallowed, may cause sore throat and burns of the mouth and throat. Prolong exposure may cause burns to the respiratory tract; contact with soft tissues may cause burns.

## 12. Ecological Information

There is no specific information on the product. Use according to good working practices, avoiding release of the product into environment.

## 13. Disposal Considerations

May be disposed of in landfill or Incinerator in accordance with local, state and federal regulations

## 14. Transport Information

<b>14.1 Transport at land</b>	<b>ADR</b>	<b>8</b>	<b>RID</b>	<b>8</b>
	<b>UN Number</b>	<b>1805</b>	<b>Kemler Number</b>	<b>---</b>
	<b>Packing Group</b>	<b>III</b>		
	<b>Proper shipping name</b>	Phosphoric acid, liquid		
<b>14.2 Transport at sea</b>	<b>ADNR</b>	<b>8</b>	<b>IMDG</b>	<b>31-02</b>
	<b>UN Number</b>	<b>1805</b>		
	<b>EMS</b>	<b>F-E, S-B</b>	<b>MFAG</b>	<b>700</b>
	<b>Packing Group</b>	<b>III</b>		
	<b>Proper shipping name</b>	Phosphoric acid, liquid		
<b>14.3 Air transport</b>	<b>ICAO / IATA-DGR</b>	<b>Klasse 8</b>		
	<b>UN Number</b>	<b>1805</b>		
	<b>Proper shipping name</b>	Phosphoric acid solution		
	<b>Subsidiary Risk</b>	<b>----</b>		
	<b>Labels</b>	<b>Corrosive</b>		
	<b>Packing Group</b>	<b>III</b>		

**U.S. DOT Shipping Name:** Not Regulated

**U.S. DOT Hazard Class:** None U.N. / N.A.

**U.N./N.A. Number** None

**U.S. DOT Packing Group:** None

**Other:** Not considered hazardous cargo

## 15. Regulatory Information

This product requires classification according to the criteria of EC.

The product is a medical device according to the EC-directive 93/42.

**15.1 UN Number** 1805

**15.2 National regulations**

**15.3 EU number** 231-633-2

**15.4 Hazard symbols**



**15.5 Hazard designation** C : Contains Phosphoric Acid, solution in water

**15.6 Risk phrases** R:34 (34 causes burns)

R:36 Irritating to eyes

R:37/38 Irritating to respiratory system and skin

**15.7 Safety phrases** S: 1/2, 26, 37/39, 45

1/2 Keep locked out and out of the reach of children.

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

37/39 Wear suitable gloves and eye/face protection.

45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

**U.S.-O.S.H.A. Status:** This material is not hazardous under the criteria of the U.S Federal Hazard Communication Standard.

## 16. Other Information

**Premier's revision date:** 12/17/2015

**Revision number:** 2

### **Relevant R-phrases**

**34** Causes burns

**36** Irritating to eyes

**37/38** Irritating to respiratory system and skin

Material should be maintained in original containers. Empty containers should not be re-used.

### **ANSI/NFPA 704 Data**

Fire = 0

Health = 1

Reactivity = 0

Supplier number: 073014

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