

SAFETY DATA SHEETS

This SDS packet was issued with item:

075819909

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).

075771704

MATERIAL SAFETY DATA SHEET

Premier® Etch

Revision E EU acc. To ISO 11014

Last Revised: 28-02-11

Approved for Use: 28-02-11

1. Chemical Product and Company Identification

Product Name: Premier Etch

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

Manufacturer:

Premier® Dental Products Company

1710 Romano Drive

Plymouth Meeting, PA 19462

Phone: 610-239-6053 Fax: 610-239-6171

2. Composition / Information on Hazardous Ingredients

Hazardous Ingredients	CAS #	Hazard Identification & Risk Phrases
Phosphoric acid	7664-38-2	C, R34
Fumed Silica	7631-86-9	R36/37/38

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

3. 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.

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

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

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	C  Contains Phosphoric Acid, solution in water
15.5 Hazard designation	
15.6 Risk phrases	R:34 (34 causes burns)
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

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall establish a legally valid contractual relationship.

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

This information is based on data considered accurate. However, no warranty is expressed or implied regarding the accuracy of these data, or the results to be obtained from use thereof. In no event will the manufacturer or distributor be responsible for damages of any nature whatsoever resulting from the use of, or reliance upon this information. General properties described herein are to be regarded as guides and are not guaranteed for all samples.

031140 Rev3

SAFETY DATA SHEET

Premier® Etch and Spot-On™ Etch

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

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

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: 04-28-2015

Revision number: 1

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall establish a legally valid contractual relationship.

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 date: 07-30-2014

This SDS is offered solely for your information, consideration and investigation. This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. Premier Dental Products Company provides no warranties; either expressed or implied, and assumes no responsibility for the accuracy or completeness of data contained herein. Premier Dental Products Company urges persons receiving this information to make their own determination as to the information suitability for their particular application.

051535 Rev1