

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Acid Etching Gel, Acid Etching Semi-Gel, Acid Etching Liquid
Common Name: Adhesives - Acid Etching Agent
Material: Phosphoric Acid Etching Agent
Restrictions on Use: American Orthodontics' products are used for the treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. Federal law restricts this device to use by or on the order of a dentist or orthodontist.

EC No.: 231-633-2

REACH Registration No.: 01-2119485924-24-XXXX

CAS No.: 7664-38-2 (Phosphoric Acid)

1.2 Relevant Identified Uses/ Uses Advised Against

Relevant identified uses: Dental/Orthodontic use only
Uses advised against: Not for Consumer use. Please see "Restrictions on Use"

1.3 Details of the Supplier of the Safety Data Sheet

Company Name:
 American Orthodontics
 3524 Washington Avenue
 Sheboygan, WI 53081
 Phone: 920-457-5051
 Fax: 920-457-1485

E-mail: info@americanortho.com
National Contact: Safety Department

1.4 Emergency Telephone Number

Emergency Response Number:
 920-457-5051
 Only available during office hours: 8:00AM – 5:00PM (Central Time)
 Language of Phone Service: English

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP]
 Skin Corr. 1B (H314)
 Eye Irrit. 2 (H319)

2.1.2 Classification according to Directive 67/548/EEC
 Corrosive (C)
 R34: Causes burns
 R36/37/38: Irritating to eyes, respiratory system and skin

2.2 Label Elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard Pictogram(s): GHS05



Signal Word(s): DANGER

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.

Supplemental Hazard information (EU):

None

2.3 Other Hazards

None

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Phosphoric Acid	7664-38-2	231-633-2	proprietary
Others (proprietary)	N/A	N/A	proprietary

4. FIRST-AID MEASURES

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 if case of uncertainty.

Inhalation: Move to fresh air. If necessary, administer oxygen and/or artificial respiration and seek medical attention.

Skin Contact: Immediately flush skin with running water for 15 minutes.. Prolonged contact may destroy tissue. Seek medical attention for persistent irritation or burns.

Eye Contact: Remove contact lenses. Keep eyelids apart and flush with running water for 15+ minutes or until pH of tears is 7. Seek medical attention as soon as possible.

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.

Precautions for First Responders: Ventilate the area. Wear safety glasses, gloves and lab coat.

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

5. FIRE AND EXPLOSION HAZARDS

5.1 Extinguishing Media

Not a fire hazard. Use spray to keep fire-exposed containers cool. Extinguish fire with agent suitable for surrounding fire.

5.2 Special Exposure Hazards from Substance/Mixture

Phosphoric acid can react with metals to liberate hydrogen, a flammable gas. Combustion by-products include oxides of phosphorus.

5.3 Advice for Firefighters

Special protective equipment for firefighters: A self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear chemical splash goggles and gloves.

Environmental Precautions: Avoid releasing large quantities into the environment as phosphoric acid may affect pH of water or soil.

Methods for Clean-up: For small quantities: 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. HANDLING AND STORAGE

Handling Precautions: 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.

Safe Storage Conditions: Store at temperature not exceeding 83°F (30°C)

Other Restrictions/Recommendations: None

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

Component	OSHA PELs (Permissible Exposure Limits)	ACGIH TLVs (Threshold Limit Values)
Phosphoric Acid	1 mg/ m ³ TWA	3mg/m ³ TLV

8.2 Exposure Controls

Occupational Exposure Controls: No special equipment required under normal conditions of use of this product in the quantity provided.

Respiratory Protection: Good general ventilation is sufficient to control airborne vapors.

Hand Protection: No special requirements other than surgical gloves.

Eye Protection: No special requirements other than safety glasses.

Skin Protection: No special requirements. Good personal hygiene and safety practices, wearing a lab coat will protect from unnecessary exposure to etchant.

Other Controls: Emergency eye wash fountain should be available. Protect soft tissue from etchant during intraoral procedures. Wash hands after use.

Environmental Exposure Controls: Avoid releasing large quantities of phosphoric acid into the environment as phosphoric acid may affect pH of water or soil.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	Green liquid
Odor:	Negligible
pH:	~1
Melting Point/Freezing Point:	N/A
Initial Boiling Point & Boiling Range:	~100°C
Flash Point:	N/A
Flammability (solid, gas):	No
Vapor Pressure:	<760mm Hg @ 100°C
Vapor Density:	<1
Solubility(ies):	Soluble in water

9.2 Other Information

Reactivity in Water	Not reactive
Specific Gravity (H ₂ O=1)	~1.2

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use and storage.

Conditions/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. Avoid exposure to light and temperatures above 83°F. (30°C)

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.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: Not Toxic

Irritation & 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 temperature.

Potential Acute Health Effects: Eye irritation upon contact. Skin irritation upon prolonged exposure.

Potential Chronic Health Effects: Possibility of severe skin/eye damage upon prolonged or repeated exposure.

Sensitization: Not applicable.

Sub-acute, sub-chronic, prolonged Toxicity: None known

Carcinogen, Mutagenicity, Reproductive Toxicity: Not considered a carcinogen, mutagen, teratogen or reproductive toxin

Empirical Data: Not available

Clinical Experience: Using phosphoric acid etchants to prepare for bonding procedures is a well-established (more than 20 years) industry accept dental procedure. Etching enamel with phosphoric acid is safe and effective treatment in the hands of a dental professional.

12. ECOLOGICAL INFORMATION

No ecological damage or impact anticipated upon exposure of material to the environment in quantities as packaged. Use according to good working practices.

13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with all federal, state, and local regulations.

14. TRANSPORTATION INFORMATION

14.1 UN Number
UN-1805

14.2 UN Proper Shipping Name
Phosphoric Acid

14.3 Transport Hazard Class(es)
Class 8, Corrosive

14.4 Packing Group
III

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

None

Other EU Regulations:

None

National Regulations (USA):

None

15.2 Chemical Safety Assessment:

No chemical safety assessment has been carried out for this substance/mixture by the supplier.

16. ADDITIONAL INFORMATION

16.1 Indication of changes/revision to SDS:

1. New format
2. Inclusion of EC Requirements
3. **Revision Date:** 6/4/2015

16.2 Abbreviations and acronyms:

None

16.3 Key literature references and sources for data

1. Guidance on the Compilation of Safety Data Sheets; European Chemical Agency (ECHA); Version 2.1, February 2014
2. Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

16.4 Classification and procedure used to derive classification for mixtures according to Regulation (EC) 1272/2008[CLP]:

None

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in the SDS was obtained from sources that we believe are reliable and is believed to be valid and accurate. American Orthodontics, however, makes no warranty, express or implied, regarding its correctness of the information provided. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by the Company, this SDS information may not be applicable. **Reasonable safety precautions must always be observed.**

