

1. IDENTIFICATION OF THE COMPANY

Company Name

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

24 HR EMERGENCY TELEPHONE NUMBER

(920) 457-5051
Telephone for Information
(920) 457-5051

2. IDENTIFICATION OF THE PRODUCT

Product Name: Acid Etchant (Gel/Liquid)
Product Description: Adhesives – 37% Phosphoric Acid Etchant
Product Part Number: REF 020-028536 & REF 020-028535
Material: Phosphoric Acid

3. INDICATIONS FOR USE, DOMAIN OF USAGE

Acid Etchant is a phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials.

4. CONTRAINDICATIONS

It is the primary responsibility of the dental professional and/or orthodontist to identify any possible contraindications that may preclude the use of American Orthodontics' products.

5. WARNINGS

Acid Etchant contains phosphoric acid and is corrosive. Avoid contact with the eyes, mucous membrane and skin. Refer to American Orthodontics' SDS "Phosphoric Acid".

Acid Etchant contains Copper Polyphthalocyanine and Quinoline Yellow/FD&C Yellow No. 10. Patients who are sensitive or allergic to these dyes should not be in contact with this product.

6. SIDE EFFECTS

During use unwanted side effects may include allergic reaction, and minor discomfort and pain.

7. PRE-STARTING PROCEDURES

1. Using a rotary instrument with a rubber cup or brush, prophylax the enamel surface(s) to be bonded.
2. Do not use prophylax pastes which contain oil. This can leave a film that will inhibit the etch.
3. Rinse thoroughly and dry teeth with oil/moisture free compressed air.

8. STEP-BY-STEP INSTRUCTIONS

NOTE: If using other gel etching systems, consult the manufacturer's instructions for use. The below procedure is only relevant to American Orthodontics' Acid Etchant.

1. Dispense Acid Etchant onto mixing pad.
2. Isolate the teeth for etching.
3. Dab the Acid Etchant onto the entire area to be bonded. Do not rub Acid Etchant onto enamel. Avoid placing Acid Etchant onto soft tissue.
4. Allow 30 seconds for etching (60 seconds for deciduous teeth).
5. Rinse each tooth with water/air spray for 10 seconds (20 seconds for gel etch) to stop etching process. The etched area should appear frosty white. If not, re-etch for an additional 10-15 seconds.
6. Remove demineralized particles

9. STORAGE AND TRANSPORT CONDITIONS

Storage

- Keep container tightly sealed.
- Store between 50°- 77°F (10°- 25°C)
- Shelf life at room temperature is per the expiration date. Rotate inventory to optimize shelf life.

Transport

- Transport with temperatures between 50°- 77°F (10°- 25°C)
- Harsh or rough handling may cause damage to product

10. DISPOSAL CONSIDERATIONS

Small amounts of Acid Etchant may be diluted with copious amount of water down the drain. Larger amounts must be disposed of in accordance to local/state laws. Empty packaging can be recycled after thorough and proper cleaning.

11. WARRANTY LIABILITY

Buyer's remedies with respect to any claim arising out of any defect in any goods or services shall be limited exclusively to the right of repair or replacement of such goods (at the seller's option) or to repayment of the purchase price thereof. In no event shall seller be liable for any consequential or incidental damages including lost profits incurred by buyer with respect to any goods or services furnished by seller. Claims for damage or shortage must be made within 30 days of receipt of order.

12. REGULATORY INFORMATION



MT Promedt Consulting GmbH • Altenhofstrasse 80 • 66386 St. Ingbert, Germany



American Orthodontics • 3524 Washington Avenue • Sheboygan, WI 53081 • (920) 457-5051



SEE INSTRUCTIONS FOR USE



WARNING CORROSIVE



NON STERILE



CAUTION – CONSULT IFU



STORE BETWEEN 50°F - 77°F (10° - 25°C)



SEE WWW.AMERICANORTHO.COM FOR SYMBOL GLOSSARY

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE TO OR ON THE ORDER OF A DENTIST/ORTHODONTIST.

The information contained in the IFU is believed to be valid and accurate. American Orthodontics, however, makes no warranty, either expressed or implied, as to the completeness of information in all possible conditions. **Reasonable safety precautions must always be observed.**