

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: MTP Light Curable Moisture Tolerant Primer
Product Description: Orthodontic Adhesive Sealant/Primer

CAUTION: Federal law restricts this device to sale to or on the order of the dentist/orthodontist.

3. INDICATIONS FOR USE, DOMAIN OF USAGE

Orthodontic Primers are intended to be used in the bonding procedure (direct or indirect) of brackets and tubes by preparing the enamel during orthodontic treatment to increase adhesion to wet or dry, normal and atypical enamel surfaces. The Primer wets the bonding surface of the object to be bonded (i.e. enamel, composite materials, etc.) to promote adhesion.

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.

This product is not indicated for use to bond composite/plastic brackets. If a patient has known allergies against or hypersensitivities towards a component of this product, we recommend not to use it or to do so only under strict medical supervision. In such cases, we will supply the composition of our medical device upon request. The dentist should consider known interactions and cross reactions of the product with other materials already in the patient's mouth before using the product.

5. SIDE EFFECTS

During treatment, unwanted side effects may include: tooth discolorations, decalcification, root resorption, periodontal complications, allergic reactions, difficulties in oral hygiene maintenance, discomfort and pain.

6. WARNINGS & PRECAUTIONS

- Danger: This product contains 2-HEMA (2-hydroxyethyl methacrylate).
- May cause an allergic skin reaction.
- Avoid breathing vapors/spray.
- Wear protective gloves/protective clothing/eye protection/face protection.
- If skin irritation or rash occurs: Get medical advice/attention.
- Do not use after expiration date. Dispose of product in accordance to local and governing laws.
- Phenolic substance (i.e. Eugenol) will inhibit polymerization. Do not store near phenolic products or products containing Eugenol.
- Use proper debonding techniques to avoid enamel damage.

7. PRE-STARTING PROCEDURES

Tooth preparation

- a) Prophylaxis teeth with oil-free pumice or paste
- b) Air dry thoroughly using an oil and moisture-free source.

Acid Etch

- a) Apply acid etch to teeth surfaces following the manufacturer's instructions.
- b) Rinse thoroughly with water to ensure total removal of etchant. Remove excess water but drying of tooth surface is not necessary.

8. STEP-BY-STEP INSTRUCTIONS

- a) Priming surfaces with MTP Light Curable Moisture Tolerant Primer
 - i. Dispense into primer well. Tightly cap bottle to prevent evaporation.

- ii. Dip and completely saturate brush tip. Apply one liberal coat to the entire etched surface of the tooth. Avoid touching gingival area.
 - iii. Re-dip brush into primer for each additional tooth.
 - iv. Gently blow air on each tooth, aiming the airstream perpendicular to the labial surface of the tooth until a thin, even layer of primer remains.
- b) Follow your chosen adhesive instructions for appropriate bonding procedures.

9. STORAGE AND TRANSPORT CONDITIONS

Storage

- Do not expose materials to elevated temperatures or intense light.
- Do not store material in proximity to eugenol-containing products, as this may inhibit the proper adhesive curing.
- Store between 50°-77°F (10°-25°C).
- The expiration date on the product label defines shelf life at room temperature.
- Rotate inventory to optimize shelf life.

Transport

- Transport with temperatures between 35°-80°F (2°-27°C).
- Harsh or rough handling may cause damage to product.

10. DISPOSAL CONSIDERATIONS

It is the primary responsibility of the dental professional and/or orthodontist to follow applicable laws relating to the disposal of used orthodontic medical devices.


Refer to product SDS for relevant Disposal Considerations.


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

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

 NOT STERILIZED  KEEP AWAY FROM DIRECT SUNLIGHT  WARNING IRRITANT

 STORE BETWEEN 55°F – 77°F (10°C - 25°C)  HEALTH HAZARD  WARNING FLAMMABLE

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SEE WWW.AMERICANORTHO.COM FOR SYMBOL GLOSSARY

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.**