

MPa Universal™

Light-Cure Adhesive

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www.clinicianschoice.com

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT IDENTIFIER

TRADE NAME:
MPa Universal™ Light-Cure Adhesive

USE OF THE PREPARATION:
Dental adhesive

SUPPLIER:
 Clinician's Choice® Dental Products, Inc
167 Central Avenue, London, ON
Canada, N6A 1M6

TELEPHONE:
For emergencies or product information
1-800-265-3444 or 519-641-3066
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SECTION 2: HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to Regulation (EC) No 1272/2008:

Skin Irrit. 2, H315 Causes skin irritation.
Eye Irrit. 2, H319 Causes serious eye irritation.
Skin Sens1, H317. May cause allergic skin reaction.

Information concerning particular hazards for human and environment:
The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

LABEL ELEMENTS:

Labeling according to Regulation (EC) 1272/2008:

Hazard pictograms 

Signal word
Warning

Hazard statements

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause allergic skin reaction.

Precautionary statements:

P280:
Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 IF IN EYES:
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P302+P352 IF ON SKIN:
Wash with plenty of soap and water.

Labeling according to EU guidelines:
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

Other hazards:

Results of PBT and vPvB assessment
PBT: Not applicable
vPvB: Not applicable

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

CHEMICAL CHARACTERIZATION:

Description: Modified methacrylates, MDP, catalysts, stabilizers in ethanol

MPa Universal™

Light-Cure Adhesive

INSTRUCTIONS FOR USE

MPa Universal™ is a simple-to-use light-cure universal adhesive.

MPa Universal can be used with the self-etch technique, with preceding selective enamel etching or with the total-etch technique. It is suitable for moist, wet, and dry surfaces. Based on innovative MDP technology MPa Universal allows an excellent adhesion.

For applications, where light-cure cannot be ensured (e.g. in the root canal), MPa Universal has to be used in combination with MPa Universal Dual-Cure Catalyst. Please refer to the instructions for MPa Universal Dual-Cure Catalyst.

INDICATIONS

Adhesive for the self-etch technique, selective enamel etching or total-etch technique for:

- Direct light-cure composite and compomer restorations.
 - Core build-ups with light-, dual- and self-cure composites (e.g. Zircoles™ Zirconia Nano-Filled Core Material) if light-cure of the adhesive is possible.
 - Cementing of inlays, onlays, crowns and bridges with light, dual and self-cure composite cements if light-cure of the adhesive is possible.
 - Repair of fractured composite restorations.
- Use MPa Universal only with dual-cured or self-cured composites if light-cure of the adhesive is guaranteed.

SIDE EFFECTS

In singular cases, the material may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of calcium hydroxide material.

INCOMPATIBILITY WITH OTHER MATERIALS

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the material. Neither store the material in proximity of eugenol containing products, nor let the material come into contact with materials containing eugenol.

APPLICATION

1. ISOLATION

Rubber dam is the recommended method of isolation.

2. CAVITY PREPARATION

Prepare the cavity according to the principles of the adhesive restoration technique.

Hazardous components:

CAS 868-77-9	2-Hydroxyethyl-methacrylate	GHS07, H315, H319, H317
CAS 64-17-5	Ethanol	GHS02, H225

SECTION 4: FIRST AID MEASURES

General information: Seek medical advice, if symptoms occur, which can be caused by the product.

After skin contact: Wash with plenty of water and soap.

After inhalation: Fresh air.

After eye contact: Rinse opened eye for several minutes under running water and consult a doctor.

After swallowing: Consult a physician.

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing media:

- CO₂ powder, water spray.
- Use extinguishing method and media suitable to surrounding fire.

Special hazards arising from the substance or mixture: No further relevant information available.

Protective equipment: Wear self-contained respiratory protective equipment.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Do not inhale vapors/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms.

Environmental precautions:

Do not allow to enter drains/surface water/ground-water.

Methods for cleaning up:

Absorb with liquid binding material. Clean up affected area.

Reference to other sections:

- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

Handling: This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Precautions for safe handling: Observe normal care for working with chemicals.
Information about fire and explosion protection: Keep away from heat and fire. Take precautions to prevent electrostatic charge.

Storage: Store in a dry place. Store tightly closed. Storage temperature <77°F/25°C.

Requirements at storerooms and containers:
Store only in the original containers.

Further information on storage conditions:
Store away from food.

Specific end uses: No further relevant information available.

3. PULP PROTECTION

For pulp protection areas close to the pulp should be covered with a thin layer of calcium hydroxide material.

4. CONDITIONING WITH ETCHING GEL (OPTIONAL)

Selective enamel etching or etching by application of the total-etch technique can be used to improve the bond to enamel.

Note:

Unprepared enamel surfaces must always be conditioned with etching gel (e.g. Max Etch 35% Phosphoric Acid).

Etching Precaution:

It is essential that etched areas are not contaminated by anything.

If contamination occurs, re-etch, rinse with water and dry as described below. Avoid etching gel contact with oral soft tissues, eyes and skin. If accidental contact occurs, flush immediately with copious amounts of water.

a. Selective Enamel Etching

Apply etching gel (e.g. Max Etch) onto the enamel surfaces and leave in place for at least 15 seconds. Deciduous teeth are etched correspondingly longer. Rinse for 20 seconds with water and dry it in a water-free and oil-free airstream. The etched enamel surface should have a chalky white appearance.

b. Total-Etch Technique

Apply etching gel onto the enamel and dentin surfaces beginning with the enamel bevels. Condition the enamel for at least 15 seconds and the dentin for 15 seconds. Deciduous teeth are etched correspondingly longer. Rinse for 20 seconds with water. Dry in a water-free and oil-free airstream, but do not desiccate. The etched enamel bevel should have a chalky white appearance.

5. APPLICATION OF MPa UNIVERSAL

Bottle:

Dispense one or two drops of MPa Universal into a mixing well and use immediately after dispensing.

Close bottle immediately after use.

Unit-Dose:

Make sure that the unit-dose is opened just before use. Hold the snap-off unit-dose at each end. (Place thumb below the center score). Press firmly until the unit-dose separates. Discard the cap. Remove the adhesive with a suitable brush under rotation and apply.

Apply MPa Universal with a brush onto the whole enamel and dentin surface in a thin and even layer. Keep the adhesive agitated for at least 20 seconds. Applying the adhesive on the tooth surface without agitation is inadequate. The material should build a homogeneous layer.

Air thin gently (at least 5-10 seconds) to remove the volatile components and to disperse the adhesive until a glossy and uniform layer results. Then light-cure with a suitable dental halogen light unit or an LED (wavelength 400–500 nm, light intensity min. 1000 mW/cm²) for 20 seconds.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with limits of values to be supervised at the workplace:

CAS-No.	Name	Art	Value	Unit
64-17-5	Ethanol	TRGS 900	500 or 960	ml/m ³ (ppm) mg/m ³

Additional information: The lists valid during the making were used as basis.

Personal protective equipment:

General protective and hygienic measures:
The usual precautionary measures are to be adhered to when handling chemicals. Keep away from food and beverages. Avoid contact with eyes or skin.

Hand protection:

Protective gloves.
Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection:

Safety glasses.
Respiratory protection: Required, when aerosols are generated.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Form: Liquid

Color: Yellowish

Odor: Characteristic

SAFETY RELEVANT BASIC DATA

Melting point/melting range: n.a.

Boiling point/boiling range: n.a.

Flash point: n.a.

Safety relevant basic data: No information available

Danger of explosion: No information available

Density:

1.07 g/cm³

Vapor pressure:

n.d.

pH:

2-3

Water:

soluble

Content of solvents:

Organic solvents: ethanol

SECTION 10: STABILITY AND REACTIVITY

THERMAL DECOMPOSITION / CONDITIONS TO BE AVOIDED

Possibility of hazardous reactions: No information available.

Conditions to avoid: Heat, direct sunlight and radical starters. The product is stable by proper use. Avoid contact with amines, peroxy compounds, polymerisation initiators, acids, bases, oxidizing agents.

Hazardous decomposition products:

No information available.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity: (ethanol)

LD₅₀ (oral, rat) 6200 mg/kg

Primary irritation:

Skin: irritant

Eye: Irritant

Sensitization: Sensitization by skin contact possible.

Additional toxicological information:
Allergic reactions to methacrylates after long-term exposure are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

6. APPLICATION OF A COMPOSITE

Refer to manufacturer's instructions for placement of the light-, dual- or self-cure restorative material.

Note for direct restorations:

Best results are obtained with the application of a thin layer of a light-cure flowable composite (e.g. Evanesce™ Flow) followed by the application of a moldable composite (e.g. Evanesce™). Light-cure each composite layer separately according to the corresponding user instructions.

SIDE EFFECTS

- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates.
- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

STORAGE

Do not store above 77°F (25°C)! Avoid storage in direct sunlight. Do not use after expiration date.

MPa Universal as a snap-off unit-dose is single use only.

WARRANTY

Clinician's Choice® Dental Products, Inc. warrants this product will be free from defects in material and manufacture. Clinician's Choice Dental Products, Inc. makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusively remedy and Clinician's Choice Dental Products, Inc. sole obligation shall be repair or replacement of the Clinician's Choice Dental Products, Inc. product.

LIMITATION OF LIABILITY

Except where prohibited by law, Clinician's Choice Dental Products, Inc. will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Keep away from children!

For dental use only!

Rx Only



Manufactured for:
Clinician's Choice Dental Products, Inc
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1.800.265.3444 • 519.641.3066 • clinicianschoice.com

Labeling

Dual-Cure Catalyst
Manufactured for
Made in Germany

753212500 R.0 02/24SN

SECTION 12: ECOLOGICAL INFORMATION

General information: Avoid transfer into environment.

Classification of water endangerment:
WGK=1 (slightly polluting substance).

SECTION 13: DISPOSAL CONSIDERATIONS

PRODUCT:
Recommendation: Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

UNCLEANED PACKAGING:
Recommendation: Disposal must be made according to official regulations.

SECTION 14: TRANSPORT INFORMATION

Land transport ADR/RID and GGVs/GGVG (Germany):

Not subject to transport regulations.

Sea transport IMDG: Not subject to transport regulations.

Air transport ICAO-TI and IATA-DGR:
Not subject to transport regulations.

SECTION 15: REGULATORY INFORMATION

Classification according to EC-guidelines:
The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment:
A Chemical Safety Assessment has not been carried out.

California Proposition 65:
This product does not contain any chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

SECTION 16: OTHER INFORMATION

Changes compared with the previous version:

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

Preparation by: Peter G. Jordan

