

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Bracepaste MTP Light Cure Primer
Common Name: Adhesives – Light-Cure Resin
Material: Light-Cure Resin
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.: 200-578-6 (Ethanol); 212-782-2 (2-hydroxyethyl methacrylate); 217-388-4 (2-hydroxy-1,3-propanediyl bismethacrylate)

REACH Registration No.: 01-2119490169-29-0000 through 01-2119490169-29-0037 (2-hydroxyethyl methacrylate)

CAS No. / IUPAC: 64-17-5 (Ethanol); 868-77-9 (2-hydroxyethyl methacrylate); 1830-78-0 (2-hydroxy-1,3-propanediyl bismethacrylate)

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]

Flam. Liq. 2	H225	Highly flammable liquid and vapor.
Skin Irrit. 2	H315	Causes skin irritation.
Eye Irrit. 2A	H319	Causes serious eye irritation.
Skin Sens. 1	H317	May cause an allergic skin reaction.
Carc. 1A	H350	May cause cancer. *

* In an uncured state, product contains ethanol, which by the IARC is considered a carcinogen. In a cured state, product does not contain significant amounts of ethanol.

Alcoholic beverages and ethanol in alcoholic beverages have been classified by the IARC as carcinogenic to humans. There are also data associating human consumption of alcoholic beverages with developmental toxicity and liver toxicity. Exposure to ethanol during the foreseeable use of this product is not expected to cause cancer, developmental toxicity, or liver toxicity.

2.2 Label Elements

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

Hazard Pictogram(s)



Signal Word(s): Danger

Hazard-determining components of labeling:

- Ethanol
- 2-hydroxyethyl methacrylate

Hazard Statements:

- Highly flammable liquid and vapor.
- Causes skin irritation.
- Causes serious eye irritation.
- May cause an allergic skin reaction.
- May cause cancer.

Precautionary Statements:

- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
- Keep container tightly closed.
- Ground/bond container and receiving equipment.
- Use explosion-proof electrical/ventilating/lighting/equipment.
- Use only non-sparking tools.
- Take precautionary measures against static discharge.
- Avoid breathing dust/fume/gas/mist/vapors/spray
- Wash thoroughly after handling.
- Contaminated work clothing must not be allowed out of the workplace.
- Wear protective gloves/protective clothing/eye protection/face protection.
- If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- IF exposed or concerned: Get medical advice/attention.
- Specific treatment (see on this label).
- If skin irritation or rash occurs: Get medical advice/attention.
- If eye irritation persists: Get medical advice/attention.
- Take off contaminated clothing and wash it before reuse.
- Wash contaminated clothing before reuse.

In case of fire: Use for extinction: CO₂, powder or water spray.
 Store in a well-ventilated place. Keep cool.
 Store locked up.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other Hazards

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

NFPA Ratings (scale 0-4)

Health = 2
 Fire = 3
 Reactivity = 0

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Ethanol	64-17-5	200-578-6	25-50%
2-hydroxyethyl methacrylate	868-77-9	212-782-2	10-25%
2-hydroxy-1,3-propanediyl bismethacrylate	1830-78-0	217-388-4	2.5-10%

4. FIRST-AID MEASURES

4.1 Description of First-Aid Measures

General Notes
 Immediately remove any clothing soiled by the product.
 Inhalation
 Supply fresh air; consult doctor in case of complaints.
 Skin Contact
 Immediately wash with water and soap and rinse thoroughly.
 Eye Contact
 Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
 Ingestion/Swallowing
 Seek medical treatment.
 Self-Protection of First-Aider
 Wear protective equipment.

4.2 Important Symptoms and Effects

Irritation of skin, mucous membranes, eyes.

4.3 Medical Attention & Special Treatment Necessary

No further relevant information available.

5. FIRE AND EXPLOSION HAZARDS

5.1 Extinguishing Media

Suitable Extinguishing Media:

- CO₂, extinguishing powder or water spray. Fight larger fires with water spray or

alcohol resistant foam.

Extinguishing Media which should not be used:

- Water with full jet.

5.2 Special Exposure Hazards from Substance/Mixture

Hazardous Combustion Products:

- No further relevant information available.

5.3 Advice for Firefighters

Firefighting Methods:

- No special measures required.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment & Emergency Procedures

6.1.1 For Non-Emergency Personnel

Protective Equipment

- Tightly sealed goggles, protective gloves – butyl rubber, BR.

Emergency Procedure

- Wear protective equipment. Keep unprotected persons away. Keep away from ignition sources.

6.1.2 For Emergency Responders

See Section 6.1.1 for Protective Equipment.

6.2 Environmental Precautions

Do not allow to enter sewers / surface or ground water.

6.3 Methods & Material for Containment & Cleaning Up

6.3.1 For Containment

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

6.3.2 For Cleaning Up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to Section 13.

6.3.3 Other Information

Ensure adequate ventilation.

6.4 Reference to other sections (as applicable)

Refer to Sections 7, 8, and 13 for Handling and Storage, Exposure Controls and Personal Protection, and Disposal Considerations.

6.5 Other Information

Protective Action Criteria for Chemicals

PAC-1		
64-17-5	Ethanol	1,800 ppm
868-77-9	2-hydroxyethyl methacrylate	1.9 mg/m ³
PAC-2		
64-17-5	Ethanol	3,300 ppm

868-77-9	2-hydroxyethyl methacrylate	21 mg/m ³
PAC-3		
64-17-5	Ethanol	15,000 ppm
868-77-9	2-hydroxyethyl methacrylate	1,000 mg/m ³

7. HANDLING AND STORAGE

7.1 Precautions for Safe-Handling

Protective Measures:

Measures to prevent fire:

- Keep ignition sources away - do not smoke. Protect against electrostatic charges.

Measures to prevent aerosol and dust generation:

- Prevent formation of aerosols. Ensure good ventilation/exhaustion at the workplace.

Measure to protect the environment

- Do not allow to enter sewers/ surface or ground water.

Advice on General Occupational Hygiene:

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures & Storage Conditions

- Store between 10 °C and 25 °C. Keep receptacle tightly sealed. Store in cool, dry conditions in well-sealed receptacles.

Requirements for Storage Rooms & Vessels

- One common storage facility not required.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

Component	OSHA PELs (Permissible Exposure Limits)	OSHA RELs (Recommended Exposure Limits)	ACGIH TLVs (Threshold Limit Values)
64-17-5 (Ethanol)	Long-term value: 1900 mg/m ³ , 1000 ppm	Long-term value: 1900 mg/m ³ , 1000 ppm	Short-term value: 1880 mg/m ³ , 1000 ppm

8.2 Exposure Controls

8.2.1 Personal Protective Equipment

8.2.1.1 Eye & Face Protection

- Tightly sealed goggles.

8.2.1.2 Skin Protection

Hand Protection

- Protective gloves – butyl rubber, BR. Penetration time of glove material (0.1 – 0.2 mm): 5 minutes.

8.2.1.3 Respiratory Protection

- Not necessary if room is well-ventilated.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	Yellowish fluid.
Odor:	Alcohol-like.
Odor Threshold:	Not determined.
pH:	Not determined.
Melting Point/Freezing Point:	Undetermined.
Initial Boiling Point & Boiling Range:	78 °C (172.4 °F)
Flash Point:	13 °C (55.4 °F)
Evaporation Rate:	Not determined.
Flammability (solid, gas):	Not applicable.
Upper/Lower Flammability or Explosive Limits:	
	Lower: 3.5 Vol %
	Upper: 15 Vol %
Vapor Pressure:	59 hPa (44.3 mm Hg) @ 20°C (68 °F)
Vapor Density:	Not determined.
Relative Density:	Not determined.
Solubility(ies):	Partially miscible.
Partition Coefficient (n-octanol/water):	Not determined.
Auto-Ignition Temperature:	Product is not self-igniting.
Decomposition Temperature:	Not determined.
Viscosity:	Not determined.
Explosive Property:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

9.2 Other Information

Ignition Temperature: 425 °C (797 °F)

10. STABILITY AND REACTIVITY

10.1 Reactivity

No further relevant information available.

10.2 Chemical Stability

No further relevant information available.

10.3 Conditions of Instability

No decomposition if used according to specifications

10.4 Possibility of Hazardous Reactions

No dangerous reactions known.

10.5 Conditions to Avoid

No further relevant information available.

10.6 Incompatible Materials

No further relevant information available.

10.7 Hazardous Decomposition Products

No dangerous decomposition products known.

10.8 Hazardous Polymerization

No further relevant information available.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Information

- Acute Toxicity
Irritant to skin and mucous membranes. Irritating effect on the eye.
- Serious Eye Damage/Irritation
Irritating effect on the eye.
- Respiratory/Skin Sensitization
Sensitization possible through skin contact.
- Signs & Symptoms of Exposure
Irritation of skin, mucous membranes, eyes.

11.1.1 Acute Toxicity

- Method:
Ethanol - LD/LC 50, rat.
- Routes of Exposure:
LD50 Oral.
LC50 Inhalation.
- Effective Dose:
LD50 Oral: 10,470 mg/kg rat, OECD 401.
LC50 Inhalation: 117 mg/l rat, OECD 402.

11.1.2 Carcinogenic Categories

IARC (International Agency for Research on Cancer)		
64-17-5	Ethanol	1
NTP (National Toxicology Program)		
None of the ingredients are listed.		
OSHA (Occupational Safety & Health Administration)		
None of the ingredients are listed		

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

General Notes

Water hazard class 1 (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.2 Persistence and Degradability

No further relevant information available.

12.3 Bioaccumulative Potential

No further relevant information available.

12.4 Mobility in Soil

No further relevant information available.

12.5 Results of PBT and vPvB Assessment

Not applicable.

12.6 Other Adverse Effects

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods

13.1.1 Product/Packaging disposal:

Must be specially treated adhering to official regulations. Must not be disposed of together with household garbage. Uncleaned packaging: disposal must be made according to official regulations.

13.1.2 Sewage Disposal –relevant information:

Do not allow product to reach sewage system.

14. TRANSPORTATION INFORMATION

14.1 UN Number

DOT, ADR, IMDG, IATA: UN1993

14.2 UN Proper Shipping Name




DOT: Flammable liquids, n.o.s. (Ethanol, Epoxy Methacrylate)

ADR: 1993 Flammable liquids, n.o.s. (Ethanol, Epoxy Methacrylate)

IMDG: FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL), Epoxy Methacrylate)

IATA: FLAMMABLE LIQUID, N.O.S. (ETHANOL, Epoxy Methacrylate)

14.3 Transport Hazard Class(es)

	DOT	ADR	IMDG, IATA
Label Image			
Class	3 Flammable liquids	3 (F1) Flammable liquids	3 Flammable liquids
Label	3	3	3

14.4 Packing Group

DOT, ADR, IMDG, IATA: II

14.5 Environmental Hazards

Not applicable.

14.6 Special Precautions for User

Warning: Flammable liquids.

Danger code (Kemler): 33

EMS Number: F-E, S-E

Stowage Category: B

14.7 Transport in Bulk According to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

14.8 Additional Information

ADR:

Excepted quantities (EQ):

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

IMDG:

Limited quantities (LQ):

1L

Excepted quantities (EQ):

Code E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

UN “Model Regulation”: UN 1993 FLAMMABLE LIQUIDS, N.O.S. (ETHANOL, EPOXY METHACRYLATE), 3, II

15. REGULATORY INFORMATION

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

EU Regulations

MAK (German Maximum Workplace Concentration)

64-17-5 (ethanol) - 5

National Regulations (USA):

TSCA (Toxic Substances Control Act)

64-17-5	Ethanol
868-77-9	2-hydroxyethyl methacrylate
1830-78-0	2-hydroxy-1,3-propanediyl bismethacrylate
41137-60-4	di-urethane dimethacrylate
10287-53-3	ethyl 4-(dimethylamino)benzoate
58109-40-3	diphenyliodonium-hexafluorophosphate
10373-78-1	dl-bornane-2,3-dione
7732-18-5	water, distilled, conductivity or of similar purity

TLV (Threshold Limit Value established by ACGIH)

64-17-5 (ethanol) – A3

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:** 03/13/2019

16.2 Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IARC: International Agency for Research on Cancer

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 NFPA: National Fire Protection Association (USA)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 NIOSH: National Institute for Occupational Safety
 OSHA: Occupational Safety & Health
 TLV: Threshold Limit Value
 PEL: Permissible Exposure Limit
 REL: Recommended Exposure Limit
 Flam. Liq. 2: Flammable liquids – Category 2
 Skin Irrit. 2: Skin corrosion/irritation – Category 2
 Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
 Skin Sens. 1: Skin sensitization – Category 1
 Carc. 1A: Carcinogenicity – Category 1A

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.**