

according to 1907/2006/EC, Article 31

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 01-2119490169-29-0044 (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. 2	H319	Causes serious eye irritation.
Skin Sens. 1	H317	May cause an allergic skin reaction.

2.2 Label Elements

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

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Hazard Pictogram(s)



Signal Word(s): Danger

Hazard-determining components of labeling:

2-hydroxyethyl methacrylate

Hazard Statements:

H225 Highly flammable liquid and vapor.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

Precautionary Statements:

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P241 Use explosion-proof electrical/ ventilating/ lighting equipment.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P501 Dispose of contents/container in accordance with local/ regional/ national/ international regulations.

Labeling of packages where the contents do not exceed 125 ml

Hazard Pictogram(s)



Signal Word(s): Danger

Hazard-determining components of labeling:

2-hydroxyethyl methacrylate

Hazard Statements:

H317 May cause an allergic skin reaction.

Precautionary Statements:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

P280 Wear protective gloves.

P302+P352 IF ON SKIN: Wash with plenty of water.

P321 Specific treatment (see on this label).

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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P501 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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Chemical Characterization: Mixtures

Description: Mixture of substances listed below are nonhazardous additions.

Dangerous Components	Wt. % Content	CAS No.	EINECs No.
Ethanol <i>Flam. Liq. 2, H225</i>	25 – 50 %	64-17-5	200-578-6
2-hydroxyethyl methacrylate <i>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens 1, H317</i>	10 – 25 %	868-77-9	212-782-2
2-hydroxy-1,3-propanediyl bismethacrylate <i>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</i>	2.5 – 10 %	1830-78-0	217-388-4

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:

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- 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 – do not smoke.

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.

7. HANDLING AND STORAGE

7.1 Precautions for Safe-Handling

Protective Measures:

Measures to prevent fire:

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- 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

Ingredients with limit values that require monitoring at the workplace:	
64-17-5 (Ethanol)	
WEL	Long-term value: 1920 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

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Flash Point:	13 °C
Evaporation Rate:	Not determined.
Flammability (solid, gas):	Not applicable.
Ignition Temperature:	425 °C
Upper/Lower Flammability or Explosive Limits:	
	Lower: 3.5 Vol %
	Upper: 15 Vol %
Vapor Pressure:	59 hPa (44.3 mm Hg) @ 20°C
Vapor Density:	Not determined.
Density:	0.97 g/ml
Solubility(ies):	Partially miscible in water.
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

No further relevant information available.

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

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11.1 Information on Toxicological Information

- Acute Toxicity
Based on available data, the classification criteria are not met.
- Skin Corrosion/Irritation
Causes skin irritation.
- Serious Eye Damage/Irritation
Causes serious eye irritation.
- Respiratory/Skin Sensitization
May cause allergic skin reaction.
- Signs & Symptoms of Exposure
Irritation of skin, mucous membranes, eyes.
- Germ Cell Mutagenicity
Based on available data, the classification criteria are not met.
- Carcinogenicity
Based on available data, the classification criteria are not met.
- Reproductive Toxicity
Based on available data, the classification criteria are not met.
- STOT-Single Exposure
Based on available data, the classification criteria are not met.
- STOT-Repeated Exposure
Based on available data, the classification criteria are not met.
- Aspiration Hazard
Based on available data, the classification criteria are not met.

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.

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

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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.

European Waste Catalogue	
07 01 04	Other organic solvents, washing liquids and mother liquids

13.1.2 Sewage Disposal –relevant information:

Do not allow product to reach sewage system.

14. TRANSPORTATION INFORMATION

14.1 UN Number

ADR, IMDG, IATA: UN1993



14.2 UN Proper Shipping Name

ADR: 1993 FLAMMABLE LIQUID, N.O.S. (vapour pressure at 50°C not more than 110 kPa) (ETHANOL (ETHYL ALCOHOL), 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)

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

14.4 Packing Group

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.

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14.8 Additional Information

ADR:

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
 Transport Category:
2
 Tunnel Restriction Code:
D/E

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. (VAPOUR PRESSURE AT 50°C NOT MORE THAN 110 KPA) (ETHANOL (ETHYL ALCOHOL), EPOXY METHACRYLATE), 3, II

15. REGULATORY INFORMATION

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.
 Seveso category P5c FLAMMABLE LIQUIDS
 Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
 Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
 REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

National Regulations:

Technical Instructions (air):

Class	Share in %
NK	25-50

Water Hazard Class:

Water hazard class 1 (self-assessment): slightly hazardous for water.

15.2 Chemical Safety Assessment:

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

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16. ADDITIONAL INFORMATION

16.1 Indication of changes/revision to SDS:

1. SDS according to 1907/2006/EC, Article 31
2. **Revision Date:** 11/10/2020

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

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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.**