

according to 1907/2006/EC

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Bracepaste Adhesive
Common Name: Orthodontic Bracket Adhesive
Material: Proprietary
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.: 218-218-1; 278-355-8

REACH Registration No.: 01-2119967415-30-0000, 01-2119967415-30-0002, 01-2119967415-30-0003, 2119967415-30-0004, 01-2119967415-30-XXXX

01-2119972295-29-0000 thru 01-2119972295-29-0026

CAS No. / IUPAC: 2082-81-7; 75980-60-8; 24448-20-2

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:

+1 920-457-5051

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]

Skin Sens. 1 H317 May cause an allergic skin reaction.

2.1.3 Reference to Other Sections

See Section 7 for information on Safe Handling.

See Section 8 for information on Personal Protective Equipment.

See Section 13 for Disposal Information.

2.2 Label Elements

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

This product is classified and labeled according to the Globally Harmonized System (GHS)

according to 1907/2006/EC

Hazard Pictogram(s):



GHS07

Signal Word(s): Warning

Hazard-determining components of labeling

Ethoxylated Bisphenol A Dimethacrylate
Tetramethylene dimethacrylate
Diphenyl (2, 4, 6- trimethylbenzoyl)phosphine oxide

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P280 Wear protective gloves
P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice / attention.
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):



GHS07

Signal Word(s): Warning

Hazard-determining components of labeling

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

Other Hazards

Results of PBT and vPvB assessment
PBT: Not applicable

according to 1907/2006/EC

vPvB: Not Applicable

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures

Description:

Liquid based on methacryl acid ester, containing an activator.
Adhesive material for dental use.

Dangerous Components	Wt. % Content	CAS No.	EC No.
Ethoxylated Bisphenol A Dimethacrylate <i>Skin Sens. 1, H317</i>	2.5 – 12%	24448-20-2	N/A
Tetramethylene Dimethacrylate <i>Skin Sens. 1B, H317</i>	< 3%	2082-81-7	218-218-1
Diphenyl(2, 4, 6-trimethylbenzoyl)phosphine oxide <i>Repr. 2, H361f; Aquatic Chronic 2, H411; Skin Sens. 1B, H317.</i>	< 3%	75980-60-8	278-355-8

For the wording of the listed risk phrases refer to Section 16.

Note: The above information pertains only to the ingredients or raw materials used to make this product. In vitro cytotoxicity testing was performed on the finish product (bracepaste) and the results were: no reactivity (Grade 0).

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

If skin irritation continues, consult a doctor. Immediately wash with water and soap and rinse thoroughly.

Eye Contact

Rinse opened eye for several minutes under running water. Then consult a doctor.

Ingestion/Swallowing

Do not induce vomiting; immediately call for medical help.

4.2 Important Symptoms and Effects

No further relevant information available.

4.3 Medical Attention & Special Treatment Necessary

No further relevant information available.

5. FIRE AND EXPLOSION HAZARDS

5.1 Extinguishing Media

Suitable Extinguishing Media:

according to 1907/2006/EC

- Foam
- Fire-extinguishing powder
- Water haze
- Carbon dioxide

5.2 Special Exposure Hazards from Substance/Mixture

Hazardous Combustion Products:

- No further relevant information available

5.3 Advice for Firefighters

Special protective equipment for fire-fighters:

- Wear self-contained respiratory protective device.

6. ACCIDENTAL RELEASE MEASURES**6.1 Personal Precautions, Protective Equipment & Emergency Procedures****6.1.1 For Non-Emergency Personnel**

Protective Equipment

- Not required.

Emergency Procedure

- Not required.

6.2 Environmental Precautions

Do not allow to enter sewers/surface 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

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

6.4 Reference to other sections (as applicable)

No dangerous substances are released.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment

See Section 13 for disposal information

7. HANDLING AND STORAGE**7.1 Precautions for Safe-Handling**

Keep receptacles tightly sealed.

Ensure good ventilation / exhaustion at the workplace.

Prevent formation of aerosols.

Protective Measures:

Measures to prevent fire:

according to 1907/2006/EC

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

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures & Storage Conditions

- Store away from foodstuffs

Requirements for Storage Rooms & Vessels

- Close container immediately after use and protect product from light incidence.
- Storage between 10 °C and 25 °C.

Storage Class:

Protect from heat and direct sunlight.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Additional information about design of technical systems: No further data; see item 7.

8.1 Control Parameters

This product does not contain any relevant qualities of materials with critical values that have to be monitored at the workplace.

Additional information: the lists that were valid during the creation were used as a basis.

8.2 Exposure Controls

8.2.1 Personal Protective Equipment

General:

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

8.2.1.1 Eye & Face Protection

- Goggles recommended.

8.2.1.2 Skin Protection

Hand Protection

- Protective gloves
 - Butyl rubber, BR
 - Penetration time of glove material: 0.1mm - 0.2mm = 5 minutes; 0.3mm = 60 min.

8.2.1.3 Respiratory Protection

- Not necessary if room is well-ventilated.

Reference Section 5 for specific personal protective equipment advice

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:

Pasty.

Yellowish.

Odor:

Weak, characteristic.

Odor Threshold:

Not determined.

according to 1907/2006/EC

pH:	Not determined.
Melting Point/Freezing Point:	Undetermined.
Initial Boiling Point & Boiling Range:	Undetermined.
Flash Point:	101 °C (213.8 °F)
Evaporation Rate:	Not determined.
Flammability (solid, gas):	Not applicable.
Ignition Temperature:	370°C (698°F)
Upper/Lower Flammability or Explosive Limits:	Not determined.
Vapor Pressure:	Not determined.
Vapor Density:	Not determined.
Relative Density:	Not determined.
Solubility(ies):	Not miscible or difficult to mix.
Partition Coefficient: n-octanol/water:	Not determined.
Auto-Ignition Temperature:	Product is not self-igniting.
Decomposition Temperature:	Not determined.
Viscosity:	330,000 mPas
Explosive Property:	Product does not present an explosion hazard.
Oxidizing:	0,0%

9.2 Other Information

Density at 20 °C (68 °F): 1.89 g/cm³ (15.77 lbs/gal)

10. STABILITY AND REACTIVITY

10.1 Reactivity

No further relevant information available.

10.2 Chemical Stability

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.3 Conditions of Instability

No decomposition if used according to specifications.

10.4 Possibility of Hazardous Reactions

Photoreactive
Danger of polymerization

10.5 Conditions to Avoid

No further relevant information available.

10.6 Incompatible Materials

In the presence of radical formers (e.g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

10.7 Hazardous Decomposition Products

No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Information

- Cytotoxicity
 - In vitro cytotoxicity testing was performed on the finish product (bracepaste) and the results were: no reactivity (Grade 0).
- Acute Toxicity
 - Based on available data, the classification criteria are not met.
- LD/LC50 values that are relevant for classification:
 - Tetramethylene dimethacrylate
 - LD-50 oral >5000mg/kg (rat)
- Primary Irritant Effect
 - Skin corrosion / irritation: Based on available data, the classification criteria are not met.
 - Serious eye damage / irritation: Based on available data, the classification criteria are not met.
- Respiratory or Skin Sensitization
 - May cause an allergic skin reaction.
- CMR Effects
 - 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.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

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 General Notes

Water hazard class 2 (self-assessment): hazardous for water.

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

12.6 Results of PBT and vPvB Assessment

PBT: Not applicable.

vPvB: Not applicable.

according to 1907/2006/EC

- 12.7 Other Adverse Effects**
No further relevant information available.

13. DISPOSAL CONSIDERATIONS

- 13.1 Waste Treatment Methods**
Recommendation
Must be specially treated adhering to official regulations
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
European Waste Catalogue:
08 04 10 waste adhesives and sealants other than those mentioned in 08 04 09
- 13.2 Uncleaned packages**
Recommendation
Packages that cannot be cleansed are to be disposed of in the same manner as the product
Recommended cleansing agent: alcohol.

14. TRANSPORTATION INFORMATION

- 14.1 UN Number**
Void
- 14.2 UN Proper Shipping Name**
Void
- 14.3 Transport Hazard Class(es)**
Void
- 14.4 Packing Group**
Void
- 14.5 Environmental Hazards**
No.
- 14.6 Special Precautions for User**
Not applicable.
- 14.7 Transport in Bulk According to Annex II of MARPOL73/78 and the IBC Code**
Not applicable.
- 14.8 U.N. "Model Regulation"**
Void.

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 1: None of the ingredients listed.
Regulation (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 15.2 Technical Instructions (air)**
- | Class | Share in % |
|-------|------------|
| III | < 2,5 |
- 15.3 Water Hazard class:**
Water hazard class 2 (self-assessment): hazardous for water.
- 15.4 Chemical Safety Assessment:**
A chemical safety assessment has not been carried out.

16. ADDITIONAL INFORMATION

16.1 Indication of changes/revision to SDS:

1. Safety Data Sheet according to 1907/2006/EC (REV02)
2. **Revision Date:** 12/13/2019

16.2 Relevant Phrases

- H317 May cause an allergic reaction.
H361f Suspected of damaging fertility.
H411 Toxic to aquatic life with long lasting effects.

16.3 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)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised 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

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

Repr. 2: Reproductive toxicity – Category 2

Aquatic Chronic 2: Hazardous to the aquatic environment – long-term aquatic hazard –
Category 2

16.4 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

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.**