

**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, 01-2119967415-30-0001, 01-2119967415-30-0002, 01-2119967415-30-0003, 01-2119972295-29-0000, 01-2119972295-29-0001, 01-2119972295-29-0002, 01-2119972295-29-0004  
**CAS No. / IUPAC:** See below.

**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.  
Repr. 2 H361 Suspected of damaging fertility or the unborn child.

**2.1.2 Classification system**

NFPA ratings (scale 0 - 4)  
Health = 0  
Fire = 1  
Reactivity = 0

**2.1.3 Reference to Other Sections**

No dangerous substances are released.  
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)

**Hazard Pictogram(s):**



GHS07



GHS08

**Signal Word(s):** Warning

**Hazard-determining components of labeling**

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

**Hazard Statements**

- May cause an allergic skin reaction.
- Suspected of damaging fertility or the unborn child.

**Precautionary Statements**

- Avoid breathing dust/fume/gas/mist/vapors/spray
- Wear protective gloves
- Contaminated work clothing must not be allowed out of the workplace
- Obtain special instructions before use
- Do not handle until all safety precautions have been read and understood
- Specific treatment (see on this label).
- Wash contaminated clothing before reuse.
- IF exposed or concerned: Get medical advice/attention.
- IF skin irritation or rash occurs: Get medical advice/attention.
- IF ON SKIN: Wash with plenty of water.
- Store locked up.
- Dispose of contents/container in accordance with local/regional/national/international regulations.

**Other Hazards**

- Results of PBT and vPvB assessment
- PBT: Not applicable
- 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	CAS No.	EC No.	Wt. % Content
Ethoxyliertes Bisphenol A Dimethacrylate	24448-20-2	N/A	2,5 – 10%
Tetramethylene Dimethacrylate	2082-81-7	218-218-1	< 2,5%

Diphenyl(2, 4, 6-trimethylbenzoyl)phosphine oxide	75980-60-8	278-355-8	< 2,5%
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For the wording of the listed risk phrases refer to section 16.

## 4. FIRST-AID MEASURES

### 4.1 Description of First-Aid Measures

General Notes

No special measures required.

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:

- 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.

Protective Measures:

Measures to prevent fire:

- 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.

**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.

**8.2.1.3 Respiratory Protection**

- Not required.

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.
pH:	Not determined.
Melting Point/Freezing Point:	Undetermined.
Initial Boiling Point & Boiling Range:	Undetermined.
Flash Point:	101°C (214°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:	330000 mPas
Explosive Property:	Product does not present an explosion hazard.
Oxidizing:	0,0%

**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**

**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**

- Acute Toxicity
- LD/LC50 values that are relevant for classification
  - Tetramethylene dimethacrylate LD-50 oral >5000mg/kg (rat)
- Primary irritant effect
  - On skin: no irritant effect
  - On eye: no irritant effect
- Sensitization
  - Sensitization possible through skin contact.
- Additional toxicological information
  - The product shows the following dangers according to internally approved calculation methods for preparations: Irritant
- Carcinogenic categories

<b>IARC (International Agency for Research on Cancer)</b>		
60676-86-0	Silica, vitreous	3
128-37-0	2, 6-di-tert-butyl-p-cresol	3
<b>NTP (National Toxicology Program)</b>		
None of the ingredients are listed.		
<b>OSHA-Ca (Occupational Safety &amp; Health Administration)</b>		
None of the ingredients are listed.		

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

**13. DISPOSAL CONSIDERATIONS**

- 13.1 Waste Treatment Methods**
  - 13.1.1 Recommendation
    - 13.1.1.1 Must be specially treated adhering to official regulations
    - 13.1.1.2 Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- 13.2 Uncleaned packages**
  - 13.2.1 Recommendation
    - 13.2.1.1 Packages that cannot be cleansed are to be disposed of in the same manner as the product
- 13.3 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**

<b>SARA Section 355 (extremely hazardous substances)</b>
None of the ingredients listed.
<b>SARA Section 313 (specific toxic chemical listings)</b>

None of the ingredients listed.	
<b>TSCA (Toxic Substances Control Act)</b>	
60676-86-0	Silica, vitreous
24448-20-2	Ethoxyliertes Bisphenol A Dimethacrylate
2082-81-7	Tetramethylene dimethacrylate
68611-44-9	Siliciumdioxid synthetisches rontgenamorphes
75980-60-8	Diphenyl(2, 4, 6- trimethylbenzoyl)phosphine oxide
58109-40-3	Diphenyliodonium-hexafluorophosphat
10287-53-3	Ethyl 4-(dimethylamino)benzoate
10373-78-1	D,L-Camperchinon
147315-50-2	2-(4, 6-diphenyl-1, 2, 5-triazin-2-yl)-5-((hexyl)oxy)-phenol
128-37-0	2, 6-di-tert-butyl-p-cresol
<b>Prop 65 – Chemicals known to cause cancer</b>	
None of the ingredients listed.	

<b>EPA (Environmental Protection Agency)</b>		
None of the ingredients are listed.		
<b>TLV (Threshold Limit Value established by ACGIH)</b>		
128-37-0	2, 6-di-tert-butyl-p-cresol	A4
<b>MAK (German Maximum Workplace Concentration)</b>		
128-37-0	2, 6-di-tert-butyl-p-cresol	4
<b>NIOSH-Ca (National Institute for Occupational Safety and Health)</b>		
60676-86-0	Silica, vitreous	

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GHS07



GHS08

**Signal Word(s):** Warning

Hazard-determining components of labeling:

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Tetramethylene dimethacrylate

Diphenyl (2, 4, 6- trimethylbenzoyl)phosphine oxide

Hazard Statements

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

Precautionary Statements:

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves

Contaminated work clothing must not be allowed out of the workplace

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

IF exposed or concerned: Get medical advice/attention.

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



IF ON SKIN: Wash with plenty of water.  
 Store locked up.  
 Dispose of contents/container in accordance with local/regional/national/international regulations.

**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. New format
2. Inclusion of EC Requirements
3. *Revision Date:* 10/16/2017

**16.2 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

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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.**