## 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product Identifier

***Product Name:*** BracePaste Fluoride Sealant
***Common Name:*** Bonding Agents
***Material:*** Orthodontic Primer / Sealant
***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.:*** Reference Section 3.
***CAS No. / IUPAC:*** Reference Section 3.

### 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 USA
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 INDENTIFICATION

### 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 *[Pertains to the following ingredients / component parts: Diurethane dimethacrylate, Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide, Tetramethylene dimethacrylate]*

Repr. 2 H361 Suspected of damaging fertility or the unborn child. *[Pertains to the following ingredients / component parts: Tetramethylene dimethacrylate]*

#### 2.1.2 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.

*** NOTE: The above information pertains only to the ingredients or raw materials used to make this product. Biocompatibility testing was performed on the finished product (BracePaste Fluoride Sealant); BracePaste Fluoride Sealant is**

**biocompatible per ISO 7405, ISO 10993-1.**

### 2.2 Label Elements

*The product is classified and labeled according to the Globally Harmonized System (GHS).*

**Hazard Pictogram(s)**

**Signal Word(s):** Warning

**Hazard-determining components of labeling**

Diurethane dimethacrylate
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
Tetramethylene dimethacrylate

**Hazard Statements:**

| | |
|---|---|
| H317 | May cause an allergic skin reaction. *[Pertains to the following ingredients / component parts: Diurethane dimethacrylate, Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide, Tetramethylene dimethacrylate]* |
| H361 | Suspected of damaging fertility of the unborn child. *[Pertains to the following ingredients / component parts: Tetramethylene dimethacrylate]* |

**Precautionary Statements:**

| | |
|---|---|
| P201 | Obtain special instructions before use. |
| P202 | Do not handle until all safety precautions have been read and understood. |
| P261 | Avoid breathing dust/fume/gas/mist/vapors/spray. |
| P272 | Contaminated work clothing must not be allowed out of the workplace. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| P302 + P352 | IF ON SKIN: Wash with plenty of soap and water. |
| P308 + P313 | IF exposed or concerned: Get medical advice/attention. |
| P321 | Specific treatment (see on this label). |
| P333 + P313 | If skin irritation or rash occurs: Get medical advice/attention. |
| P363 | Wash contaminated clothing before reuse. |
| P405 | Store locked up. |
| 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 the substances listed below with nonhazardous additions.

| Hazard-determining component | Wt. % Content | CAS No. | EC No. |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Diurethane dimethacrylate<br>*Skin Sens. 1B, H317* | 25 – 50 % | 72869-86-4 | 276-957-5 |
| Tetramethylene Dimethacrylate<br>*Skin Sens. 1B, H317* | 10 – 25 % | 2082-81-7 | 218-218-1 |
| Diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide<br>*Skin Sens. 1B, H317, Repr. 2, H361* | < 2.5 % | 75980-60-8 | 278-355-8 |

**NOTE: The above information pertains only to the ingredients or raw materials used to make this product. Biocompatibility testing was performed on the finished product (BracePaste Fluoride Sealant); BracePaste Fluoride Sealant is biocompatible per ISO 7405, ISO 10993-1.**

## 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. If skin irritation continues, consult a doctor.
**Eye Contact:** Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
**Ingestion/Swallowing:** Rinse out mouth and then drink plenty of water. Seek medical treatment.

### 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 spray
- 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 equipment.

## 6 ACCIDENTAL RELEASE MEASURES

### 6.1 Personal Precautions, Protective Equipment & Emergency Procedures

#### 6.1.1 For Non-Emergency Personnel

Protective Equipment

- Protective gloves, goggles

Emergency Procedure

- Wear protective equipment.
- Prevent formation of aerosols.
- Ensure adequate ventilation

### 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

Dispose contaminated materials as waste according to Section 13.

### 6.4 Reference to other sections (as applicable)

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

Protective Measures:

Measures to prevent fire:

- No special measures required.

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 undiluted product or large quantities of it to reach ground water, water course or sewage system.

Advice on General Occupational Hygiene:

- Store away from foodstuff.
- Immediately remove all soiled and contaminated clothing.
- Wash hands before breaks and at the end of work.

### 7.2 Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures & Storage Conditions

- Store between 3 °C and 25 °C
- Close container immediately after use and protect product from light incidence.

Requirements for Storage Rooms & Vessels

- Ensure good ventilation / exhaustion at the workplace.

## 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control Parameters

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

### 8.2 Exposure Controls

#### 8.2.1 Appropriate Engineering Controls

Ensure good ventilation / exhaustion at the workplace.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.

#### 8.2.2 Personal Protective Equipment

##### 8.2.2.1 Eye & Face Protection

- Goggles

##### 8.2.2.2 Skin Protection

Hand Protection

- Protective gloves – butyl rubber (BR), nitrile rubber (NBR).
- Penetration time of glove material:
  - 0.1 – 0.2 mm: 5 min.
  - 0.3 mm: 60 min.

##### 8.2.2.3 Respiratory Protection

- Breathing equipment not necessary if room is well-ventilated.

Reference Section 5 for specific personal protective equipment advice

#### 8.2.3 Environmental Exposure Controls

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

## 9 PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Basic Physical & Chemical Properties

| Property | Characteristic |
|---|---|
| Appearance | Viscous, Yellowish |
| Odor | Weak, characteristic |
| Odor Threshold | Not determined |
| pH | Not determined |
| Melting Point/Freezing Point | Undetermined |
| Initial Boiling Point & Boiling Range | 251 °C (483.8 °F) |
| Flash Point | 113 °C (235.4 °F) |
| Flammability (solid, gas) | Not applicable |
| Upper/Lower Flammability or Explosive Limits | Not determined |
| Ignition Temperature | Product is not self-igniting |
| Auto-Ignition Temperature | 400 °C (752 °F) |
| Explosive Property | Product does not present an explosion hazard |
| Decomposition Temperature | Not determined |

| | |
|---|---|
| Vapor Pressure @ 110°C (230°F) | 1.3 hPa (1 mm Hg) |
| Density @ 20°C (68°F) | 1.34g/cm$^3$ (11.1823 lbs/gal) |
| Vapor Density | Not determined |
| Relative Density | Not determined |
| Evaporation Rate | Not determined |
| Solubility in / Miscibility with Water | Fully miscible |
| Partition Coefficient (n-octanol/water) | Not determined |
| Viscosity | Not determined |
| Oxidizing | Not determined |

## 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 further relevant information available.
**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**: No further relevant information available.
- **Respiratory/Skin 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**
  - IARC (International Agency for Research on Cancer)
    - 128-37-0 – Butylated hydroxytoluene – 3
  - NTP (National Toxicology Program)
    - None of the ingredients are listed
  - OSHA-Ca (Occupational Safety & Health Administration)
    - None of the ingredients are listed

## 12 ECOLOGICAL INFORMATION

**12.2 Toxicity**
Aquatic Toxicity: No further relevant information available.
**12.3 Persistence and Degradability**
No further relevant information available.

**12.4 Bio accumulative Potential**
No further relevant information available.

**12.5 Mobility in Soil**
No further relevant information available.

**12.6 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.
Also poisonous for fish and plankton in water bodies.
Toxic for aquatic organisms.

**12.7 Results of PBT and vPvB Assessment**
PBT: Not applicable.
vPvB: Not applicable.

**12.8 Other Adverse Effects**
No further relevant information available.

## 13 DISPOSAL CONSIDERATIONS

**13.2 Waste Treatment Methods**
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.

**13.3 Uncleaned Packages**
Disposal must be made according to official regulations.

## 14 TRANSPORTATION INFORMATION

**14.2 Transportation Information**

| **UN Number** | |
|---|---|
| DOT | Void |
| ADR, IMDG, IATA | UN3082 |
| **UN Proper Shipping Name** | |
| DOT | Void |
| ADR | 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (di-urethane dimethacrylate) |
| IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (di -urethane dimethacrylate, diphenyl (2,4,6-trimethylbenzoyl)phosphine oxide), MARINE POLLUTANT |
| IATA | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (di-urethane dimethacrylate) |
| **Transport Hazard Class(es)** | |
| **DOT**<br>Class: Void | |

| | |
|---|---|
| **ADR**<br>Class: 9 (M6) Miscellaneous dangerous substances and articles<br>Label: 9 |  |
| **IMDG, IATA**<br>Class: 9 Miscellaneous dangerous substances and articles<br>Label: 9 |  |
| **Packing Group** | |
| DOT | Void |
| ADR, IMDG, IATA | III |
| **Environmental Hazards** | |
| Marine Pollutant | Symbol (fish and tree) |
| Special Marking (ADR) | Symbol (fish and tree) |
| Special Marking (IATA) | Symbol (fish and tree) |
| **Special Precautions for User** | |
| Warning | Miscellaneous dangerous substances and articles |
| Hazard Identification Number (Kemler code) | 90 |
| EMS Number | F-A, S-F |
| Stowage Category | A |
| **Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code** | |
| Not applicable | |
| **Transport / Additional Information** | |
| ADR<br>Excepted quantities (EQ) | Code: E1<br>Maximum net quantity per inner packaging: 30 ml<br>Maximum net quantity per outer packaging: 1000 ml |
| IMDG<br>Limited quantities (LQ)<br>Excepted quantities (EQ) | <br>5L<br>Code: E1<br>Maximum net quantity per inner packaging: 30 ml<br>Maximum net quantity per outer packaging: 1000 ml |
| UN "Model Regulation" | UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (DI-URETHANE DIMETHACRYLATE), 9, III |

## 15 REGULATORY INFORMATION

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

| |
|---|
| **SARA Section 355 (extremely hazardous substances)** |
| None of the ingredients are listed. |
| **SARA Section 313 (specific toxic chemical listings)** |
| None of the ingredients are listed. |
| |
| **TSCA (Toxic Substances Control Act)** |
| All components have the value of ACTIVE. |

| | | |
|---|---|---|
| | | |
| **Hazardous Air Pollutants** | | |
| None of the ingredients are listed. | | |
| | | |
| **Prop 65 - Chemicals known to cause cancer** | | |
| None of the ingredients are listed. | | |
| | | |
| **Cancerogenity Categories** | | |
| **EPA (Environmental Protection Agency)** | | |
| None of the ingredients are listed. | | |
| **TLV (Threshold Limit Value)** | | |
| 128-37-0 | Butylated hydroxytoluene | A4 |
| **MAK (German Maximum Workplace Concentration)** | | |
| 128-37-0 | Butylated hydroxytoluene | 4 |
| **NIOSH-Ca (National Institute for Occupational Safety and Health)** | | |
| None of the ingredients are listed. | | |
| | | |
| **Water Hazard Class** | | |
| Water Hazard Class (Self-assessment): Slightly hazardous for water. | | |

### 15.3 Chemical Safety Assessment:

A chemical safety assessment has not been carried out for this substance/mixture.

## 16 ADDITIONAL INFORMATION

### 16.2 Indication of changes/revision to SDS:

1. Creation of SDS according to OSHA HCS (Version 3, May 3, 2024)
2. ***Revision Date:*** 10/15/2024 (REV 0)

### 16.3 Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
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)
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
Sensitization - Skin 1: Skin sensitisation – Category 1
Toxic to Reproduction 2: Reproductive toxicity – 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

**16.5 Classification and procedure used to derive classification for mixtures according to Regulation (EC) 1272/2008[CLP]:**
None.

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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.**