

According to 1907/2006/EC, Article 31

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: BracePaste® Band and Build LC
Common Name: Orthodontic Band Cement
Material: Light-Cure Band Cement
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

REACH Registration No.: 01-2119967415-30-0000 through 01-2119967415-30-0005, 01-2119967415-XXXX

CAS No. / IUPAC: 2082-81-7

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]

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

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.

2.2 Label Elements

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

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Hazard Pictogram(s)



Signal Word(s): Warning

Hazard-determining components of labeling

Tetramethylene dimethacrylate

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.

Labelling of packages where the contents do not exceed 125 ml

Hazard Pictogram(s)



Signal Word(s): Warning

Hazard-determining components of labeling

Tetramethylene dimethacrylate

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.

2.3 Other Hazards

Results of PBT and vPvB assessment:

PBT: Not applicable.

vPvB: Not applicable.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Chemical Characterization: Mixtures

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

Hazard-determining component	Wt. % Content	CAS No.	EINECS No.
Tetramethylene Dimethacrylate <i>Skin Sens. 1B, H317</i>	< 2.5%	2082-81-7	218-218-1

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.

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:

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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

- Protective gloves, goggles

Emergency Procedure

- Wear protective equipment. Prevent formation of aerosols.

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)

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

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. Keep receptacles tightly sealed.

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 foodstuffs. 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 10 and 25 °C.
- Close container immediately after use and protect product from light incidence. Keep receptacles tightly sealed.

Requirements for Storage Rooms & Vessels

- Ensure good ventilation / exhaustion at the workplace.

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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.

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.
 - 0.3mm: 60 min.

8.2.2.3 Respiratory Protection

- 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

Appearance:	Pasty, Blue
Odor:	Weak, characteristic
Odor Threshold:	Not determined.
pH:	Not determined.
Melting Point/Freezing Point:	Undetermined.
Initial Boiling Point & Boiling Range:	251 °C
Flash Point:	151 °C
Evaporation Rate:	Not available.
Flammability (solid, gas):	Not applicable.
Ignition Temperature:	400 °C
Upper/Lower Flammability or Explosive Limits:	Not determined.
Vapor Pressure:	Not determined.

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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:	450,000 mPas (dynamic 20 °C)
Explosive Property:	Product does not present an explosion hazard.
Oxidizing:	Not available.

9.2 Other Information

Density:	2.44 g/cm ³
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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

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

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.

10.8 Hazardous Polymerization

Photoreactive. Danger of polymerization.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Information

- 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 > 5,000 mg/kg (rat)
- Primary irritant effect:
Skin Corrosion/Irritation: Based on available data, the classification criteria are not met.

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Serious Eye Damage/Irritation: Based on available data, the classification criteria are not met.

- **Respiratory/Skin Sensitization:**
May cause an allergic skin reaction.
- **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 Bio accumulative Potential

No further relevant information available.

12.4 Mobility in Soil

No further relevant information available.

12.5 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.

12.6 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

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.

13.2 Uncleaned Packages

Packaging 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

ADR, ADN, IMDG, IATA: Void

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- 14.2 UN Proper Shipping Name**
ADR, ADN, IMDG, IATA: Void
- 14.3 Transport Hazard Class(es)**
ADR, ADN, IMDG, IATA: Void
- 14.4 Packing Group**
ADR, IMDG, IATA: Void
- 14.5 Environmental Hazards**
Marine pollutant: 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 UN "Model Regulation":**
Void.

15. REGULATORY INFORMATION

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

Direction 2012/18/EU

Named Dangerous Substances – ANNEX 1: None of the ingredients is listed.

Regulation (EC) No 1907/2006 ANNEX XVII: Conditions of restriction: 3

National Regulations (USA):

Technical Instructions (air):

Class	Share in %
III	<2.5

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.

16. ADDITIONAL INFORMATION

- 16.1 Indication of changes/revision to SDS:**
 1. Creation of SDS according to 1907/2006/EC, Article 31
 2. **Revision Date:** 11/19/2020
- 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)
 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)

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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 Sensitization – Category 1

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

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.**