

**1. PRODUCT AND COMPANY IDENTIFICATION**

**1.1 Product Identifier**

**Product Name:** Bandtite™ Glass Ionomer Self Cure Band Cement  
**Common Name:** Adhesive - Glass Ionomer Cement (Powder; Liquid)  
**Material:** Glass Ionomer  
**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.:** N/A  
**REACH Registration No.:** N/A  
**CAS No. / IUPAC:** N/A

**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]**

Eye Irrit. 2  
 STOT SE 3  
 Skin Irrit. 2  
 Skin Sens.1

**2.1.2 Classification according to Directive 67/548/EEC**

Irritant (Xi); R 36/37/38-43

**2.1.3 Additional information:**

None

**2.2 Label Elements**

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

**Hazard Pictogram(s)**



**Signal Word(s): Warning**

Hazard Statements:

- May cause eye irritation
- May cause respiratory irritation
- May cause skin irritation
- May cause an allergic skin reaction

Precautionary Statements:

- Avoid breathing powder/dust
- Wear protective gloves and eye protection
- If in eyes, rinse cautiously with water for several minutes
- If eye irritation persists, get medical advice/attention
- If on skin, wash with plenty of soap and water
- If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing
- If irritation or rash occurs, get medical advice/attention

Supplemental Hazard information (EU):

Not applicable

**2.3 Other Hazards**

None

**3. COMPOSITION / INFORMATION ON INGREDIENTS**

Glass Ionomer cements in two parts, powder and liquid that are mixed together before use.

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Liquid	N/A	N/A	Proprietary
Powder	N/A	N/A	Proprietary

**4. FIRST-AID MEASURES**

**4.1 Description of First-Aid Measures**

General Notes: May be irritating to eyes, respiratory system, mucous membranes and skin. Liquid may cause sensitization by prolonged or repeated skin contact. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

Inhalation: Move to fresh air. If necessary, administer oxygen and/or artificial respiration and seek medical attention.

Skin Contact: Wash skin thoroughly with soap and running water

Eye Contact: Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention if irritation persists.

Ingestion/Swallowing: Rinse mouth and seek medical attention. Never give anything by mouth to an unconscious person.

Self-Protection of First-Aider: Wear safety glasses, gloves and lab coat. If powder has dispersed into the air, wear dust mask.

**4.2 Important Symptoms and Effects**

Red and/or irritated eyes, mucous membranes or skin  
Liquid may cause sensitization by prolonged or repeated skin contact

**Notes to the Doctor:**

Treat symptomatically

**5. FIRE AND EXPLOSION HAZARDS**

**5.1 Extinguishing Media**

Suitable Extinguishing Media:  
Carbon dioxide, dry chemical, alcohol foam or water fog  
Extinguishing Media which should not be used:  
Avoid direct water stream

**5.2 Special Exposure Hazards from Substance/Mixture**

None

**5.3 Advice for Firefighters**

Self-contained breathing apparatus should be worn by firefighting personnel.

**6. ACCIDENTAL RELEASE MEASURES**

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

**6.1.1 For Non-Emergency Personnel**

Ventilate area. Wear gloves, lab coat and safety glasses

**6.1.2 For Emergency Responders**

Ventilate area. Wear gloves, lab coat and safety glasses

**6.2 Environmental Precautions**

Contain spilled material. Follow all government regulations.

**6.3 Methods & Material for Containment & Cleaning Up**

Absorb or wipe up spill with suitable material (paper towels or cloths). Collect for disposal in covered container. Wash area of spill with alcohol or soap and water.

## 7. HANDLING AND STORAGE

### 7.1 Precautions for Safe-Handling

For use only by dental professionals trained in the use of dental materials. Follow good hygiene practices. Cap product immediately after use. Avoid cross contamination between parts and dispersion of powder into the air.

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

Technical Measures & Storage Conditions: Store at cool room temperature not exceeding 75°F (24°C), in dry conditions. Avoid excessive moisture, direct strong light and exposure to elevated temperatures.

Packaging Materials: Keep containers tightly closed. Store product in original container.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control Parameters

No data available but non-toxic

### 8.2 Exposure Controls

#### 8.2.1 Appropriate Engineering Controls

No special equipment required under normal conditions of use of this product in the quantity provided.

#### 8.2.2 Personal Protective Equipment

##### 8.2.2.1 Eye & Face Protection

No special requirements other than the usual safety glasses.

##### 8.2.2 Skin Protection

No special requirements. Good personal hygiene and safety practices should protect from unnecessary exposure to material. Surgical gloves will limit contact with Glass Ionomer material.

##### 8.2.2.3 Respiratory Protection

No special equipment required under normal conditions of use

#### 8.2.3 Environmental Exposure Controls

Powder is inert. Liquid should not be discharged into environment. Follow all government regulations.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Basic Physical & Chemical Properties**

	<u>Liquid</u>	<u>Powder</u>
Appearance:	Clear liquid	Fine white powder
Odor:	Mild Characteristic odor	Odorless
Odor Threshold:	Mild	N/A
pH:	N/A	N/A
Melting Point/Freezing Point:	N/A	N/A
Initial Boiling Point & Boiling Range:	ca 105°C	N/A
Flash Point:	N/A	N/A
Flammability (solid, gas):	N/A	N/A
Vapor Pressure:	ca 720mm Hg @ 100°C	Negligible @ ambient temperature
Vapor Density:	ca 0.62	N/A
Solubility(ies):	Soluble in water	Negligible
Auto-Ignition Temperature:	N/A	N/A
Explosive Property:	N/A	N/A
Oxidizing:	N/A	N/A
Specific Gravity:	N/A	ca 3.0 (H2O=1)

**9.2 Other Information**

None

**10. STABILITY AND REACTIVITY**

**10.1 Reactivity**

Stable

**10.2 Chemical Stability**

Stable if stored and used as directed

**10.3 Conditions of Instability**

Avoid contact with alkaline metals with liquid

**10.4 Possibility of Hazardous Reactions**

None

**10.5 Conditions to Avoid**

Elevated temperatures  
Cross Contamination  
Avoid moisture with powder

**10.6 Incompatible Materials**

Alkaline metals

**10.7 Hazardous Decomposition Products**

None

**10.8 Hazardous Polymerization**

Will not occur

**11. TOXICOLOGICAL INFORMATION**

**11.1 Information on Toxicological Information**

Acute Toxicity: Not toxic. Minimal health hazard in the quantities present in this product and under normal conditions of use.

Chronic Health Effects: Prolonged/frequent skin contact may cause eye, skin, mucous membrane and respiratory system irritation.

Skin Corrosion/Irritation: May be irritating to eyes, respiratory system, mucous membranes or skin on contact or with prolonged exposure.

Serious Eye Damage/Irritation: Prolonged/frequent skin contact may cause eye, skin, mucous membrane and respiratory system irritation.

Respiratory/Skin Sensitization: May be sensitizing. Prolonged/frequent skin contact with liquid may cause allergic skin reaction.

Carcinogenicity: No ingredient listed as a carcinogen

**12. ECOLOGICAL INFORMATION**

To the best of our knowledge, no ecological damage or impact is anticipated upon exposure of material to the environment. Liquid should not be discharged into the environment. Follow all government regulations.

**13. DISPOSAL CONSIDERATIONS**

Dispose of product and contaminated packaging in accordance with all federal, state, and local regulations.

**14. TRANSPORTATION INFORMATION**

No restrictions. Not regulated.

**15. REGULATORY INFORMATION**

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

**EU Regulations**

None

**Other EU Regulations:**

None

**National Regulations (USA):**

None

**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. New format
2. Inclusion of EC Requirements
3. *Revision Date:* 04/17/2015

**16.2 Abbreviations and acronyms:**

None

**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

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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.**