

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Radiance Brackets, Empower Clear Brackets, 20/40; Ceramic Button
Common Name: Ceramic Bracket; Lingual Attachments
Material: Aluminum Oxide
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.: 215-691-6

REACH Registration No.: 01-2119529248-35-XXXX

CAS No. / IUPAC: 1344-28-1

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

General Hazard Statement:

This product is a manufactured article as defined under REACH. No labeling is required for finished product.

This product is classified as "articles" and do not constitute a hazardous material in solid form und the definitions of the OSHA Hazard Communication Standard (29CFR1910.1200). Any articles manufactured from these solid products would be generally classified as non-hazardous.

However some hazardous elements contained in these products may be emitted under certain processing conditions. Products in the solid state present no fire or explosion hazards. The following classification information is for the hazardous elements which may be released during processing.

2.1 Classification of the substance or mixture

Considered Non-Hazardous

2.2 Label Elements

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

Hazard Pictogram(s)



Signal Word(s) – Warning (applicable only to US)

Hazard Statements:

May be harmful if swallowed (H303)

Maybe harmful in Inhaled (H333)

Precautionary Statements:

Do not eat, drink or use tobacco when using this product

Do not breathe dust

If inhaled: Call Poison Control Center or doctor/physician if you feel unwell

Supplemental Hazard information (EU):

Not applicable

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Aluminum Oxide	1344-28-1	215-691-6	100

4. FIRST-AID MEASURES

4.1 Description of First-Aid Measures

Inhalation: Remove from exposure, treat symptomatically, consult a physician

Skin Contact: Wash with soap and water. Consult physician if irritation develops or persists.

Eye Contact: Eye irritation. Flush immediately with large amounts of water for at least 15 minutes. Consult physician if irritation develops or persists.

Ingestion/Swallowing: Give several glasses of water to drink to dilute. If large amounts were swallowed, consult physician.

4.2 Important Symptoms and Effects

Symptoms of Exposure: In dust form, it may cause irritation to eyes, nose and throat

5. FIRE AND EXPLOSION HAZARDS

Aluminum Oxide is not flammable and not explosive

6. ACCIDENTAL RELEASE MEASURES

Solid Pieces: Sweep up broken pieces and containers. Use laceration resistant gloves if handling broken pieces.

Dust Form: Avoid getting Aluminum Oxide dust in eyes. Use safety glasses with side-shields or goggles. Use a NIOSH approved dust mask or particular respirator. If the powder is airborne, allow time for the dust to settle. Clean up the powder with a damp mop or cloth.

Respiratory Protection: NIOSH approved respirator when used in powder form for prolonged periods of time.

7. HANDLING AND STORAGE

Do not cause physical damage. Avoid creating airborne dust.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

Component	OSHA PELs (Permissible Exposure Limits)	ACGIH TLVs (Threshold Limit Values)
Aluminum Oxide – Total Dust	15mg/ m ³ TWA (8 hr.)	10mg/m ³ TWA (8 hr.)
Aluminum Oxide – Respirable Fraction	5mg/ m ³ TWA (8 hr.)	1mg/ m ³ TWA (8 hr.)

Others:

NIOSH REL 8 hr. TWA: 10m/g m³ (Total Dust)

United Kingdom OEL TWA: 5mg/ m³ (Nuisance Dust)

“MAK” Germany TWA: 2mg/ m³ (Inhalable Dust)

France (INRS) TWA: 10mg/ m³ (Nuisance Dust)

Japan Society of Occupational Health OEL TWA: 0.5mg/ m³ (Respirable Dust)

8.2 Exposure Controls

8.2.1 Appropriate Engineering Controls

None needed

8.2.2 Personal Protective Equipment

8.2.2.1 Eye & Face Protection

Safety glasses or goggles if dust is generated

8.2.2 Skin Protection

Use impermeable gloves as a good practice to avoid getting it on hands. The material is not considered a skin hazard, but using gloves can help prevent accidental transfer to the mouth by contaminated hands.

8.2.2.3 Respiratory Protection

NIOSH approved respiratory protection is recommended where the exposure limits are or may be exceeded. Type of respirator to be worn is based on the level of exposure.

8.2.3 Environmental Exposure Controls

No Information Available

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	Clear
Odor:	Odorless
pH:	N/A due to insolubility
Melting Point:	2053°C
Boiling Point (760mm Hg):	>2977°C
Flammability (solid, gas):	N/A
Solubility in Water:	Insoluble

9.2 Other Information

Specific Gravity (H2O=1):	3.99
Molecular Weight:	101.94

10. STABILITY AND REACTIVITY

Stability/Incompatibility: Stable; not reactive. There are no materials to avoid. There are no hazardous decomposition products.

Hazardous Reaction/Decomposition Product: None Known

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Information

Toxicokinetics: No bioaccumulation potential

CMR Effects: Negative. There is no evidence of any CMR (Carcinogenic, Mutagenic, or Reproductive) effects

Exposure Routes:

- Inhalation: If dust is generated
- Ingestion: If proper hygiene practices are not utilized
- Eye: Dust in the eye will cause physical irritation

Effects of Overexposure: Lungs – Prolonged overexposure to dust could cause pneumoconiosis and potential nervous system disorder

11.1.1 Acute Toxicity

Acute Effects/Toxicity Tests:

Oral: Rat; >2000mg/Kg bw

Inhalation: Rat; LC50:7.6ng/L

Skin Corrosion: Rabbit; Non Corrosive

Skin Irritation: Rabbit; Not Irritating

Eye Irritation: Rabbit; Not Irritating

Sensitization: Not Sensitizing

Repeated Dose Toxicity:

Chronic (Rat): NOAEL 30mg/Kg bw/day

Subchronic (Rat): NAOEC 70mg/m³

12. ECOLOGICAL INFORMATION

Ecotoxicity: No information was found in the references reviewed

Environmental Fate: No information was found in the references reviewed

13. DISPOSAL CONSIDERATIONS

The generator of waste material has the responsibility for proper waste classification, transportation and disposal with accordance applicable federal, state/provincial and local regulations.

14. TRANSPORTATION INFORMATION

Not a hazardous material for USDOT, IATA and IMDG transportation

15. REGULATORY INFORMATION

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

EU Regulations

European Inventory of Existing Chemicals (EINECS): All of the components of this product are included on EINECS.

Label Name: Sapphire:

EU Risk (R) and Safety (S) Phrases:

Irritating to Eyes (R36)

When using do not eat, drink or smoke (S20/21)

Wear suitable gloves (S37)

National Regulations (USA):

Comprehensive Environmental Response & Liability Act of 1980 (CERCLA) RQ: No
 EPCRA Section 313 Toxic Chemical: No
 EPCRA Section 304 (EHS) RQ: No
 SARA Section 311/312 (40CFR370) Hazard Categories:
 Acute: Yes
 Chronic: No
 Fire Hazard: No
 Pressure Hazard: No
 Reactivity Hazard: No
 Toxic Substance Control Act (TSCA): Yes
 Clean Air Act (CAA) 112(r) TQ: No

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:* 06/12/2018

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

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.**