

1. PRODUCT AND COMPANY IDENTIFICATION**1.1 Product Identifier**

Product Name: Sierra Brackets, Sierra Classic – Gold Brackets, Colored Ligatures, Colored Chain, Memory Chain, E-Z Tie Tubing, Arch Wire Sleeve, Plastic Tie, Clear Rotation Wedges, Separators

Common Name: Orthodontic Brackets, Elastomerics

Material: Thermoplastic Polyurethane (TPU)

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.: None

REACH Registration No.: None

CAS No. / IUPAC: Not Available

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

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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Thermoplastic polyurethane	not available	None	100

4. FIRST-AID MEASURES

In case of skin contact (Contact with Hot Melt): Cool immediately with plenty of water. Do not remove product crusts which may have formed neither forcibly nor by applying any solvents to the skin involved. To obtain treatment for possible burns, and appropriate skin care, seek medical advice immediately.

In case of skin contact (Contact with Room Temperature Material): Wash affected areas thoroughly with soap and plenty of water.

5. FIRE AND EXPLOSION HAZARDS

5.1 Extinguishing Media

Suitable Extinguishing Media:

- Water, Foam, Dry Chemical

5.2 Special Exposure Hazards from Substance/Mixture

- Burning releases carbon monoxide, carbon dioxide, oxides of nitrogen and traces of hydrogen cyanide. In the event of fire and/or explosion do not breathe fumes.
- Do not allow contaminated extinguishing water to enter the soil, ground-water or surface waters

5.3 Advice for Firefighters

- Firemen must wear self-contained breathing apparatus

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment & Emergency Procedures

Put on protective equipment (see section 8). Granules are a slip hazard! Ensure adequate ventilation/exhaust extraction. Keep unauthorized persons away.

6.2 Environmental Precautions

Do not flush into surface water or sanitary sewer system.

6.3 Methods & Material for Containment & Cleaning Up

Use mechanical handling equipment. Avoid dust formation. Sweep up and shovel into suitable containers for disposal.

6.4 Reference to other sections (as applicable)

Reference Section 8 for appropriate personal protective equipment

7. HANDLING AND STORAGE

7.1 Precautions for Safe-Handling

Adequate ventilation and, if necessary, effective exhaust must be provided at the workplace when opening fresh drums, drying granules and processing the material. Under recommended processing conditions, small amounts of emissions may occur.

Provide good ventilation and/or local exhaust systems are used. The Workplace Exposure Limit(s) stated in Section 8 should not be exceeded. Dust must be removed by effective exhaust ventilation.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Keep container tightly closed and dry.

VCI storage class (VCI=German Association of the Chemical Industry): 11

Storage Temperature: <104°C/40°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

The regulations for the substances listed below must be observed when processing this product, particularly if processing takes place at elevated temperatures. The provision of effective fresh-air and exhaust ventilation equipment at the points where vapors may be generated will ensure compliance with the tolerance limits quoted below:

Tetrahydrofuran (CAS# 109-99-9)

TRGS 900: 50ppm; 150mg/m³; Ceiling Limit: 2; If in compliance with the OEL and BEL values, then there should be no risk of reproductive damage

TRGS 900: Skin; Dermal absorption possible

TRGS 900: STEL CL; Category I: substances for which the localized effect has an assigned OEL respiratory passages

EU ELV: TWA: 50ppm; 150mg/m³; Dermal absorption possible

EU ELV: STEL: 100ppm; 300mg/m³

General limiting value of dust:

TRGS 900: 10mg/m³; Ceiling Limit: 2; inhalable fraction

TRGS 900: 3mg/m³; Ceiling Limit: 2; alveolar fraction

TRGS 900: STEL CL; Category II: substances with a resorptive effect

8.2 Exposure Controls

Hand Protection: Suitable materials for safety gloves

Other Skin Protection: Wear suitable protective clothing

Respiratory Protection: In case of dust formation, use respiratory equipment with filter type particle filter P1 according to EN 143

Eye & Face Protection: Wear eye/face protection

Other protective measures: Do not breathe dust/vapor. Keep away from foodstuffs, drinks and tobacco. Wash hands and face before breaks and at the end of work. Keep working clothes separately. Change contaminated clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	granular, various colors
Odor:	almost odorless
Odor Threshold:	N/A
pH:	N/A
Softening Point:	248°F/120°C
Ignition Temperature:	>410°F/210°C
Vapor Pressure:	N/A
Bulk Density:	500-700 kg/m ³
Density:	ca. 1.2 g/cm ³
Solubility(ies):	practically insoluble

9.2 Other Information

None

10. STABILITY AND REACTIVITY

10.1 Reactivity

Stable

10.2 Chemical Stability

Stable

10.3 Conditions of Instability

None Known

10.4 Possibility of Hazardous Reactions

None observed

10.5 Conditions to Avoid

None Known

10.6 Incompatible Materials

None known

10.7 Hazardous Decomposition Products

Smoldering or incomplete combustion leads to the formation of toxic gas mixtures: Carbon Monoxide, Carbon Dioxide and Nitrogen Oxides.
Thermal decomposition begins at 230°C

10.8 Hazardous Polymerization

None Known

11. TOXICOLOGICAL INFORMATION

The product has no harmful side effects on health if properly handled.

Under recommended processing conditions, small amounts of isocyanates may be emitted. Exceeding the recommended processing temperature leads to a significant increase in the amount of isocyanate vapor generated.

Over-exposure entails a risk of concentration-dependent inhalatory irritation and/or sensitization by isocyanates (delayed appearance of difficulty breathing, coughing, asthma is possible)

The regulations for the substances listed below must be observed when processing this product, particularly if processing takes place at elevated temperatures.

Isocyanates (all, as-NCO): R42 May cause sensitization by inhalation

Tetrahydrofuran (CAS# 109-99-9): R36/37 Irritating to eyes and respiratory system

12. ECOLOGICAL INFORMATION

The product is practically insoluble in water. In view of its consistency and insolubility in water, no ecological problems are to be expected if the product is properly handled. The product is not readily biodegradable.

Do not allow to escape into waterways, wastewater or soil.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with applicable international, national and local laws, ordinances and statutes. For disposal within the EC, the appropriate code according to European Waste Catalogue (EWC) should be used.

After containers have been emptied as thoroughly as possible (e.g. by pouring, scraping or draining until "drip-dry"), they can be sent to an appropriate collection point set up within the framework of the existing take-back scheme of the chemical industry. Containers must be recycled in compliance with national legislation and environmental regulations.

The product is suitable for mechanical recycling. After appropriate treatment it can be remelted and reprocessed into new moulded articles. Mechanical recycling is only possible if the material has been selectively retrieved and carefully segregated according to type.

14. TRANSPORTATION INFORMATION

Not dangerous cargo.

Keep dry.

Keep separated from foodstuffs.

15. REGULATORY INFORMATION

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

EU Regulations

None

Other EU Regulations:

(Germany) Not water endangering

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:** 04/24/2015

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

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.**