

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Beta Titanium Wire
Common Name: Orthodontic Wires
Material: Titanium Alloy
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.: See Section 3

REACH Registration No.:

Titanium (01-2119484878-14-XXXX)
Molybdenum (01-2119472304-43-XXXX)
Zirconium (01-2119490102-49-XXXX)
Tin (01-2119486474-28-XXXX)

CAS No. / IUPAC: See 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
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

Considered Non-Hazardous

2.2 Label Elements

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

Hazard Pictogram(s)

No pictograms.

2.3 Other Hazards

None

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Titanium, Ti	7440-32-6	231-142-3	60-85
Molybdenum, Mo	7439-98-7	231-107-2	10-20
Zirconium, Zr	7440-67-7	231-176-9	5-10
Tin, Sn	7440-31-5	231-141-8	1-5

4. FIRST-AID MEASURES

No first aid required for contact with solid product. The following information applies to contact from processing.

Inhalation: If irritation or other symptoms develop, remove to fresh air. Get medical attention if symptoms persist.

Skin Contact: Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops.

Eye Contact: Flush with large quantities of water, holding the eyelids apart to assure that the material is washed out. Get medical attention if irritation persists.

Ingestion/Swallowing: If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.

5. FIRE AND EXPLOSION HAZARDS

5.1 Extinguishing Media

This material is not combustible in solid form. Use media that is appropriate for the surrounding fire. Suitable extinguishing media are:

- Dry sand
- Graphite powder
- Lith-A powder
- Dry chemical or other media appropriate for a Class D fire.

Extinguishing Media which should **not** be directly used for fires involving fine dust or filings:

- Water
- CO₂
- Foam

5.2 Special Exposure Hazards from Substance/Mixture

Fine powders or filings may burn with intense heat. Fine dust may present an explosion hazard. Dousing burning metal with water may generate explosive hydrogen gas.

Thermal decomposition or combustion products include oxides or the metals listed in Section 2 which may be highly toxic.

5.3 Advice for Firefighters

Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment & Emergency Procedures

Avoid contact with eyes, skin or clothing. Do not breathe dust.

6.2 Environmental Precautions

Prevent entry into sewers and waterways

6.3 Methods & Material for Containment & Cleaning Up

Pick up solid material for reuse or disposal. For spills of dust, wear respirator and protective clothing (see Section 8). Vacuum using an explosion-proof, HEPA vacuum and non-sparking tools. Do not breathe dust or allow it to contaminate skin or clothing. Spill and release reporting requirements vary. Consult local authorities regarding requirements.

6.4 Reference to other sections (as applicable)

None

7. HANDLING AND STORAGE

7.1 Precautions for Safe-Handling

Do not breathe dust or fumes from processing. Avoid contact with dust. Wear protective clothing and equipment as described in Section 8. Process only with adequate ventilation. Keep containers closed when not in use. Do not eat, drink or smoke in the work area.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Store in cool, well ventilated location away from incompatible materials.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

Component	OSHA PELs (Permissible Exposure Limits)	ACGIH TLVs (Threshold Limit Values)
Titanium, Ti	Not Established	Not Established
Molybdenum, Mo	15mg/ m ³ TWA (total dust)	3mg/ m ³ TWA (respirable fraction)
Zirconium, Zr	5mg/ m ³ TWA (as Zn compounds)	5mg/ m ³ TWA
Zirconium, Zr	2mg/ m ³ TWA (as Zn compounds)	N/A
Tin, Sn	2mg/ m ³ TWA	2mg/ m ³ TWA

Additional Information:

Zn: 1mg /m³ TWA DFG MAK; 5 mg /m³ TWA UK; 10 mg /m³ TWA STEL UK WEL
 Sn: 2 mg /m³ TWA UK; 4mg /m³ TWA STEL UK WEL (as tin inorganic compounds)

8.2 Exposure Controls

8.2.1 Appropriate Engineering Controls

None needed under normal use. If dust or fumes are generated during processing, use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

8.2.2 Personal Protective Equipment

8.2.2.1 Eye & Face Protection

Wear safety glasses or other eye protection consistent with industrial safety practice for the process being performed.

8.2.2 Skin Protection

Wear protective gloves if needed to prevent cuts or other injuries.

8.2.2.3 Respiratory Protection

None needed under normal use. If the occupational exposure limits are exceeded during processing, an approved respirator with high efficiency particulate filters may be used. For higher exposures (greater than 10 times the exposure limit) a supplied air respirator may be required. Respirator selection and use should be based on contaminant type, form and concentration. Follow OSHA 1910.134, ANSI Z88.2 or local authority regulations and good Industrial Hygiene practice.

8.2.2.4 Thermal Hazards

Thermal decomposition or combustion products include oxides or the metals listed in Section 2 which may be highly toxic.

Reference Section 5 for specific personal protective equipment advice

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	Silver wire
Odor:	Odorless
pH:	N/A
Melting Point/Freezing Point:	3050°F / 1676.7°F
Initial Boiling Point & Boiling Range:	N/A
Flash Point:	N/A
Evaporation Rate:	N/A
Flammability (solid, gas):	N/A
Solubility (H2O):	Insoluble

9.2 Other Information

None

10. STABILITY AND REACTIVITY**10.1 Reactivity**

N/A

10.2 Chemical Stability

Stable

10.3 Conditions of Instability

None known

10.4 Possibility of Hazardous Reactions

None known

10.5 Conditions to Avoid

None known

10.6 Incompatible Materials

Acids, alkalis, oxidizing agents, potassium nitrate and turpentine.

10.7 Hazardous Decomposition Products

Metal fumes and oxides are emitted when product is heated above the melting point

10.8 Hazardous Polymerization

N/A

11. TOXICOLOGICAL INFORMATION**11.1 Information on Toxicological Information**

Chronic Health Effects: Prolonged inhalation of dust may cause lung damage, fibrotic lung disease and effects on the cardiovascular system. Chronic exposure to tin oxide dusts and fumes may result in stannosis (benign pneumonconiosis). Repeated skin contact with zirconium compounds may cause allergic skin sensitization.

Serious Eye Damage/Irritation: Dust or fines may cause mechanical irritation

Respiratory/Skin Sensitization: Dust may cause skin irritation

Ingestion: No acute effects expected from swallowing small amounts

Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP, ACGIH, OSHA or the EU Directive.

Aspiration Hazard: Dust or fumes may cause irritation of the mucous membranes and upper respiratory tract

Medical Conditions Generally Aggravated by Exposure: Individuals with pre-existing skin disorders may be at increased risk from exposure.

11.1.1 Acute Toxicity

No data available

12. ECOLOGICAL INFORMATION

No data available at this time

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations

14. TRANSPORTATION INFORMATION

None, not regulated for Transport of Dangerous Goods (DOT, IATA, IMDG)

15. REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****EU Regulations**

European Community Labeling: This product is a manufactured article as defined under REACH. No labeling is required for finished products.

European Inventory of New and Existing Chemicals Substances (EINECS): This product is a medical device and not subject to chemical notification requirements.

National Regulations (USA):**SARA TITLE III:**

Hazard Category for Section 311/312: Not hazardous unless processing creates dust or fumes

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements under SARA Title III, Section 313 (40CFR372): None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substance Control Act (TSCA) Status: This product is a medical device and not subject to chemical notification requirements

International Regulations:

Canadian WHMIS Classification: Medical devices are not subject to WHMIS

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:** 04/22/2015

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.**