

**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
- CO<sub>2</sub>
- 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 <sup>3</sup> TWA (total dust)	3mg/ m <sup>3</sup> TWA (respirable fraction)
Zirconium, Zr	5mg/ m <sup>3</sup> TWA (as Zn compounds)	5mg/ m <sup>3</sup> TWA
Zirconium, Zr	2mg/ m <sup>3</sup> TWA (as Zn compounds)	N/A
Tin, Sn	2mg/ m <sup>3</sup> TWA	2mg/ m <sup>3</sup> TWA

Additional Information:

Zn: 1mg /m<sup>3</sup> TWA DFG MAK; 5 mg /m<sup>3</sup> TWA UK; 10 mg /m<sup>3</sup> TWA STEL UK WEL  
Sn: 2 mg /m<sup>3</sup> TWA UK; 4mg /m<sup>3</sup> 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

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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.**