Material Safety Data Sheet

Document number: AR/TH-MS-004b

Updated number:A/0Next Updated:A/1Date of updated:April 2, 2019Updated by:Jenny HeDate of approval:April 3,2019Approved by:Benson Wang

1. Product and Company Identification		
Company Name:	Product Grade/ Name:	
Astar Orthodontics Inc.	Orthodontic Archwires(Metal)	
Address:	Product Use :	
Suite1503, Lidu#1 Mansion, Lane#500, South Zhongshan Rd.	Beta Titanium Archwires(TMA Archwires)	
City: Shanghai		
Country: China	Indication of use:	
Telephone: +86-21-6303 1017	For Professional Orthodontic treatment only.	
E-mail: service@astar-ortho.com.cn		

Exposure to specialty steel alloys occurs primarily from inhalation of dust or fumes. However, constituents of these alloys may cause effects directly upon the skin or eyes. Certain constituents may also be harmful is swallowed.

2. Main Composition/Information on Ingredients				
Material	CAS Number	%(Weight)	ACGIH-TLV	OSHA-PEL
Titanium	7440-32-6	Balance	None Established	None Established
Molybdenum	7439-98-7	0-37	10 mg/m³ TWA(inhalable) 3 mg/m³ TWA(repirable)	15 mg/m ³ TWA(total dust)
Zirconium	7440-67-7	0-15	5 mg/m³ TWA 10 mg/m³ Ceiling	5 mg/m³TWA
Tin	7440-31-5	0-8	2 mg/m³ TWA	2 mg/m³ TWA

The terms "hazardous" and "hazardous materials" as used within this MSDS should be interpreted as defined by, and in accordance with, the OSHA Hazard Communication Standard (29 CFR Part 2920, 1200) including Appendices, Lists, References, etc., all of which are hereby incorporated by reference.

3	B. Hazard	Identification	
Solid metallic products are generally classified as "articles" and do not consitute a hazardous material in their solid form.			
During processing, dusts and fumes generated have the following hazards:			
Physical		Health	
Combustible Dust Non-Hazardous			
Hazards not otherwise classified: None			
Signal word: WARNING!			
Hazard statement(s):			
May form combustible dust concentrations in air during processing.			
Precautionary statement(s):None			

4.First Aid Measures	
Routes of Exposure	First Aid Measures
Eye contact	Flush well with running water to remove particulates
	and get medical attention.
Skin contact	Brush off excess dust. Wash area well with soap and
	water. If skin irritation occurs, get medical attention.



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Inhalation	Remove to fresh air, if condition continues, consult
	physician.
Ingestion	If dust is swallowed, drink enough warm water for
	vomiting. Seek medical help if large quantities of
	material have been ingested.

Most important symptoms/effects, acute and delayed: Eye and skin contact with dust may cause mechanical irritation. May cause gastrointestinal effects if swallowed. Excessive exposure to welding fumes, gases or dust may cause irritation of eyes, nose or throat. Inhalation of fumes may result in metal fume fever (metallic taste in mouth, dryness and irritation of throat, chills and fever).

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is generally not required.

5. Fire Fighting Measures		
Suitable Extinguishing Media:	Not flammable in the form as distributed. Use any	
Unsuitable Extinguishing Media: media that is appropriate for the surrounding fire.		

Finely divided particles, dusts or pieces resulting from processing of this product may burn or ignite. Use dry sand, dry graphite, or inert gas to smother the fire. Do not use water or CO2 on burning metal as an explosion may occur.

Specific hazards arising from the chemical:

Very fine, high surface area material resulting from grinding, buffing, polishing, or similar processes of this product may ignite and burn. Fine particles resulting from processing of this product may form combustible dust-air mixtures. Settled dust presents a fire hazard. Re-suspension of the dust into the air by vibration, traffic, material handling, etc. in high concentrations in the presence of an ignition source could result in a dust explosion. Minimize the generation and accumulation of dust.

Burning may produce the following hazardous decomposition products: Titanium dioxide an IARC Group 2B carcinogen. Vanadium pentoxide (V205) affects eyes, skin, respiratory system.

Protective Equipment for Fire-Fighters:	Firefighters should wear full emergency equipment and NIOSH approved positive
	pressure self-contained breathing apparatus
	for ail fires involving chemical products.

6.Accidental Release Measures

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment (see section 8). Avoid contact with skin, eyes or clothing. Do not breathe dust or fume.

Environmental precautions: Avoid release into the environmental. Report releases as required by local, state and federal authorities.

Methods and materials for containment and cleaning up: Pick up material and place into a container for disposal or reprocessing. If dust is present, wet down and collect in a manner to minimize the generation of airborne dusts or vacuum with a high efficiency vacuum cleaner. If a vacuum is used, explosion proof equipment is required. Non-sparking tools should be used. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentrations. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air.).



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7. Handling and Storage

Precautions for safe handling: Avoid contact with eyes, skin and clothing. Avoid creating and breathing dusts. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Launder contaminated clothing before re-use. Wash thoroughly with soap and water after handling. Minimize the generation and accumulation of dust. Keep dust away from open flames, hot surfaces and sources of ignition. Follow good housekeeping practices to keep surfaces, including areas overhead such as piping, drop ceilings, ductwork, etc. free from settled dust. Provide adequat precautions, such as electrical grounding and bonding, or inert atmospheres.

Empty containers retain product residues.

Conditions for safe storage, including any incompatibilities: Store in a dry location. Keep away from Acids, Oxidizing Agents, Halogens.

8.Exposure Control/Personal Protection				
Exposure guidelines: See Section2				

Personal Protective Equipment:

Respiratory protection: Use NIOSH approved respirator if exposure limits are exceeded or where dust/fume exposures are excessive. Selection of respiratory protection depends on the contaminant type, form and concentration. Select and use respirators in accordance with OSHA 1910.134 and good industrial hygiene practice.

Skin protection: Wear protective gloves. Fire/flame resistant/retardant clothing may be appropriate during hot work with the product.

Eye protection: Safety glasses with side shields.

Other: Protective clothing as needed to prevent contamination of personal clothing. Thermal protection as needed when working with heated material.

9.Physical and Chemical Characteristics		
Appearance and Odor	Odorless solid with metallic luster. Wire forms.	
Solubility in Water:	Does not soluble	
Melting Point/Rang:	1660° C /3020° F	
Boiling Point:	N/A	
Flash Point:	N/A	
Freezing Point:	N/A	



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Autoignition		N/A	
Density:		N/A	
PH Value (at 10g/1H 2O):		N/A	

10.Stability and Reactivity		
Stability?	Conditions to Avoid	
■ Stable □ Unstable	Avoid dust formation	
Hazardous Decomposition Products: Extreme heat from fire or processing (e.g. welding, brazing, machining, etc.) may produce toxic or irritating airborne particulate, including metal and metallic oxide fumes. Reaction with water, steam, acids, etc. can evolve hydrogen, which is highly dangerous fire and explosion hazard.		
Hazardous Polymerization? Conditions to Avoid		
☐ May Occur ■ Will not Occur N/A		
Incompatibility Material to Avoid: Acid, Oxidizing Agents, Halogens.		

11.Toxicological Information

Routes of exposure:

Ingestion: None expected under normal use conditions. May cause gastrointestinal effects if swallowed. Inhalation: Excessive exposure to fumes, gases or dust may cause irritation of nose or throat. Inhalation of dusts / fumes may result in metal fume fever (metallic taste in mouth, dryness and irritation of throat, chills and fever).

Eye: Dust particles or filings may cause abrasive injury to the eyes.

Skin: May cause mechanical irritation or abrasions.

Chronic: Long-term overexposure to dust may cause lung damage (fibrosis) with symptoms of coughing, shortness of breath and diminished breathing capacity.

Carcinogenicity: None of the components are listed as a carcinogen or potential carcinogen by OSHA, NTP or IARC.

Numerical measures of toxicity:

Titanium: Oral rat LD50 > 5000 mg/kg

Molybdenum: Oral rat LD50 > 2000 mg/kg, Inhalation rat LC50 > 3.92 mg/L, Dermal rat LD50 > 2000 mg/kg

Vanadium: Oral rat LD50 > 2000 mg/kg; inhalation rat LC50 > 5.05 mg/L/ 4 hr.

Chromium: Oral rat LD50 > 5000 mg/kg

Niobium: Oral rat LD50 >2000 mg/kg; Dermal rat LD50 >2000 mg/kg Zirconium: Oral rat LD50 > 5000 mg/kg, Inhalation rat LC50 > 4.3 mg/L/4 hr

Tin: Oral rat LD50 >2000 mg/kg; Dermal rat LD50 >2000 mg/kg, Inhalation rat LC50 4.75 mg/L/4 hr.

Aluminum: Oral rat LD50 > 15900 mg/kg, Inhalation rat LC50 > 0.888 mg/L

Silicon: Oral rat LD50 > 5000 mg/kg, inhalation rat LC50 > 2.08 mg/L, Dermal rabbit LD50 > 5000 mg/kg



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12. Ecological Information

Ecotoxicity:

Titanium: 96 hr. LC50 Oncorhynchus mykiss >100 mg/L Molybdenum: 96 hr. LC50 Pimephales promelas 609.1 mg/L Vanadium: 96 hr. LC50 Danio rerio 16.5 mg/L

Zirconium: 96 hr. LC50 Danio rerio >100 mg/L , 48 hr. EC50 daphnia magna >100 mg/L Tin: 96 hr. LC50 Pimephales promelas >12.4 ug/L Aluminum: 96 hr. NOEC Lepomis cyanelius > 50 mg/L

Persistence and degradability: Biodegradation is not applicable to inorganic compounds. Bioaccumulative potential: No data available Mobility in soil: No data available.

Other adverse effects: No data available.

13. Disposal Considerations

Regulations:

Dump in accordance with local regulations.

Properties(Physical/Chemical) Affecting Disposal

NA

Follow instructions under points6 and 12.

14.Transport Information

Technical Shipping Name: Not regulated

Freight Class Bulk: N/A
Freight Class Package: N/A

Hazard Class or Division: Non-Hazardous

15. Regulatory Information

Final products :European Community: assigned to Class II a by Medical Device Directive 93/42 EEC

U.S.A: assigned to Class I Medical Devices by U.S. Food and Drug Administration(FDA)

Final products :Label information follow the EN980: 2008 《Symbols for use in the labelling of medical devices》

16.Other Information

This information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. Therefore, it should not be construed as guaranteeing specific properties.

The information in this MSDS is based on technical data that we believe to be reliable. Astar assumes no responsibility and makes no warranties, expressed or implied, regarding the accuracy or currency of any data so provided. Since conditions of storage, use, and disposal of this products are beyond our control, we make no warranties, expressed or implied, and assume no liability in connection with the use of this product.



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Attention:

- 1. The product should be sterilized before used. 75% alcohol is recommended.
- 2. There should be no change on the color and the shape of the products after sterilization, as well as no impact to the treatment.
- 3. Disposable only.
- 4. For professional use only.
- 5. Single use to the correspondent tooth only. Please follow the advice on the product label. Mixed or wrongly placement of the tubes might lead to unexpected problem in clinic.
- 6. This product contains nickel and chromium. If patient reaction is suspected, contact a physician.

N/A=not applicable NA= not available N/D= not determined

