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1. Product and Company Identification

Company Name: **Astar Orthodontics Inc.**	Product Grade/ Name: **Orthodontic Archwires(Metal)**
Address: Suite1503, Lidu#1 Mansion, Lane#500, South Zhongshan Rd.	Product Use : **CuNiTi Archwires(Copper NiTi 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
Nickel	7440-02-0	45-60	1.5 mg/m^3 TWA(inhalable)	1.0 mg/m^3(Dust)
Titanium	7440-32-6	40-50	None Established	None Established
Copper	7440-50-8	5-6	1.0 mg/m^3 TWA(Dust) 0.2 mg/m^3 TWA(Fume)	1.0 mg/m^3 TWA(Dust) 0.1 mg/m^3 TWA(Fume)

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.

No permissible exposure limits (PEL) or threshold limit values (TLV) exist for Nickel base alloys. Values shown are applicable to component elements.

3. Hazard Identification

Nitinol is generally not considered hazardous in the form shipped (solid bars, billets wire, etc.), however, if your process involves grinding, melting, welding, cutting, or any other process that causes a release of dust or fume, hazardous levels of dust or fume of the constituents of these alloys could be generated. The following is a list of potential health effects for all hazardous elements that are possibly contained in an of our alloys, Please refer to section II titled “hazardous ingredients” for a list of those specific elements contained in this particular alloy.

Nickel: Fumes are respiratory irritants and may cause respiratory disease, skin contact can also cause an allergic skin rash, nickel and its compounds have been reported to cause cancer of the lungs and sinuses.

Titanium: No observed health hazards.

POTENTIAL HEALTH EFFECTS: No information is available on this specific mixture as a whole. The information presented is based on each of the components present at concentrations greater than 1% (0.1 % for hazardous substances other than those classified as Xn, Xi, or as category 3 carcinogens, mutagens, or toxic for reproduction). Machining,grinding or sawing this material may generate harmful dusts. Inhalation of copper fumes, while not expected to occur under typical conditions of use, may cause metal fume fever.

Prolonged or repeated exposure may cause dermatitis. See Section 8 for exposure controls.

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.
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:	This material is not combustible in solid form. Use media that is appropriate for the surrounding fire. For fires involving fine dust or filings, do not use water, CO2 or foam directly on the burning metal. Use dry sand, graphite powder, Lith-X powder, dry chemical or other media appropriate for a class D fire.
Unsuitable Extinguishing Media:	

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.

Known or Anticipated Hazardous Products of Combustion: Thermal decomposition or combustion products include oxides of the metals listed in Section 2 which may be highly toxic.

6.Accidental Release Measures

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

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.).

7.Handling and Storage

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.

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

8.Exposure Control/Personal Protection

Exposure guidelines:	See Section2

Personal Protective Equipment:

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

Skin Protection: Wear protective gloves if need to prevent cuts or other injuries.

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.

Other Protective Clothing or Equipment: Use protective clothing consistent with industrial.

Skin Irritation: Wear gloves during prolonged contact to avoid skin irritation from dust.

Work/Hygiene Practices: Good personal hygiene should be exercised by all users of this product.

9.Physical and Chemical Characteristics	
Appearance and Odor	Odorless solid with metallic luster. Wire forms.
Solubility in Water:	Does not soluble
Melting Point/Rang:	N/A
Boiling Point:	N/A
Flash Point:	N/A
Freezing Point:	N/A
Autoignition	N/A
Density:	N/A
PH Value (at 10g/1H $_2$O):	N/A

10.Stability and Reactivity	
Stability? ■ Stable ☐ Unstable	Conditions to Avoid 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? ☐ May Occur ■ Will not Occur	Conditions to Avoid N/A
Incompatibility Material to Avoid: Acid, Oxidizing Agents,Halogens.	

11.Toxicological Information

Potential Health Effects:

Eyes: Dust or fines may cause mechanical irritation.

Skin: Dust may cause skin irritation. May cause allergic skin reaction (sensitization).

Ingestion: No acute effects expected from swallowing small amounts. Ingestion of large amounts of copper may cause abdominal pain, nausea or vomiting.

Inhalation: Exposure to nickel dust or fumes may cause irritation of the mucous membranes and upper respiratory tract. May cause allergic respiratory reaction (sensitization). Exposure to copper dust may cause cough, headache, shortness of breath, and eye, skin and respiratory irritation. Exposure to fumes may cause metal fume fever or skin and hair discoloration.

Chronic Health Effects: Prolonged or repeated skin contact to nickel may cause sensitization. Prolonged inhalation of dust may cause lung damage, fibrotic lung disease, and effects on the cardiovascular system. Prolonged inhalation of nickel dust or fumes may cause perforation of the nasal septum and lung damage. Long-term exposures to copper may cause respiratory, liver and kidney effects.

Carcinogenicity: Nickel compounds (may be formed in welding) are classified by IARC as known human carcinogens (Group 1) and by NTP as “Known Human Carcinogens”. Metallic nickel is classified by IARC as possibly carcinogenic to humans (Group 2B) and by NTP as “Reasonably Anticipated to be a Carcinogen”. None of the other components is listed as a carcinogen by IARC, NTP, ACGIH or OSHA.

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

NIOSH RTECS No.: GL5325000

Acute Toxicity Data:

Nickel: No data available

Titanium: No data available

Copper:No data available

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 IIa 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.

Attention for final products(Orthodontic archwires):

The final product should be sterilized before used. 75% alcohol is recommended.

There should be no change on the color and the shape of the products after sterilization, as well as no impact to the treatment.

Disposable only.

For professional use only.

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 .

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

mg/m3= milligrams per cubic meter C = ceiling PEL = permissible exposure limit