

Document number: AR/TH-MS-004a
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 Date of approval: May,16th,2013
 Next Updated: A/1
 Updated by:
 Approved by: Jenny He

1. Product and Company Identification

Company Name: Astar Orthodontics Inc.	Product Grade/ Name: Nickel Titanium(Metal)
Address: Suite1503, Lidu#1 Mansion, Lane#500, South Zhongshan Rd.	Product Use : SurperElastic NiTi Archwire, Thermal Activated NiTi Archwire, Reverse Curved NiTi wire, NiTi Open and Close Coil Springs
City: Shanghai	Indication of use: For Professional Orthodontic treatment only.
Country: China	
Telephone: +86-21-6303 1017	
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. Composition/Information on Ingredients

Material	CAS Number	%(Range)	ACGIH-TLV	OSHA-PEL
Nickel	7440-02-0	54.5-56.3	1 mg/m ³	1 mg/m ³ (Dust)
Carbon	7440-44-0	<0.12	None	None
Iron	7439-89-6	<0.15	None	None
Silicon	7440-21-3	<0.1	10 mg/m ³	None
Nitrogen	7727-37-9	<0.015	None	None
Hydrogen	1333-74-0	<0.015	None	None
Oxygen	7782-44-7	<0.15	None	None
Titanium	13463-67-7	Banlance	5.0 mg/m ³	15.0 mg/m ³ (Dust)

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

<p>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.</p> <p>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.</p> <p>Titanium: No observed health hazards</p> <p>Potential Environmental Effects : NA</p>

4.First Aid Measures

Routes of Exposure	First Aid Measures
Eye contact	Flush well with running water to remove particulates

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	and get medical attention.
Skin contact	Brush off excess dust. Wash area well with soap and water.
Inhalation	Remove to fresh air, if condition continues, consult physician.
Ingestion	Drink enough warm water for vomiting. Seek medical help if large quantities of material have been ingested.

5.Fire Fighting Measures

Suitable Extinguishing Media:	Sand
Unsuitable Extinguishing Media:	N/A
Protective Equipment for Fire-Fighters:	N/A

6.Accidental Release Measures

Ventilation: If your process causes a release of dust or fume, use local and general exhaust ventilation to keep airborne concentrations of dust or fumes below the TLV.
Respiratory Protection: If your process causes a release of dust or fume in excess of the permissible exposure limit, use approved respirators for protection against airborne dust or fumes should be worn. Respirators should be used in accordance with 29CFR 1910.134.
Protective Equipment: Gloves and barrier creams may be necessary to prevent skin sensitization and dermatitis. If your process involves grinding or any other action that causes the release of dust or fumes, approved safety glasses or goggles should be worn.
Environmental Precautions: No hazard
Special Instructions: N/A

7.Handling and Storage

Handling No special cares are requested. In case of spillage, sweep up, so as to avoid possible risk of slipping.
Storage Packed with sealed plastic bags, or paper boxes. (see attached file) No special precautions, keep the package and containers closed and stored in the ventilated room. Avoid the corrosive gases.

8.Exposure Control/Personal Protection

Ventilation	See Section6
Personal Protective Equipment:	See Section6

9.Physical and Chemical Characteristics

Appearance and Odor	Odorless solid with metallic luster. Wire forms.
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Solubility in Water:	Does not soluble
Melting Point/Rang:	2500° F to 2700° F
Boiling Point:	N/A
Flash Point:	N/A
Freezing Point:	N/A
Autoignition	N/A
Density:	N/A
PH Value (at 10g/1H zO):	NA
Viscosity (20 °C)	Solid
No dangers for the human body and health.	

10.Stability and Reactivity

Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid Avoid strong acids
Hazardous Decomposition Products: None	
Hazardous Polymerization? <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> Will not Occur	Conditions to Avoid N/A
Incompatibility Material to Avoid: React with strong acids to form hydrogen gas.	

11.Toxicological Information

Oral Toxicity:	Reference Step 3 and Step 6
Inhalation:	Reference Step 3 and Step 6
Skin Irritation:	Reference Step 3 and Step 6
Sensitization:	Reference Step 3 and Step 6
Eye Irritation:	Reference Step 3 and Step 6
Further Details:	None

12.Ecological Information

Biodegradability: N/D
Biodaccumulation: N/D
Follow the local regulation for non-hazardous metallic materials.

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

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Technical Shipping Name: Not regulated
Freight Class Bulk: N/A
Freight Class Package: N/A
Hazard Class or Division: Non-Hazardous

15.Regulatory Information

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)
Label information follow the EN980: 2008 «Symbols for use in the labelling of medical devices»

16.Other Information

<p>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.</p> <p>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.</p>
<p>Attention:</p> <ol style="list-style-type: none"> 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.
<p>N/A=not applicable NA= not available N/D= not determined mg/m³= milligrams per cubic meter C = ceiling PEL = permissible exposure limit</p>