

Document number: AR/TH-MS-001
 Updated number: A/0
 Date of updated:
 Date of approval: Sept.,2nd,2010
 Next Updated: A/1
 Updated by:
 Approved by: Jenny He

1. Product and Company Identification

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| Company Name: Astar Orthodontics Inc. | Product Grade/ Name: STAINLESS STEEL: 316L,17-4,304,321 |
| Address: Suite1503, Lidu#1 Mansion, Lane#500, South Zhongshan Rd. | Product Use : Orthodontic Brackets, Tubes, Bands, Lingual attachment(Lingual Sheath, Lingual Cleat, Lingual Rings, Lingual Buttons, Lingual Retainers, Lingual Lugs/Hooks), Face bows |
| City: Shanghai | |
| Country: China | |
| Telephone: +86-21-6303 1017 | |
| E-mail: service@astar-ortho.com.cn | Indication of use: For Professional Orthodontic treatment only. |

2. Composition/Information on Ingredients

| Material | CAS Number | %(Range) | ACGIH-TLV | OSHA-PEL |
|------------|------------|--|-----------------------|------------------------------|
| Iron | 7439-89-6 | 65-75 | None | None |
| Chromium | 7440-47-3 | 16.00—18.00 0.05 mg/m ³ /M2 (Cr+6) | 0.5 mg/m ³ | 1 mg/m ³ (Dust) |
| Nickel | 7440-02-0 | 12.00—15.00 | 1.5 mg/m ³ | 1 mg/m ³ (Dust) |
| Molybdenum | 7439-98-7 | 2.00-3.00 | 10 mg/m ³ | 15 mg/m ³ (Dust) |
| Aluminum | 7429-90-5 | 0-2 | 10 mg/m ³ | 15 mg/m ³ (Dust) |
| Copper | 7440-50-8 | 0-4 | 1 mg/m ³ | 1 mg/m ³ (Dust) |
| Tungsten | 7440-33-7 | 0-4 | 5 mg/m ³ | None |
| Manganese | 7439-96-5 | <2.00 | 0.2 mg/m ³ | C 5 mg/m ³ (Dust) |
| Silicon | 7440-21-3 | <1.00 | 10 mg/m ³ | None |
| Cobalt | 7440-48-7 | 0-5 | 0.5 mg/m ³ | 0.1 mg/m ³ (Dust) |

3. Hazard Identification

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| <p>Made by stainless steel which is widely used in dental field to be proved safe enough, does not contain hazardous or volatile substance. Non-hazardous for human body and health. However, subsequent operations such as brazing, burning, cutting, grinding, heat treating, picking, welding, or processing in any other fashion may produce potentially hazardous dust or fume which can be inhaled, swallowed, or come in contact with skin, eyes, or mucous membranes.</p> <p>Possible symptoms of exposure to dust , fumes, or gages</p> <p>Acute: Irritation of eyes, nose, throat, and skin; metallic taste in mouth, nausea ,metal fume fever.</p> <p>Chronic: only after six to ten years of exposure to iron dust or fumes does one present any signs of pneumoconiosis. Physical examinations of those exposed to iron dust have not indicated any disability. Excess inhalation of Chromium fumes has been associated with respiratory cancer.</p> <p>Excessive and prolonged inhalation to manganese(generally over 2 years exposure) can cause damage to the central nervous system. Specifically, the pathology resembles Parkinson’s Disease.</p> <p>Carcinogenicity: Chromium, Cobalt-Chromium Alloys, and Nickel have been identified by the international Agency for Research on Cancer as potential cancer causing agents.</p> <p>Potential Environmental Effects : NA</p> |
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4.First Aid Measures

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| 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. |
| Inhalation | Remove to fresh air, if condition continues, consult physician. |
| Ingestion | Seek medical help if large quantities of material have been ingested. |

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| 5.Fire Fighting Measures |
| N/A |

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| 6.Accidental Release Measures |
| Containment Techniques: N/A |
| Spill/Leak Clean-up procedures and equipment Sweep up with mechanical means. |
| Evacuation Procedures N/A |
| Special Instructions N/A |

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| 7.Handling and Storage |
| <p>Handling No special cares are requested. In case of spillage, sweep up, so as to avoid possible risk of slipping.</p> <p>Storage Packed with sealed plastic bags, or different specified plastic trays. (see attached file) No special precautions, keep the package and containers closed and stored in the ventilated room. Avoid the corrosive gases.</p> |

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| 8.Exposure Control/Personal Protection | |
| Ventilation | Local exhaust recommended while burning, grinding, and/or welding and airborne levels if metal oxides exceed applicable OSHA Standards. |
| Personal Protective Equipment: Respiratory Protection: if fumes, misting or dust conditions occurs and exceeds applicable OSHA Standards. Personal Protection: Respiratory: if fumes, misting or dust conditions occur and exceed applicable OSHA Standards, provide NIOSH approved air-supplied respirators. | |
| Eye Protection | Recommend approved safety glasses when grinding, welding, etc. |
| Hand Protection | Gloves: As required. |

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| | Other Clothing: As required. |
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| 9.Physical and Chemical Characteristics | |
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| Appearance and Odor | Odorless solid with metallic luster. |
| Physical State: Solid | Solubility in Water: Does not soluble |
| Odor/Flavor: Not Noticeable | Not noticeable |
| Boiling Point: | NA |
| Freezing Point: | NA |
| Flash Point: | NA |
| Autoignition | NA |
| Density: | NA |
| Viscosity: | NA |
| 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 N/A | |
| Hazardous Decomposition Products: Metal fumes and certain noxious gases, such as CO, may be produced during welding or burning operations. | | |
| 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. | | |
| Material | ACGIH-TLV | OSHA-PEL |
| Aluminum | 5 mg/m ³ | None |
| Carbon Monoxide | 25ppm | 50ppm |
| Chromium | 0.05 mg/m ³ | 0.5 mg/m ³ |
| Cobalt Fume | 0.05 mg/m ³ | 0.1 mg/m ³ |
| Copper Fume | 0.2 mg/m ³ | 0.1 mg/m ³ |
| Iron | 5 mg/m ³ | 10 mg/m ³ fume |
| Manganese fume | 0.2 mg/m ³ | C 5 mg/m ³ |
| Molybdenum | 5 mg/m ³ | 5 mg/m ³ |
| Nickel | 0.1 mg/m ³ | 1 mg/m ³ |
| Nitrogen Dioxides | 3ppm | C 5 ppm |
| Ozone | 0. 10ppm | 1ppm |
| Silicon | 10 mg/m ³ | None |
| Tungsten Fume | 1 mg/m ³ | None |

| 11.Toxicological Information |
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| No toxic effect would be expected from exposure to the solid form of Steel products. Prolonged, repeated exposure to fumes or dust generated during subsequent operations may or may cause |

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adverse health effects associated with the listed constituents in excess of OSHA permissible exposure limits. This material contains nickel, which for some individuals, could result in development of nickel sensitization. This material should not be used for individuals with a known nickel sensitivity and should be discontinued for individuals whom develop nickel sensitization after prolonged contact.

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| 12.Ecological Information |
| Biodegradability: N/D |
| Biodaccumulation: N/D |
| Follow the local regulation for non-hazardous metallic materials. |

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| 13.Disposal Considerations |
| Regulations: Dump in accordance with local regulations. |
| Properties(Physical/Chemical) Affecting Disposal NA |
| Follow instructions under points6 and 12. |

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| 14.Transport Information |
| Technical Shipping Name: Not regulated |
| Freight Class Bulk: N/A |
| Freight Class Package: N/A |
| Hazard Class or Division: Non-Hazardous |

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| 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》 |

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| 16.Other Information |
| Attention: <ol style="list-style-type: none"> The 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 . |
| N/A=not applicable NA= not available N/D= not determined mg/m ³ = milligrams per cubic meter C = ceiling PEL = permissible exposure limit |