

<b>I – Identification of the Substance and of the Company</b>	
Supplier: Hangzhou ORJ Medical Inst.&Mat. Co., Ltd. No.8, XiYuan 5 <sup>th</sup> Road, West Lake Tech. & Eco. District (SanDun) Hangzhou City, 310030, China, Tel: 0086-571-88185501, 88185502 Fax: 0086-571-88185503	Trade Name: ORJ Description: orthodontic brackets, orthodontic bands, orthodontic tubes, crimpable hooks, lingual buttons, lingual retainers, lingual sheaths, face bow, ligature wires, palatal bars, orthodontic Face mask.
Product Grade / Name: <b>STAINLESS STEEL,</b> 304, 316L,17-4PH	

<b>II – Composition / Information on Ingredients (Principal Ingredients)</b>				
<u>MATERIAL</u>	<u>CAS Number</u>	<u>% (RANGE)</u>	<u>ACGIH-TLV</u>	<u>OSHA-PEL</u>
IRON	7439-89-6	65-75	None	None
CHROMIUM	7440-47-3	16-20	0.5mg/m <sup>3</sup> (Dust)	1mg/m <sup>3</sup> (Dust)
NICKEL	7440-02-0	4-14	1mg/m <sup>3</sup> (Dust)	1mg/m <sup>3</sup> (Dust)
MOLYBDENUM	7439-98-7	2.0-3.0 (316L)	10mg/m <sup>3</sup> (Dust)	15mg/m <sup>3</sup> (Dust)

**III – Hazards Identification**

Steel products in their usual solid physical state do not constitute any physical or health hazard. However, subsequent operations such as brazing, burning, cutting, grinding, heat treating, pickling, welding, or processing in any other fashion may produce potentially hazardous dust or fume which can be inhaled, swallowed, or come in contact with the skin, eyes, or mucous membranes.

Possible symptoms of exposure to dust, fumes, or gases:

Acute: Irritation of eyes, nose, throat, and skin; metallic taste in mouth; nausea; metal fume fever.

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.

Carcinogenicity: Chromium and Nickel have been identified by the International Agency for Research on Cancer (IARC and the National Program (NTP) as potential cancer causing agents.

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<b>IV – First Aid Measures</b>	
<b>PRIMARY ROUTES OF ENTRY:</b>	<b>EMERGENCY FIRST AID:</b>
Inhalation	Remove to fresh air, if condition continues, consult physician.
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.
Ingestion	Seek medical help if large quantities of material have been ingested.

<b>V – Fire Fighting Measures</b>
Flash Point: N/A Flammable Limits in Air % by Volume: N/A Extinguisher Media: N/A Auto-Ignition Temperature: N/A Special Fire Fighting Procedures: N/A Unusual Fire and Explosive Hazards: N/A

<b>VI – Accidental Release Measures</b>
Spill or Leak Procedures: Remove by mechanical means.

<b>VII – Handling and Storage</b>
Use good housekeeping procedures to prevent accumulation of dusts, thus minimizing airborne dust concentrations.

<b>VIII – Exposure Controls / Personal Protection</b>
Ventilation Requirements: Local exhaust recommended while burning, grinding, and / or welding and airborne levels of metal oxides exceed applicable OSHA Standards.
Personal Protective Equipment: Respiratory Protection: If fumes, misting or dust conditions occurs and exceed 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 / goggles when grinding, welding, etc.
Hand Protection: Gloves: As required. Other Clothing: As required.

## IX – Physical and Chemical Properties

Boiling Point: N/A  
Specific Gravity: (H<sub>2</sub>O=1) Approx. 8  
Vapor Pressure: (mm Hg) N/A  
Percent Volatile by Volume (%): N/A  
Evaporation Rate=1: N/A  
Solubility in Water: N/A  
Reactivity in Water: N/A  
Appearance and Odor: Odorless solid with metallic luster.

## X – Stability and Reactivity

### Stability:

Unstable ( ) Stable (X)  
Conditions to Avoid: N/A

### Incompatibility:

Material to Avoid: React with strong acids to form hydrogen gas.

### Hazardous Decomposition Products:

Metal fumes and certain noxious gases, such as CO, may be produced during welding or burning operations.

### Hazardous Polymerization:

May Occur ( ) Will Not Occur (X)  
Conditions to Avoid: N/A

<u>MATERIAL</u>	<u>ACGIH-TLV</u>	<u>OSHA-PEL</u>
CARBON MONOXIDE	50ppm	50ppm
CHROMIUM(D)	0.05mg/m <sup>3</sup> Suspected carcinogen-NTP & IARC Listed See Sections 5&7	0.1mg/m <sup>3</sup>
IRON(B)	5mg/m <sup>3</sup>	10mg/m <sup>3</sup>
MOLYBDENUM	5mg/m <sup>3</sup>	5mg/m <sup>3</sup>
NICKEL	0.1mg/m <sup>3</sup> Suspected carcinogen-NTP & IARC Listed See Sections 5&7	1mg/m <sup>3</sup>
NITROGEN DIOXIDES	3ppm	5ppm Maximum
OZONE	0.1ppm	0.1ppm

## XI – Toxicological Information

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 not cause adverse health effects associated with the listed constituents in excess of OSHA permissible exposure limits established in 29 CFR Part 2920.1200 (See Section 2. Generic Ingredients). This material contains nickel, which for some individuals, could result in development of nickel sensitization. This material should not be used for individuals with already known nickel sensitivity and should be discontinued for individuals whom develop nickel sensitization after prolonged contact.

## XII – Ecological Information

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No ecological effects are known.

### **XIII – Disposal Considerations**

Solids – Sell as scrap for reuse.

Dust – Follow the government and local regulations regarding disposal.

Grinding, Cutting and Welding Residue – Follow the government and local regulations regarding disposal.

### **XIV – Transportation Information**

Technical Shipping Name: Not regulated

Freight Class Bulk: N/A

Freight Class Package: N/A

Product Label: N/A

Hazard Class or Division: Non-Hazardous

Hazard Class Division Number: Not Hazardous by D.O.T. Regulations

### **XV – Regulatory Information**

These products are manufactured using ISO 13485:2003 quality system and are regulated as Class II Medical Device by Chinese Food and Drug Administration, Class I Medical Devices by the U.S. Food and Drug Administration, Class II by the Canada CMDR, and Class IIa by the Medical Device Directive 93/42 EEC for the European Community.

### **XVI – Other Information**

Note: While the information and recommendations set forth on this data sheet are believed to be accurate as received from our suppliers, Hangzhou ORJ Medical Instrument & Material Co., Ltd. makes no warranty with respect thereto and disclaims all liability from reliance thereon.