

**1. PRODUCT AND COMPANY IDENTIFICATION****1.1 Product Identifier**

**Product Name:** Empower (Metal Clip), Empower Clear (Metal Clip), Jones Jigs, Multiphase Blue Chromium Cobalt Wire, ART Auxiliary Spring  
**Common Name:** Stainless Steel Brackets, Ceramic Brackets, Fixed & Functional, Wires  
**Material:** Chromium Cobalt Alloy  
**Restrictions on Use:** American Orthodontics' products are used for the treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. Federal law restricts this device to use by or on the order of a dentist or orthodontist.

**EC No.:** 231-111-4 (Nickel)  
231-158-0 (Cobalt)

**REACH Registration No.:** 01-2119438727-29-XXXX (Nickel)  
01-2119517392-44-00XX (Cobalt)

**CAS No. / IUPAC:** 7440-02-0 (Nickel)  
7440-48-4 (Cobalt)

**1.2 Relevant Identified Uses/ Uses Advised Against**

**Relevant identified uses:** Dental/Orthodontic use only

**Uses advised against:** Not for Consumer use. Please see "Restrictions on Use"

**1.3 Details of the Supplier of the Safety Data Sheet**

**Company Name:**  
American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081  
Phone: 920-457-5051  
Fax: 920-457-1485

**E-mail:** info@americanortho.com  
**National Contact:** Safety Department

**1.4 Emergency Telephone Number**

**Emergency Response Number:**  
920-457-5051  
Only available during office hours: 8:00AM – 5:00PM (Central Time)  
Language of Phone Service: English

**2. HAZARDS IDENTIFICATION**

**General Hazard Statement:**

This product is a manufactured article as defined under REACH. No labeling is required for finished product.

This product is classified as “articles” and do not constitute a hazardous material in solid form und the definitions of the OSHA Hazard Communication Standard (29CFR1910.1200). Any articles manufactured from these solid products would be generally classified as non-hazardous.

However some hazardous elements contained in these products may be emitted under certain processing conditions. Products in the solid state present no fire or explosion hazards. The following classification information is for the hazardous elements which may be released during processing.

**2.1 Classification of the substance or mixture**

- Serious Eye Damage/Irritation - Category 2B
- Respiratory Sensitizer - Category 1
- Skin Sensitizer - Category 1
- Germ Cell Mutagenicity - Category 2
- Carcinogenicity - Category 1B
- Toxic to reproduction - Category 1B
- Specific target organ toxicity - Single exposure - Category 1 (kidneys, respiratory system)
- Specific target organ toxicity - Repeated exposure - Category 1 (respiratory system, skin)
- Hazardous to aquatic environment - Acute Hazard - Category 1
- Hazardous to aquatic environment - Chronic Hazard - Category 1

**2.2 Label Elements**

*Labelling according to Regulation (EC) No 1272/2008 [CLP]*

**Hazard Pictogram(s)**



**Signal Word(s): Danger**

Hazard Statements:

- Causes eye irritation
- May cause allergy or asthma symptoms or breathing difficulties if inhaled
- May cause an allergic skin reaction
- Suspected of causing genetic defects
- Suspected of causing cancer
- Causes damage to organs (kidneys, respiratory system)
- Causes damage to organs through prolonged or repeated exposure (respiratory system)
- Very toxic to aquatic life
- Very toxic to aquatic life with long lasting effects

May cause long lasting harmful effects to aquatic life

**Supplemental Hazard information (EU):**

- Do not breathe dust/fume/gas/mist/vapors/spray.
- In case of inadequate ventilation wear respiratory protection
- Contaminated work clothing should not be allowed out of the workplace.
- Wash thoroughly after handling
- Wear protective gloves/protective clothing/eye protection/face protection
- Obtain special instructions before use
- Do not handle until all safety precautions have been read and understood
- Use personal protective equipment as required
- Do not eat, drink or smoke when using this product.
- Avoid release to the environment

**Response**

- IF exposed or concerned: Get medical advice/attention
- IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical advice/attention.
- If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
- IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
- If exposed or concerned: Get medical advice/attention.
- Collect spillage

**Storage**

Store locked up

**Disposal**

Dispose of contents/container in accordance with local/regional/national/international regulations.

**3. COMPOSITION / INFORMATION ON INGREDIENTS**

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Nickel, Ni	7440-02-0	231-111-4	0-35
Cobalt, Co	7440-48-4	231-158-0	25-65
Chromium, Cr	7440-47-3	N/A	15-35
Molybdenum, Mo	7439-98-7	N/A	0-15
Titanium, Ti	7440-32-6	N/A	0-5
Iron, Fe	7439-89-6	N/A	0-5

Nickel, cobalt, and chromium in their elemental forms are regulated as toxic chemicals under Section 313, SARA Title III and CFR 372. Other elements may be present, such as Carbon, Silicon, Manganese, Phosphorus, Sulfur and Boron. These are either not hazardous or below 0.1% by weight. All other trace elements are below the levels specified in the European ELV, and RoHS Directives, the Japanese Green Procurement Standardization Initiative, and the US EIA Joint Industry Guide JIG.



## 4. FIRST-AID MEASURES

### 4.1 Description of First-Aid Measures

#### Inhalation

Not applicable to alloy in solid form. If breathing becomes difficult due to inhalation of dust and/or fumes resulting from machining operations, remove person from exposed area to fresh air. Immediately consult a physician.

#### Skin Contact

In individuals that are already sensitive to nickel, prolonged skin contact may result in an allergic reaction. For skin irritation or laceration, wash area thoroughly with plenty of soap and water. In case of heavy injury, immediately consult a physician.

#### Eye Contact

For irritation from particulate (dust or fume) from mechanical processing, flush with clean water for 15 minutes. Immediately consult a physician.

#### Ingestion/Swallowing

If ingested, immediately consult a physician.

## 5. FIRE AND EXPLOSION HAZARDS

### General Fire Hazards

See Section 9 for Flammability Properties.

This product does not present fire or explosion hazards as shipped. Small chips, fines, and dust from processing may be explosive or readily ignitable.

### Hazardous Combustion Products

Thermal decomposition can lead to release of irritating gases and vapors. In the event of fire and/or explosion do not breathe fumes. May cause sensitization by inhalation and skin contact.

### Extinguishing Media

Class D extinguishing agents on fines, dust or molten metal. Use coarse water spray on chips and fines.

### Unsuitable Extinguishing Media

DO NOT use halogenated extinguishing agents on small chips or fines. DO NOT use water for fires involving molten metal. These fire extinguishing agents will react with burning material.

### Fire Fighting Equipment/Instructions

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

### General

No notable environmental hazard is anticipated from the "release" of this material in bulk solid form on land. This material should be recovered from aquatic environments.

### Recovery and Neutralization

Avoid dust formation. Collect scrap for recycling.

**Materials and Methods for Clean-Up**

If product is molten, contain the flow using dry sand or salt flux as a dam. All tools and containers which come in contact with molten metal must be preheated or specially coated and rust free. Allow the spill to cool before remelting as scrap.

**Emergency Measures**

Keep people away from and upwind of spill/leak.

**Personal Precautions and Protective Equipment**

Wear appropriate protective clothing and respiratory protection for the situation.

**Environmental Precautions**

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not flush into surface water or sanitary sewer system.

**7. HANDLING AND STORAGE**

**Handling, storage and decontamination procedures:**

Avoid contact with skin, eyes, and clothing. Wear personal protective equipment when handling. Avoid dust creation. Keep material dry. Avoid contact with sharp edges, corners, hot metal. Good housekeeping must be practiced during storage, transfer, handling and use to avoid excessive dust accumulation.

**Incompatible Products:**

May react in contact with strong acids to release gaseous acid decomposition products, e.g. hydrogen, oxides of nitrogen. Use of strong oxidizers (high pH) on stainless steel may cause Cr(VI) compounds to form at ambient temperatures. Decomposition: Fumes generated during welding, brazing, or thermal cutting may contain: chromium compounds, including hexavalent chromium Cr(VI); nickel; manganese; iron; molybdenum; and silicon compounds.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**8.1 Control Parameters**

**Exposure Guidelines:** Chemicals are not readily available as they are bound within the alloy. Occupational exposure limits apply to some components resulting from grinding, polishing, abrasive blasting, hot rolling, hot forging, thermal cutting, or welding which may produce stainless steel dust or fumes.

Component	OSHA PELs (Permissible Exposure Limits)	ACGIH TLVs (Threshold Limit Values)
Nickel	1mg/ m <sup>3</sup> TWA (vacated) 1mg/ m <sup>3</sup> TWA	1.5 mg/ m <sup>3</sup> TWA
Cobalt, Co	0.02 mg/ m <sup>3</sup> TWA	0.02 mg/ m <sup>3</sup> TWA
Chromium, Cr	0.5 mg/ m <sup>3</sup> TWA	0.5 mg/ m <sup>3</sup> TWA
Molybdenum, Mo	10 mg/ m <sup>3</sup> TWA (vacated)	10 mg/ m <sup>3</sup> TWA (inhaled fraction) 3 mg/ m <sup>3</sup> TWA (respirable fraction)

**NIOSH IDLH:**

Alloy

Nickel: IDLH (10mg/m<sup>3</sup>); TWA (0.015 mg/m<sup>3</sup>)  
 Molybdenum: IDLH (5000mg/m<sup>3</sup>)  
 Cobalt: IDLH (20mg/m<sup>3</sup> dust & fume); TWA (0.05mg/m<sup>3</sup> dust & fume)

**8.2 Exposure Controls**

**8.2.1 Appropriate Engineering Controls**

Ensure adequate ventilation, especially in confined area (i.e. showers, eyewash stations, etc.).

**8.2.2 Personal Protective Equipment**

**8.2.2.1 Eye & Face Protection**

When processing the metal alloy wear: Tightly fitting safety goggles.

**8.2.2 Skin Protection**

When processing the metal alloy: Wear protective gloves/clothing.

**8.2.2.3 Respiratory Protection**

If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Basic Physical & Chemical Properties**

Appearance:	Silver/grey/metallic solid
Odor:	Odorless
pH:	No Data Available
Melting Point:	2719°F (1493°C) Cobalt
Initial Boiling Point & Boiling Range:	No Data Available
Flash Point:	No Data Available
Evaporation Rate:	No Data Available
Flammability (solid, gas):	No Data Available
Solubility(ies):	Insoluble
Auto-Ignition Temperature:	No Data Available
Decomposition Temperature:	No Data Available
Viscosity:	No Data Available
Explosive Property:	No Data Available

**10. STABILITY AND REACTIVITY**

**10.1 Reactivity**

No data available

**10.2 Chemical Stability**

Stable under recommended storage conditions

**10.3 Conditions of Instability**

N/A

**10.4 Possibility of Hazardous Reactions**

None under normal processing

**10.5 Conditions to Avoid**

Dust formation



Alloy

**10.6 Incompatible Materials**

May react in contact with strong acids to release gaseous acid decomposition products, e.g. hydrogen, oxides of nitrogen. Use of strong oxidizers (high pH) on stainless steel may cause Cr(VI) compounds to form at ambient temperatures. Decomposition: Fumes generated during welding, brazing, or thermal cutting may contain: chromium compounds, including hexavalent chromium Cr(VI); nickel; manganese; iron; molybdenum; and silicon compounds.

**10.7 Hazardous Decomposition Products**

None known based on information supplied

**10.8 Hazardous Polymerization**

Will not occur.

**11. TOXICOLOGICAL INFORMATION**

This mixture has not been evaluated as a whole for health effects. Grinding, polishing, abrasive blasting, hot rolling, hot forging, thermal cutting, or welding may produce dust or fumes containing complex or mixed oxides of its components. Dust particles may cause eye, skin and/or respiratory system irritation. Exposure effects listed are based on existing health data for the individual components which comprise the mixture.

**Information on Toxicological Information**

Target Organs: Respiratory System. Skin.

Chronic Health Effects: Elevated temperature processing such as welding and plasma arc cutting may release hazardous fumes. Overexposure to metal fumes may cause pulmonary edema (fluid in the lungs) and methemoglobinemia. May also cause pulmonary fibrosis and lung cancer.

Serious Eye Damage/Irritation: Contact with eyes may cause irritation.

Respiratory/Skin Sensitization: Contact with dust can cause mechanical irritation or drying of the skin. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.

Reproductive Toxicity: No Information Available

STOT-Repeated Exposure: Causes damage to organs through prolonged or repeated exposure

Inhalation Hazard: May cause irritation of respiratory tract. Inhalation of fumes may cause metal fume fever, which is characterized by flu-like symptoms with metallic taste, fever, chills, cough, weakness, chest pain, muscle pain and increased white blood cell count. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Other Potential Health Effects: May cause sensitization by inhalation and skin contact

Ingestion: May cause irritation

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Cobalt	= 6170 mg/kg ( Rat )	-	> 10 mg/L ( Rat ) 1 h

Carcinogenicity: Below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
Nickel		Group 2B	Reasonably Anticipated	X
Chromium		Group 3		
Cobalt	A3	Group 2A		X

**Numerical measures of toxicity • - Product**

The following values are calculated based on chapter 3.1 of the GHS document:

Alloy

**LD50 Oral** 389 mg/kg; Acute toxicity estimate 7500

**12. ECOLOGICAL INFORMATION**

Chemicals are not readily available as they are bound within the alloy. Exposure effects listed are based on existing health data for the individual components which comprise the mixture.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water)
Nickel	EC50 96 h: 0.174 - 0.311 mg/L static (Pseudokirchneriella subcapitata) EC50 72 h: = 0.18 mg/L (Pseudokirchneriella subcapitata)	LC50 96 h: = 1.3 mg/L semi-static (Cyprinus carpio) LC50 96 h: = 10.4 mg/L static (Cyprinus carpio) LC50 96 h: > 100 mg/L	-	EC50 48 h: = 1 mg/L Static (Daphnia magna) EC50 48 h: > 100 mg/L (Daphnia magna)
Cobalt	-	LC50 96 h: > 100 mg/L static (Brachydanio)	-	-

**13. DISPOSAL CONSIDERATIONS**

The generator of waste material has the responsibility for proper waste classification, transportation and disposal with accordance applicable federal, state/provincial and local regulations.

Chemical Name	RCRA	RCRA - Basis for	RCRA - D Series Wastes	RCRA - U Series Wastes
Nickel – 7440-02-0	(hazardous constituent -	Included in waste streams: F006,	N/A	N/A
Chromium – 7440-47-3	N/A	Included in waste streams: F032, F034, F035, F037, F038,	5.0 mg/L regulatory level	N/A
Aluminum – 7429-90-5	N/A	Included in waste streams: F006, F019, F039	N/A	N/A
Chemical Name	California Hazardous Waste			
Nickel	Toxic powder Ignitable			
Chromium	Toxic Corrosive Ignitable			
Manganese	Ignitable powder			
Molybdenum	Ignitable powder			
Titanium	Ignitable powder			
Copper	Toxic			
Cobalt	Toxic powder Ignitable			

**14. TRANSPORTATION INFORMATION**

**DOT Not Regulated**

**15. REGULATORY INFORMATION**

**International Inventories**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory: Complies

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List: Complies

**U.S. Federal Regulations**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372:

Chemical Name	CAS-No	Weight %	SARA 313 - Threshold Values %
Nickel	7440-02-0	37	0.1
Chromium	7440-47-3	26	1.0
Manganese	7439-96-5	2	1.0
Cobalt	7440-48-4	0.6	0.1

**SARA 311/312 Hazard Categories**

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

**Clean Water Act**

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42):

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Nickel		X	X	
Copper		X	X	

**CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302):

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	RQ
Nickel	100 lb		RQ 100 lb final RQ RQ 45.4 kg
Chromium			RQ 5000 lb final RQ RQ 2270 kg

**Alloy**

Copper	5000 lb		RQ 5000 lb final RQ RQ 2270 kg
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### U.S. State Regulations

#### **California Proposition 65**

This product contains the following Proposition 65 chemicals:

Chemical Name	CAS-No	California Prop. 65
Nickel	7440-02-0	Carcinogen
Cobalt	7440-48-4	Carcinogen

### U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Nickel	X	X	X	X	X
Chromium		X			X
Silicon	X	X	X		X
Manganese	X	X	X	X	X
Molybdenum	X	X	X		X
Titanium	X				
Cobalt	X	X	X	X	X

### **U.S. EPA Label Information**

EPA Pesticide Registration Number: Not applicable

## **16. ADDITIONAL INFORMATION**

#### **16.1 Indication of changes/revision to SDS:**

1. New format
2. Inclusion of EC Requirements
3. **Revision Date:** 09/16/2015

#### **16.2 Abbreviations and acronyms:**

None

#### **16.3 Key literature references and sources for data**

1. Guidance on the Compilation of Safety Data Sheets; European Chemical Agency (ECHA); Version 2.1, February 2014
2. Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

#### **16.4 Classification and procedure used to derive classification for mixtures according to Regulation (EC) 1272/2008[CLP]:**

None

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in the SDS was obtained from sources that we believe are reliable and is believed to be valid and accurate. American Orthodontics, however, makes no warranty, express or implied, regarding its correctness of the information provided. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage, or expense

**Alloy**

arising out of or in any way connected with the handling, storage, use or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by the Company, this SDS information may not be applicable. **Reasonable safety precautions must always be observed.**