

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
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 ³ TWA (vacated) 1mg/ m ³ TWA | 1.5 mg/ m ³ TWA |
| Cobalt, Co | 0.02 mg/ m ³ TWA | 0.02 mg/ m ³ TWA |
| Chromium, Cr | 0.5 mg/ m ³ TWA | 0.5 mg/ m ³ TWA |
| Molybdenum, Mo | 10 mg/ m ³ TWA (vacated) | 10 mg/ m ³ TWA (inhaled fraction) 3 mg/ m ³ TWA (respirable fraction) |

NIOSH IDLH:

Nickel: IDLH (10mg/m³); TWA (0.015 mg/m³)

Molybdenum: IDLH (5000mg/m³)

Cobalt: IDLH (20mg/m³ dust & fume); TWA (0.05mg/m³ 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

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:

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 |
| Copper | 5000 lb | | RQ 5000 lb final RQ RQ 2270 kg |

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 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.**