

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Stainless Steel Brackets; Empower (Bracket body only; for Metal Clip, refer to Chromium Cobalt Alloy SDS); T3; Master Series; Mini Master Series; Low Profile (LP); Forever Gold™; iFit; Slim Tube; Wraparound; Inconel; Maximum Retention MR™ Bands; Contoured Bands; Bondable Retainer; Bite Blocks; Tongue Director; Diastema Closer; Sheaths; Eyelets; Eruption Appliance; Cleats; Lugs; Hooks; Stops; Weldable Tubes; Stainless Steel Wires; Stainless Steel Springs; Wrap Around Hawley; Stainless Steel Retainer Wire; Ball Retainer Clasps; Kobayashi Hooks; Ligature Wires; Springs; Powerscope™; Herbst Appliances; Miniscope™ Telescoping Herbst; Hanks Telescoping Herbst™; Rollo Bands; Mini Skirt™ Crowns; Jasper Jumper; Gentle Jumper; Jones Jig; Rapid Molar Intruder; Distal Jet; Spring Jet; Mesial Jet; Uprighter Jet; Palatal Arch; Quad Helix; Expansion Screws; Quick Fix; Alexander Lip Bumper; Lip Bumper; Korn Lip Bumper; Mandibular Advancer; M.A.P.; IOA; 300 Series Facebows; 400 Series Facebows; Luno, PowerBar

Common Name: Fixed & Functional, Stainless Steel Brackets, Buccal Tubes, Wires, Stops & Hooks, Wire Spring, Bands, Lingual Attachments, Extraoral, Instruments

Material: Stainless Steels (Austenitic, Ferritic, Precipitation Hardening, Martensitic)

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.: See Below

REACH Registration No.: Nickel (01-2119438727-29-XXXX)
Aluminum (01-2119529243-XXXX)
Niobium (01-2119489003-42-XXXX)
Carbon (01-2119966900-32-XXXX)
Tantalum (01-2119974241-40-XXXX)

CAS No. / IUPAC: See Below

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:

Solid metallic products are generally classified as “articles” and do not constitute a hazardous materials in solid form under the definitions of the OSHA Hazard Communication Standard (29 CFR 1910.1200). Any articles manufactured from these solid products would be generally classified as non-hazardous. However some hazardous elements contained in these products can be emitted under certain processing conditions such as but not limited to: burning, melting, cutting, sawing, brazing, grinding, machining, milling, and welding. Products in the solid state present no fire or explosion hazard. Small chips, fines, and dust may ignite readily, though. 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

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
- 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>
Iron	7439-89-6	N/A	Balance
Nickel	7440-02-0	231-111-4	0-15
Chromium	7440-47-3	N/A	11.5-22
Silicon	7440-21-3	N/A	0-2
Manganese,	7439-96-5	N/A	0-2
Molybdenum	7439-98-7	N/A	0-6.5
Titanium	7440-32-6	N/A	0-0.7
Copper	7440-50-8	N/A	0-5
Aluminum	7429-90-5	231-072-3	0-4
Niobium	7440-03-1	231-113-5	0-0.6
Carbon	7440-44-0	231-153-3	0-1.2
Tantalum	7440-25-7	231-135-5	0-0.5

Other trace elements may also be present in minute amounts. These small quantities (less than 0.1%) are frequently referred to as “trace” or “residual” elements; generally they originate in the raw material used.

4. FIRST-AID MEASURES

4.1 Description of First-Aid Measures

Inhalation: Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Consult a physician.

Skin Contact: Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.

Eye Contact: Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Consult a physician.

Ingestion/Swallowing: Do NOT induce vomiting. Call a physician or Poison Control Center immediately. Drink plenty of water. Never give anything by mouth to an unconscious person.

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
Silicon	15 mg/ m ³ TWA (total dust) 5 mg/ m ³ TWA respirable fraction (vacated) 10 mg/ m ³ TWA total dust (vacated) 5 mg/ m ³ TWA respirable fraction	N/A
Manganese	1 mg/ m ³ TWA (vacated) 3 mg/ m ³ STEL funem (vacated) 5 mg/ m ³ Ceiling 5 mg/ m ³ Ceiling (fume)	0.2 mg/ m ³ TWA
Molybdenum	10 mg/ m ³ TWA (vacated)	10 mg/ m ³ TWA (inhaled fraction) 3 mg/ m ³ TWA (respirable fraction)
Copper	0.1 mg/ m ³ TWA (fume) 1 mg/ m ³ TWA dust & mist (vacated)	0.2 mg/ m ³ TWA

	0.1 mg/ m ³ TWA dust, fume, mist	
Aluminum	10 mg/ m ³ TWA (as metal dust) 5.0 mg/ m ³ (as welding fume)	10 mg/ m ³ TWA (as metal dust) 5.0 mg/ m ³ TWA (as welding fume)

NIOSH IDLH:

Nickel: IDLH (10mg/m³); TWA (0.015 mg/m³)
 Silicon: TWA (10mg/m³ total dust); TWA (5 mg/m³ respirable dust)
 Manganese: IDLH (500mg/m³); TWA (1 mg/m³ fume); STEL (3mg/m³)
 Molybdenum: IDLH (5000mg/m³)
 Copper: IDLH (100mg/m³ dust, fume & mist); TWA (1 mg/m³ dust & mist); TWA (0.1mg/m³fume)
 Aluminum: IDLH (10mg/m³ total dust); IDLH (5mg/m³ as respirable dust)

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 be provided in accordance with current local regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	Varies from dull to very light grey, to shiny metallic light grey or bright mirror finish
Odor:	Odorless
Odor Threshold:	No Information Available
pH:	No Data Available
Melting Point:	2498-2768°F (1370-1520°C)
Flash Point:	No Data Available
Evaporation Rate:	No Data Available
Flammability (solid, gas):	No Data Available
Upper/Lower Flammability or Explosive Limits:	No Data Available
Vapor Pressure:	No Data Available
Vapor Density:	No Data Available
Relative Density:	No Data Available

Solubility(ies):	Insoluble
Partition Coefficient: n-octanol/water:	No Data Available
Auto-Ignition Temperature:	No Data Available
Decomposition Temperature:	No Data Available
Viscosity:	No Data Available
Specific Gravity:	0.27-0.30 lbs./in ³ (7.7-8.1 kg/dm ³)

9.2 Other Information

Thermal Expansion (ambient at 100°C)	10-16x10 ⁶ m/m°C
Thermal Conductivity (ambient temperature):	12-30 W/m°C

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

In its solid form stainless steel does not present an inhalation, absorption, or ingestion hazard. Grinding, polishing, abrasive blasting, hot rolling, hot forging, thermal cutting, or welding may produce stainless steel dust or fumes containing complex or mixed oxides of its components. Metal dust particles may cause eye, skin and/or respiratory system irritation. The below information is for these instances.

Toxicity Overview:

This product contains the following components which in their pure form have the following characteristics:

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.

Chronic exposure to manganese may cause impairment to the central nervous system including sluggishness, sleepiness, muscle weakness, loss of facial muscle control, edema, emotional disturbances, spastic gait, and falling. Chronic exposure to aluminum flake has been reported to cause pneumoconiosis in workers. Repeat oral exposure to aluminum results in decrements in neurobehavioral function and development.

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
Iron	= 984 mg/kg (Rat)	-	-
Nickel	> 9000 mg/kg (Rat)	-	-
Silicon	= 3160 mg/kg (Rat)	-	-
Manganese	= 9 g/kg (Rat)	-	-
Aluminum	Unknown	-	-

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		

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)
Iron	-	LC50 96 h: = 0.56 mg/L semi-static (Cyprinus carpio) LC50 96 h: = 13.6 mg/L	-	-
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)
Copper	EC50 96 h: 0.031 - 0.054 mg/L static (Pseudokirchneriella subcapitata) EC50 72 h: 0.0426 - 0.0535 mg/L static (Pseudokirchneriella subcapitata)	LC50 96 h: 0.0068 - 0.0156 mg/L (Pimephales promelas) LC50 96 h: < 0.3 mg/L static (Pimephales promelas) LC50 96 h: = 0.052 mg/L flow-through (Oncorhynchus mykiss) LC50 96 h: = 0.112 mg/L flow-through (Poecilia reticulata) LC50 96 h: = 0.2 mg/L flow-through (Pimephales promelas) LC50 96 h: = 0.3 mg/L	-	EC50 48 h: = 0.03 mg/L Static (Daphnia magna)
Aluminum	-	LC50 96 h = 0.16 mg/l Rainbow Trout		EC50 24 h: = 3.5 mg/l Static (Daphnia)

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		

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

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

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				

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:* 04/17/2018

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.**