

MATERIAL SAFETY DATA SHEET (FOR THE METAL PARTS)

1. COMPANY AND PRODUCT IDENTIFICATION

COMPANY: **Azure Ortho**
 Division of Azure Microdynamics, Inc.
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 Phone: 949-699 3344

PRODUCT: **VECS™ Palate Expander 10mm and 14 mm**

2. COMPOSITION / INFORMATION ON INGREDIENTS

NAME OF INGREDIENTS:

Stainless Steel 17-4 PH
 Stainless Steel 316L

INFORMATION ON INGREDIENTS:

Stainless Steel 17-4 PH per ASTM A564		Stainless Steel 316L per ASTM A182	
<i>Chemistry Elements</i>	<i>% Composition</i>	<i>Chemistry Elements</i>	<i>% Composition</i>
Carbon (C)	0.07 Max	Carbon (C)	0.035 Max
Manganese (Mn)	1.00 Max	Manganese (Mn)	2.00 Max
Phosphorus (P)	0.04 Max	Phosphorus (P)	0.04 Max
Sulfur (S)	0.03 Max	Sulfur (S)	0.02 - 0.03
Silicon (Si)	1.00 Max	Silicon (Si)	1.00 Max
Chromium (Cr)	15.00 - 17.50	Chromium (Cr)	16.00 - 18.00
Nickel (Ni)	3.00 - 5.00	Nickel (Ni)	10.00 - 14.00
Copper (Cu)	3.00 - 5.00	Molybdenum (Mb)	2.00 - 3.00
Columbium (Cb) + Tantalum (Ta)	0.15 - 0.45	Iron (Fe)	Balance
Iron (Fe)	Balance		

3. HAZARD IDENTIFICATION

Health Hazard Overview:

Speciality steel alloys are generally not considered hazardous in the form shipped. However, if your process involves grinding, melting, welding, cutting and any other process that cause release of dust or fume, hazardous levels of dust or fumes of the constituents of these alloys could be generated. The following is a list of potential health effects for the hazardous elements that may be contained in any of the alloys. Please refer to the hazardous ingredients preceding for a list of those specific elements contained in particular alloy. It is the user responsibility to assess potential exposures based on their precessing of the product.

General:

Welding fume, fumes freshly generated by the welding of zinc, magnesium and copper, are know to cause metal fume fever. Inhalation of aluminum, iron, nickel, manganese, selenium and tin have also been reported to cause metal fume fever. Symptom are flu-like including: shortness of breath, coughing, muscle pain, fever and chills. Generally, symptoms resolve with rest in a few days.

Expouser Routes:

Inhalation:

Primary route of espouser, steel dusts and fume may cause irrigation to the respiratory tract. Chronic exposure may aggravate pre-existing conditions.

Skin & Eye Contact:

My cause irritation or skin sensitivity.

Ingestion:

Certain constituents may be harmful if swallowed.

SPECIFIC HEALTH EFFECTS:

CHROMIUM: The toxicity of chromium is dependent on its oxidation state. Chromium metal is relatively non-toxic. If metal is heated to high temperatures, as in welding, fumes produced may be toxic to the lungs. Under high temperatures, hexavalent chromium may be produced, in the insoluble form it is designated a confirmed human carcinogen. Other health effects include nasal irritation and possible kidney and liver damage. Chromite dust may also cause skin ulceration, dermatitis and allergic skin reactions.

COLUMBIUM: Eye or skin irritant, may cause kidney damage
(NIOBIUM)

COPPER: May irritate the upper respiratory tract, may include a metallic or sweet taste. May also cause metal fume fever.

IRON OXIDE: Repeated inhalation of iron oxide fume or dust causes benign pneumoconiosis (siderosis), but generally does not cause symptoms in the expose person.

MANGANESE: Acute effects include skin and eye irritation and metal fume fever. Chronic exposure may lead to central nervous system symptoms of headache, changes in motor activity and psychological disturbances.

MOLYBDENUM: Insoluble compounds of molybdenum have a low order of toxicity. Molybdenum trioxide is an irritant to the eyes and mucous membranes.

NICKEL: Know to cause contact dermatitis and a respiratory irritant. Nickel refining and specific compounds are considered carcinogens to humans. The International Agency for Research on Cancer lists elemental nickel as a 2B, possibility carcinogenic to humans. The National Toxicological Program (NTP) lists nickel as reasonably anticipated to be carcinogenic from studies in experimental animals. The American Conference on Governmental Industrial Hygienists recommends that nickel compounds be differentiated according to solubility for their carcinogenic effects.

SELENIUM: Selenium dust vapors and fumes are irritants of the eyes, mucous membranes and skin. Chronic exposure may cause central nervous system effects and gastrointestinal disturbance. Selenium is listed by the National Toxicological Program (NTP) as a 2B, anticipated to be carcinogenic from studies in experimental animals.

TANTALUM: Considered to have a low order of toxicity. As surgical implant material, it has demonstrated its physiological inertness.

4. FIRST AID MEASURES

As shipped, the stainless steel components are an article. The likelihood for hazardous consequences through eye or skin contact, inhalation or ingestion would be consider minimal.

Inhalation:

Remove person from exposure to fresh air. If breathing difficulty occurs, get prompt medical attention.

Skin & Eye Contact:

Flush eye with plenty of water for 15 minuets, seek medical attention if irritation persists.

Ingestion:

Seek medical attention.

5. FIRE-FIGHTING MEASURES

Flashpoint and Method:	Not applicable
Flammability Limits:	Not applicable
Autoignition Temperature:	Not available
Melting point:	2400 - 2800 degree F
General Hazard	In the form shipped, these speciality metals are not combustible
Firefighting Instructions:	No special instruction for product as shipped
Firefighting Equipment:	No special equipment for product as shipped
Hazardous Combustion Products:	In the form shipped, hazardous decomposition products are not expected

6. ACCIDENTAL RELEASE MEASURES

Land/Water Spill: As shipped, this product does not pose a hazard to the environment.

7. HANDLING AND STORAGE

Storage Temperature:	Not applicable
Storage Pressure:	Not applicable
General:	Store away from acids and oxidizers

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls:

The use of local exhaust ventilation is recommended to control emission near the source of metal being cut, ground, weld or melted.

Personal Protection:

When handling the steel product (bar shape), leather gloves are recommended. Additional personal protective equipment is dependent on the operation performed, for example safety glasses and face shield when grinding the product.

If industrial hygiene monitoring reveals an overexposure during the processing of the product, engineering controls are required to be installed to reduce exposures below OSHA permissible exposure limits. In the absence of feasible engineering controls, wear a NIOSH approved respirator for protection for the type of particulate generated.

9. PHYSICAL AND CHEMICAL PROPERTIES

Vapor Pressure:	Not applicable	Vapor Density:	Not applicable
Specific Gravity:	7.5 - 8.5	Evaporation Rate:	Not applicable
Solubility in Water:	Insoluble	Freezing Point:	Not applicable
PH:	Not applicable	Odor:	Odorless
Boiling Point:	Not applicable	Appearance:	Gray in color
Viscosity:	Not applicable	Physical State:	Solid

10. STABILITY AND REACTIVITY

General: product is stable and hazardous polymerization will not occur.

Incompatible Materials and Conditions to Avoid: Acids, bases and oxidizers

Hazardous Decomposition: None for product as shipped

11. TOXICOLOGICAL INFORMATION

12. ECOLOGICAL INFORMATION

13. DISPOSAL CONSIDERATION

General:

Recycling of all metallic byproducts as scrap is strongly encouraged. If byproducts need to be treated and/or disposed of as wastes, hazardous waste characterizations must be performed prior to treating and/or disposing. Contact appropriate parties to ensure compliance with all federal, state and local rules and regulation related to waste treatment and disposal.

14. TRANSPORT INFORMATION

For Hazardous Wastes:	DOT (Department of Transportation)
Proper Shipping Name:	Hazardous Waste Solid, n.o.s.
Hazard Class:	9
Identification Number:	NA3077
Packing Group:	III
Emergency Respond Guide Number:	171

15. REGULATORY INFORMATION

TSCA (Toxic Substances Control Act):	Not applicable
CERCLA (Comprehensive Response Compensation and Liability Act):	Not applicable

SARA Title III (Superfund Amendments and Reauthorization Act):

311/312 Hazardous Category: Not applicable for storage of items as shipped, however if processed, end product may require reporting.

313 Hazardous Category: Product ingredients subject to reporting requirements may include: chromium, nickel, manganese, cobalt, or copper.

Regulations such as Clean Air Act, Clean Water Act, Resource Conservation & Recovery Act may apply to the handling of steel grindings and articulates from processing.

California Safe Drinking Water Act (Prop 65) listing:

<u>Component</u>	<u>CAS Number</u>
NICKEL	7440-02-0
COBALT	7440-48-4

Governors list of chemicals known to cause cancer and reproductive toxicity includes hexavalent compounds of chromium and nickel dust from pyrometallurgical processing.

15. OTHER INFORMATION

Hazard Ratings:

	NFPA	HMIS
Health	0 (as shipped) 2 (if ground, welded or melted)	0 (as shipped) 2 (if ground, welded or melted)
Flammability	0	0
Reactivity	0	0

NOTE:

While the information set forth on this Material Safety Data Sheet is believed to be accurate as of the revision date, Azure Ortho and its parent company Azure MicroDynamics, Inc. makes no warranty with respect thereto and disclaims all liability from reliance thereon.

No warranty, either express or implied of merchantability or fitness or of any nature with respect to the material or data herein is made hereunder.