



CEE 91/155 and CEE/93/112 Directives **ORTHO PLUS**

28, rue Ampère - BP 28 - 91430 Igny France - Tél. /Fax: (33) 1 69 41 90 28/ (33) 1 60 19 32 22 orthoplus@orthoplus.fr

1. Identification of the substance/device :

1.1 Device name : ARCHWIRE BETA PLUS

2. Composition, information on ingredients:

Composition	CAS N° / EINECS N°	wt%
2.1 Molybdenum	7439-98-7 / 231-107-2	10-20
2.2 Zirconium	7440-67-7 / 231-176-9	5-10
2.3 Tin	7440-31-5 / 231-141-8	1-5
2.4 Titanium	7440-32-6 / 231-142-3	60-85

3. Hasards identification:

Emergency Overview: This product is not hazardous unless processed (i.e. ground, welded) in a manner that generates dust or fumes. Dust and fumes may cause eye, skin and respiratory irritation.

EU Preparation Classification (1999/45/EC): not a dangerous preparation.

4. First aid measures:

No first aid required for contact with solid product. The following information applies to contact from processing.

Eye Contact:

Flush with large quantities of water, holding the eyelids apart to assure that the material is washed out. Get medical attention if irritation persists.

Skin contact:

Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops.

Ingestion:

If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.

Inhalation:

If irritation or other symptoms develop, remove to fresh air. Get medical attention if symptoms persist.





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5. Fire fighting measures:

- Extinguishing Media: this material is not combustible in solid form. Use media that is appropriate for the surrounding fire. For fires involving fine dust or filings, do not use water, CO2 or foam directly on the burning metal. Use dry sand, graphite powder, Lith-X powder, dry chemical or other media appropriate for a class D fire.

- Fire fighting procedures:

Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus.

- Unusual Fire / Explosion Hazards:

Fine powders or filings may burn with intense heat. Fine dust may present an explosion hazard. Dousing burning metal with water may generate explosive hydrogen gas.

- Known or Anticipated Hazardous Products of Combustion:

Thermal decomposition or combustion products include oxides of the metals listed in Section 2 which may be highly toxic.

6. Accidental release measures:

- Personal Precaution: avoid contact with eyes, skin or clothing. Do not breathe dust.
- Environmental Precaution: prevent entry into sewers and waterways.
- Accidental Release Measures: pick up solid material for reuse or disposal. For spills of dust, wear respiratory and protective clothing (see Section 8). Vacuum using an explosion-proof, HEPA vacuum and non-sparking tools. Do not breathe dust or allow it to contaminate skin or clothing. Spill and release reporting requirements vary. Consult local authorities regarding requirements.

7. Handling and storage:

Handling:

Do not breathe dust or fumes from processing. Avoid contact with dust. Wear protective clothing and equipment as described in Section 8. Process only with adequate ventilation. Keep containers closed when not use. Do not eat, drink or smoke in the work area.

Storage:

Store in a cool, well ventilated location away from incompatible materials.





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8. Exposure controls/personal protection: N/A

Occupational Exposure Limits:

Molybdenum 15 mg/m³ TWA OSHA PEL (total dust) – 3 mg/m³ TWA ACGIH TLV (respirable fraction)

Zirconium 5 mg/m³ TWA OSHA PEL (as zirconium compounds) – 5 mg/m³ TWA ACGIH TLV – 2 mg/m³ TWA OSHA PEL – 1 mg/m³ TWA DFG MAK – 5 mg/m³ TWA UK WEL; 10 mg/m³ STEL UK WEL

Tin 2mg/m³ TWA OSHA PEL ⁻ 2mg/m³ TWA ACGIH TLV - 2mg/m³ TWA UK, WEL, 4 mg/m³ STEL UK WEL (as tin inorganic compounds)

Titanium None established

Engineering Controls: none needed under normal use. If dust or fume are generated during processing, use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

Personal Protective Equipment:

Eye protection: wear safety glasses or other eye protection consistent with industrial safety practice for the process being performed.

Skin protection: wear protective gloves if need to prevent cuts or other injuries.

Respiratory Protection: none needed under normal use. If the occupational exposure limits are exceeded during processing, an approved respirator with high efficiency particulate filters may be used. For higher exposures (greater than 10 times the exposure limit) a supplied air respirator may be required. Respirator selection and use should be based on contaminant type, form and concentration. Follow OSHA 1910.134, ANSI Z88.2 or local authority regulations and good Industrial Hygiene practice.

Other Protective Clothing OR Equipment: use protective clothing consistent with industrial safety practice for the process being performed.





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9. Physical and chemical properties:

Appearance and odor: silver wire with no odor.

Boiling point: not applicable Melting point: 3050°F Freezing point: not available Specific gravity: not available Solubility in water: insoluble

pH: not applicable

Vapor pressure (mmHg): not applicable

Vapor density: not applicable
Evaporation rate: not applicable
Viscosity: not applicable
% volatile by volume: none
Flashpoint: not applicable
Flammable limits in air:
LEL: not applicable

Auto ignition temperature: not applicable

10. Stability and reactivity:

- Stability: stable

UEL: not applicable

- Conditions to avoid : none know
- Incompatibility with other materials: acids, alkalies, oxidizing agents, potassium nitrate and turpentine.
- Hazardous decomposition products: metal fumes and oxides are emitted when product is heated above the melting point.

11. <u>Toxicological information:</u>

- Potential Health effects:

- ✓ **Eyes:** dust or fines may cause mechanical irritation.
- ✓ **Skin:** dust may cause skin irritation.
- ✓ **Ingestion:** no acute effects expected from swallowing small amounts.
- ✓ **Inhalation:** dust or fumes may cause irritation of the mucous membranes and upper respiratory tract.
- ✓ Chronic health effects: prolonged inhalation of dust may cause lung damage, fibrotic lung disease, and effects on the cardiovascular system. Chronic exposure to tin oxide dusts and fumes may result in stannosis (benign pneumoconiosis). Repeated skin contact with zirconium compounds may cause allergic skin sensitization.
- Carcinogenicity: none of these components are listed as carcinogens by IARC, NTP, ACGIH, OSHA or the EU Directive.
- ✓ **Medical conditions aggravated by exposure:** individuals with the pre-existing skin disorders may be at increased risk from exposure.
- ✓ Acute toxicity data:
 - Molybdenum, Zirconium, Tin and Titanium: no data available.

12. Ecological information:

No data is available at this time.





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13. <u>Disposal considerations</u>:

Dispose in accordance with national and local regulations.

14. Transport information:

- DOT shipping name: not regulated
- DOT hazard class: N/A
- UN number: N/A
- DOT labels requires (49CFR172.101): N/A
- ✓ IATA shipping name: not regulated
- ✓ IATA hazard class: N/A
- ✓ UN number: N/A
- ✓ IATA hazard labels required: N/A
- IMDG shipping name: not regulated
- IMDG class: N/A
- UM number: N/A
- IMDG label: N/A





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15. Regulatory information:

U.S. FEDERAL REGULATIONS:

<u>CERCLA:</u> this product is not regulate under CERCLA. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

SARA TITTLE III: Hazard category for section 311/312: not hazardous unless processing creates dusts or fumes.

Section 313 toxic chemicals: this product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): none.

Section 302 Extremely Hazardous Substances (TPQ): none.

EPA Toxic Substances Control Act (TSCA) Status: this product is a medical device and not subject to chemical notification requirements.

U.S. STATE REGULATIONS:

California Proposition 65: this product contains the following substances known to the State or California to cause cancer: none.

INTERNATIONAL REGULATIONS:

Canadian WHMIS classification: medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: this product is a medical device and not subject to chemical notification requirements. European Community Labeling: this product is manufactured article as defined under REACH. No labeling is required for finished products.

European Inventory of New and Existing Chemical Substances (EINECS): this product is a medical device and not subject to chemical requirements.

Australian Inventory of chemical substances: this product is a medical device and not subject to chemical notification requirements.

China Inventory of existing chemicals and chemical substances: this product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New chemical substances: this product is a medical device and not subject to chemical notification requirements.

Korean Existing chemical List: this product is a medical device and not subject to chemical notification requirements. Philippine Inventory of chemicals and chemical substances: this product is a medical device and not subject to chemical notification requirements.





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16. Other information:

HMIS Hazard Rating: Health – 1 Fire Hazard -1 Physical Hazard -0* Chronic Health Hazard

EU Classes AND Risk Phrases for Reference (See Sections 2 and 3)

- Recommended use

While the information and recommendations set forth on this data sheet are believed to be accurate as received from our suppliers, ORTHO PLUS makes no warranty with respect thereto and disclaims all liability from reliance thereon.