



MATERIAL SAFETY DATA SHEET

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product Name: Vitallium® Alloys (includes Vitallium, Vitallium 2, Vitallium III, Vitallium 5, Vitallium 2000 and Vitallium 2000 Plus)

Product Number: N001035, N001435, N001335, N001700, N001830, N001930

MSDS Code Number: 230

Manufacturer: Dentsply Prosthetics

Address: 570 West College Ave.
York, PA 17405-0872

Information Telephone Number: 717-845-7511

Emergency Telephone Number: 800-424-9300 Chemtrec

Email: Prosthetics_MSDS@Dentsply.com

Product Use: Crown and bridge and/or partial dental appliances.

Date of Last Revision: October 29, 2009

SECTION 2 HAZARDS IDENTIFICATION

Emergency Overview: CAUTION! May cause eye, skin and respiratory irritation. May be harmful if swallowed. May cause skin and respiratory sensitization (allergic reaction). Inhalation of fumes may cause metal fume fever with flu-like symptoms. Prolonged inhalation of dust or fumes from this product may cause perforation of the nasal septum and lung damage. This product contains cobalt, which may cause cancer based on animal studies. May cause long-term adverse effects in the aquatic environment.

EU Preparation Classification (1999/45/EC): Xn; R42/43, R53

SECTION 3 COMPOSITION INFORMATION ON INGREDIENTS

| Ingredient | CAS No./EINECS No. | Percent | EC Substance Classification (67/548/EEC) |
|------------|-----------------------|---------|--|
| Cobalt | 7440-48-4 / 231-158-0 | <70 | Xn R42/43, R53 |
| Chromium | 7440-47-3 / 231-157-5 | <40 | Not Applicable |
| Molybdenum | 7439-98-7 / 231-107-2 | <10 | Not Applicable |

See Section 16 for further information on EU Classification.

SECTION 4 FIRST AID MEASURES

Eye Contact: Immediately flush victim's eyes 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 prompt medical attention.

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

SECTION 5 FIRE FIGHTING PROCEDURES

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.

Firefighting 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 and may be highly toxic.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Accidental Release Measures Pick up solid material for reuse or disposal. For spills of dust, wear respirator 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. Molten metals should be allowed to cool before clean-up. Spill and release reporting requirements vary. Consult local authorities regarding requirements.

Personal Precautions: Avoid contact with skin, eyes or clothing. Do not breathe dust.

Environmental Precautions: Prevent entry into sewers and waterways.

SECTION 7 HANDLING AND STORAGE

Handling: Do not breathe dust or fumes. Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Do not eat, drink or smoke in the work area.

Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

Storage: Store in a tightly closed container in a cool, well ventilated location away from incompatible materials. Store away from food or beverages.

SECTION 8 EXPOSURE CONTROL/PERSONAL PROTECTION

Occupational Exposure Limits:

| | |
|------------|--|
| Cobalt | 0.02 mg/m ³ TWA ACGIH TLV, 0.1 mg/m ³ TWA OSHA PEL, 0.1 mg/m ³ TWA UK WEL |
| Chromium | 0.5 mg/m ³ TWA OSHA PEL, 0.5 mg/m ³ TWA ACGIH TLV, 0.5 mg/m ³ TWA UK WEL, 2 mg/m ³ TWA EU IOEL |
| Molybdenum | 10 mg/m ³ TWA ACGIH TLV (Inhalable), 3 mg/m ³ TWA ACGIH TLV (Respirable Fraction), 15 mg/m ³ TWA OSHA PEL (Total Dust), 10 mg/m ³ TWA UK WEL, 20 mg/m ³ STEL UK WEL |

Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

Personal Protective Equipment:

Eye Protection: Wear safety goggles or other eye protection consistent with industrial safety practice for the process being performed.

Skin Protection: Wear protective gloves if need to prevent burns or other injuries.

Respiratory Protection: If needed, 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: Impervious clothing as needed to avoid skin contact and contamination of personal clothing. Maintain eye wash and quick-drench facilities in the work area.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Alloy products are solid metal, shaped as wire, plate, strip or in finished forms such as ingots or nuggets for dental use.

Boiling Point: Not Applicable

Melting Point: 1300-1373°C (2372-2503°F)

Freezing Point: Not Applicable

Specific Gravity: 8.3

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:

Autoignition Temperature: Not applicable

LEL: Not Applicable

UEL: Not Applicable

SECTION 10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: None known.

Incompatibility with Other Materials: Acids, ammonium nitrate, oxidizers, lithium, hydrogen peroxides, chlorine trifluoride, fluorine, lead oxide, nitric acid, sulfuric acids.

Hazardous Decomposition Products: Toxic metal fumes and oxides are emitted when product is heated above the metal point.

SECTION 11 TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: May cause eye irritation.

Skin: May cause skin irritation. May cause allergic skin reaction (sensitization).

Ingestion: Harmful if swallowed. Ingestion may cause anemia, headache, fever, nausea, abdominal pain, and liver damage.

Inhalation: May cause respiratory irritation. May cause allergic respiratory reaction (sensitization).

Inhalation of fumes may cause metal fume fever, which is characterized by flu-like symptoms with metallic taste, fever, chills, chest pain, fatigue and muscle pain. Symptoms generally resolve in 24-48 hours.

Chronic Health Effects: Prolonged or repeated skin contact may cause sensitization. Prolonged inhalation may cause lung damage, fibrotic lung disease, and effects on the cardiovascular system.

Carcinogenicity: Cobalt and cobalt compounds are classified by IARC as possibly carcinogenic to humans (Group 2B). Molybdenum has caused lung cancer in studies with laboratory animals. None of the other components are listed as carcinogens by IARC, NTP, ACGIH, or OSHA.

Medical Conditions Aggravated by Exposure: Individuals with pre-existing skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

| | |
|------------|---------------------------|
| Cobalt | Oral rat LD50: 6174 mg/kg |
| Molybdenum | No data available |
| Chromium | No data available |

SECTION 12 ECOLOGICAL INFORMATION

No data is available at this time.

SECTION 13 DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations.

SECTION 14 TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated
DOT Hazard Class: N/A
UN Number: N/A
DOT Labels Required (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
UN Number: N/A
IMDG Label: N/A

SECTION 15 REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

CERCLA: This product is not subject to CERCLA regulation. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

SARA TITLE III:

Hazard Category For Section 311/312: Acute Health, Chronic Health

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):

| | | |
|----------|-----------|------|
| Cobalt | 7440-48-4 | <70% |
| Chromium | 7440-47-3 | <40% |

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 of California to cause cancer: Nickel (<0.1%), Cobalt

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: Contains Cobalt



Harmful

R42/43 May cause sensitization by inhalation and skin contact.
R53 May cause long-term adverse effects in the aquatic environment.
S36/37 Wear suitable protective clothing and gloves.
S59 Refer to manufacturer/supplier for information on recovery/recycling.
S61 Avoid release to the environment. Refer to Safety data sheets.

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

SECTION 16 OTHER INFORMATION

HMIS Hazard Rating:

Health – 2* Fire Hazard – 1 Reactivity – 1

* Chronic Health Hazard

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

Xn Harmful

R42/43 May cause sensitization by inhalation and skin contact.

R53 May cause long-term adverse effects in the aquatic environment.

Revision Date: 10/29/2009

Supercedes: 07/20/2006

Revision Summary: Switched Sections 2 and 3. Added e-mail address. Updated exposure limits. Comprehensive review.