DENTSPLY International
DENTSPLY PROSTHETICS

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	**Vitallium® Alloys (includes Vitallium, Vitallium 2, Vitallium III, Vitallium 5, Vitallium 2000 and Vitallium 2000 Plus)**
Product Identifier (Part/Item Number):	**N001035, N001435, N001335, N001700, N001830, N001930**
U.N. Number:	**None**
U.N. Dangerous Goods Classification:	**Not Regulated**
Recommended Use:	**Crown and bridge and/or partial dental appliances**
Restrictions on Use:	**For Professional Use Only**
Manufacturer/Supplier Name:	**Dentsply Prosthetics**
Manufacturer/Supplier Address:	**570 West College Ave.**
	York, PA 17405-0872
Manufacturer/Supplier Telephone Number:	**717-845-7511 (Product Information)**
Emergency Contact Telephone Number:	**800-424-9300 Chemtrec**
Email address:	**Prosthetics_MSDS@Dentsply.com**

2. HAZARD(s) IDENTIFICATION

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

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

Labeling in accordance with 1999/45/EC

Harmful

Contains Cobalt
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.

US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Cobalt	7440-48-4	231-158-0	Xn R42/43, R53 Resp. Sens. 1, H334 Skin Sens. 1, H317 Aquatic Chronic 4, H413	<70
Chromium	7440-47-3	231-157-5	Not Applicable	<40
Molybdenum	7439-98-7	231-107-2	Not Applicable	<10

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	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	Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops.
Inhalation	If irritation or other symptoms develop, remove to fresh air. Get medical attention if symptoms persist.
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.
Most important symptoms of exposure	May cause eye, skin and respiratory irritation. 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.
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically. Immediate medical attention is not required.	

5. FIRE-FIGHTING MEASURES

Suitable 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:	Cool exposed intact containers with water.
Specific Hazards Arising from the Chemical:	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. Thermal decomposition or combustion products include oxides of the metals listed in Section 2 and may be highly toxic.
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus.

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**THERMAL**
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Avoid contact with skin, eyes or clothing. Do not breathe dust. For spills of dust, wear appropriate respirator and protective clothing as described in Section 8.

Environmental Precautions: Prevent entry into sewers and waterways. Spill and release reporting requirements vary. Consult local authorities regarding requirements.

Methods and Materials for Containment and Clean-up: Pick up solid material for reuse or disposal. Molten metals should be allowed to cool before clean-up. For spills of dust, vacuum using an explosion-proof, HEPA vacuum and non-sparking tools. Do not breathe dust or allow it to contaminate skin or clothing.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**
			

7. HANDLING AND STORAGE

Precautions for Safe Handing: 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 and can be hazardous. Follow all SDS precautions when handling empty containers.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Cobalt	United States	0.02 mg/m3 TWA ACGIH TLV 0.1 mg/m3 TWA OSHA PEL (for metal dust and fume)
	Germany	None Established
	United Kingdom	0.1 mg/m3 TWA UK OEL
	European Union	None Established
Chromium	United States	0.5 mg/m3 TWA ACGIH TLV (chromium metal) 1 mg/m3 TWA OSHA PEL (chromium metal)
	Germany	2 mg/m3 TWA, 2 mg/m3 STEL (15 min average value) AGS (inhalable)
	United Kingdom	0.5 mg/m3 TWA UK WEL
	European Union	2 mg/m3 TW EU IOEL
Molybdenum	United States	10 mg/m3 TWA ACGIH TLV (Inhalable) 3 mg/m3 TWA ACGIH TLV(Respirable Fraction) 15 mg/m3 TWA OSHA PEL (total dust)
	Germany	None Established
	United Kingdom	10 mg/m3 TWA UK OEL, 20 mg/m3 STEL UK OEL (inhalable) 5 mg/m3 TWA UK OEL , 10 mg/m3 STEL (soluble compounds)
	European Union	None Established

Biological Exposure Limits:
Cobalt - Cobalt in urine, End of shift at end of workweek, 15 ug/L; Cobalt in blood, End of shift at end of workweek, 1 ug/L

Appropriate Engineering Controls: Use ventilation that is adequate to keep employee exposure to airborne concentrations below exposure limits.

Individual Protection Measures (PPE)

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

Specific Skin Protection: Wear protective gloves if need to prevent burns or other injuries. Impervious clothing as needed to avoid skin contact and contamination of personal clothing

Specific Respiratory Protection: If needed, an approved respirator with high efficiency particulate filters may be used. For higher exposures, a supplied air respirator may be required. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

Environmental Exposure Controls: Do not allow spills to enter sewers or waterways.

General Hygiene Considerations and Work Practices: Do not breathe dust or fumes. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Do not eat, drink or smoke in the work area.
Protective Measures During Repair and Maintenance of Contaminated Equipment: Wear appropriate protective clothing and equipment. Wash thoroughly after handling. Do not breathe dust.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Solid cylindrical shaped metal ingots	**Explosive limits:**	**LEL:** Not applicable **UEL:** Not applicable
Odor:	Not applicable	**Vapor pressure (mmHg):**	Not applicable
Odor threshold:	Not applicable	**Vapor density:**	Not applicable
pH:	Not applicable	**Relative density:**	8.3
Melting/freezing point:	1300°C (2372-2503°F)	**Solubility:**	Insoluble
Initial boiling point and range:	Not applicable	**Partition coefficient: n-octanol/water:**	Not applicable
Flash point:	Not applicable	**Auto-ignition temperature:**	Not applicable
Evaporation rate:	Not applicable	**Decomposition temperature:**	Not applicable
Flammability:	Not combustible in solid form.	**Viscosity:**	Not applicable
Explosive Properties:	Fine dust may present an explosion hazard.	**Oxidizing Properties:**	None
% Volatile by Volume:	None		

10. STABILITY AND REACTIVITY

Reactivity: Not reactive.
Chemical Stability: Stable under normal condition.
Possibility of Hazardous Reactions: None known
Conditions to Avoid: None known.
Incompatible materials: Oxidizers, acids, ammonium nitrate, lithium, hydrogen peroxides, chlorine trifluoride, fluorine, lead oxide, nitric acid, and sulfuric acids.

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

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:
Eyes: May cause eye irritation.
Skin: May cause skin irritation. May cause allergic skin reaction (sensitization).
Ingestion: 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 components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.

Mutagenicity: Chromium: Metallic chromium tested negative in an in-vitro mammalian cell transformation test. Molybdenum: There is no information on molybdenum but sodium molybdate was negative in a chromosome aberration assay.

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

Chromium: No toxicity data available

Molybdenum: No toxicity data available

Reproductive Toxicity Data: No data available.

Specific Target Organ Toxicity (STOT):
Single Exposure: Cobalt: Cobalt has been shown to cause dermatitis in humans.

Repeated Exposure: Cobalt: Workers exposed to cobalt in excess of 0.1 mg/m3 showed symptoms of coughing, wheezing shortness of breath and lung damage.

12. ECOLOGICAL INFORMATION

Toxicity:
Cobalt: 96 hr LC50 Brachydanio rerio - >100 mg/L; 48 hr Daphnia magna- NOEC- 3.2 mg/L; 72 hr Selenastrum capricornutum (algae) – NOEC – 0.01-0.015 mg/L

Persistence and Degradability: Biodegradation is not applicable to inorganic substances.

Bio-accumulative Potential: Cobalt does not bio-accumulate in organic organisms.

Mobility in Soil: No data available.

Other Adverse Effects: None
Results of PBT/vPvB Assessment: Not applicable.

13. DISPOSAL CONSIDERATIONS

Regulations: Dispose in accordance with all national and local regulations.
Properties (Physical/Chemical) Affecting Disposal: Follow all SDS precautions when handling empty containers. Refer to manufacturer/supplier for information on recovery/recycling.
Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

UN Number:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
UN proper shipping name:	ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated			
Transport hazard class(es):	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Packaging group:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions for user: Not applicable				

15. REGULATORY INFORMATION

U.S. Federal Regulations

US OSHA Hazard Classification: Irritant, Sensitizer, Target organ effects.

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has a Reportable Quantity (RQ) of 12,500 lbs. (based on the RQ for Chromium of 5,000 lbs present at <40%). Releases above the RQ must be reported to the National Response Center. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

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

Clean Water Act (CWA): Chromium <40%

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	**Yes**	**Pressure Hazard:**	**No**
Delayed Hazard:	**Yes**	**Reactivity Hazard:**	**No**
Fire Hazard:	**No**		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
Cobalt	7440-48-4	<70
Chromium	7440-47-3	<40

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
Cobalt	7440-48-4	<70
Nickel	7440-02-0	<0.1
Beryllium	7440-41-7	<1 ppm

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

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

EU REACH: All components requiring registration have been pre-registered.

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.

16. OTHER INFORMATION

HMIS Hazard Rating:
Health – 2* Flammability – 0 Physical Hazard– 0

Full text of Classification abbreviations used in Section 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.
Aquatic Chronic 4 Aquatic Chronic Toxicity Category 4
Resp. Sens. 1 Respiratory Sensitization Category 1
Skin Sens. 1 Skin Sensitization Category 1
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H413 May cause long lasting harmful effects to aquatic life.

Supersedes: 1 December 2009

Revision Summary: Change in format. Comprehensive review. Changes to all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.