

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)

Date Issued: 25 May 2004
Document Number: 230
Date Revised: 31 August 2014
Revision Number: 6

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled): Vitallium® Alloys (includes Vitallium, Vitallium 2, Vitallium III, Vitallium 5, Vitallium 2000 and Vitallium 2000 Plus)

Part/Item Number: N001035, N001435, N001335, N001700, N001830, N001930

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

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

Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: DENTSPLY Prosthetics

Manufacturer/Supplier Address: 570 West College Ave.
York, PA 17401

Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)

Email address: Prosthetics_MSDS@Dentsply.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Carcinogen Category 2 (H351) Respiratory Sensitization Category 1 (H334) Skin Sensitization Category 1 (H317)	Aquatic Chronic Toxicity Category 4 (H413)	Not Hazardous

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

2.2 Label Elements:



Signal Word: Danger

Contains: Cobalt

Hazard Phrases	Precautionary Phrases
<p>H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H351 Suspected of causing cancer. H413 May cause long lasting harmful effects to aquatic life.</p>	<p>P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P261 Avoid breathing dust or fume. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves. P285 In case of inadequate ventilation wear respiratory protection. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P333+P313 If skin irritation or rash occurs: Get medical attention. P363 Wash contaminated clothing before reuse. P304+P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor. P308 + P313 IF exposed or concerned: Get medical attention. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.</p>

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Cobalt	7440-48-4	231-158-0	Xn R42/43, R53 Carc. 2, H351 Resp. Sens. 1, H334 Skin Sens. 1, H317 Aq. Chronic 4, H413	<70%
Chromium	7440-47-3	231-157-5	Not Applicable	<35%
Molybdenum	7439-98-7	231-107-2	Not Applicable	<10%
Non-Hazardous Ingredients	Mixture	Mixture	Not Applicable	<5%
Manganese	7439-96-5	231-105-1	Not Applicable	0-1%

Nickel	7440-02-0	231-111-4	Massive Form: Carc. Cat 3, T, R40, R48/23, R43 Skin Sens. Cat 1, H317 Carc. Cat 2, H351 STOT-RE Cat 1, H372 Powder Form: Carc. Cat 3, T, R40, R48/23, R43, R52/53 Carc. Cat 2, H351 Skin Sens. Cat 1, H317 STOT-RE Cat 1, H372 Aquatic Chronic Cat 3, H412	0-0.1%
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The exact concentration is being withheld as a trade secret.

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	If particles enter eyes, do not rub your eyes. Dust particles may cause abrasive eye injury. Wash eyes with water, while holding the eyelids apart. Get medical attention if irritation persists.
Skin	No first aid should be required. If contact with dust occurs, do not rub or scratch. Remove contaminated clothing. Rinse exposed skin with cold water then wash skin with soap and water. Get medical attention if irritation or rash occurs. Launder clothing before re-use.
Inhalation	No first aid should be required. If exposed to fumes or dust from cutting or handling: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get immediate medical attention if breathing is difficult.
Ingestion	Not an anticipated route of exposure. If product is swallowed, do not induce vomiting. Seek immediate medical advice.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Dust may cause mechanical eye, skin and respiratory irritation. Dust particles may cause abrasive injury to the eyes. May cause skin and respiratory tract 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. Risk of cancer depends on duration and level of exposure.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention is required if breathing is difficult or if product is swallowed.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:

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.

5.2 Special Hazards Arising from the Substance or Mixture:





This product is not classified as flammable or combustible. 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. Toxic metal fumes and oxides are emitted when product is heated.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures: Cool fire exposed containers with water. Contain water used in firefighting from entering sewers or natural waterways.

Precautions for Fire Fighters: Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.



Recommended Protective Equipment for Fire Fighters:

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES**6.1 Personal Precautions, Protective Equipment and Emergency Procedures:**

Avoid contact with skin, eyes or clothing. Do not breathe dust, fumes or allow it to contaminate skin or clothing. Avoid contact with molten product. For spills of dust, wear respirator and protective clothing (see Section 8).

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

6.2 Environmental Precautions:

Avoid releases to the environment. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Pick up solid material for reuse or disposal. Molten metals should be allowed to cool before clean-up. Dust suppression methods should be used to clean up dust such as wet sweeping or vacuuming. Compressed air or dry sweeping methods should not be used. Place dry material into an appropriate container for disposal. Flush spill area with water to remove residue.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with the eyes, skin and clothing. Do not breathe dust or fumes. 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. Use good housekeeping to prevent the accumulation of dust on surfaces. 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.

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

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Cobalt (as Cobalt and inorganic compounds)	United States	0.02 mg/m ³ TWA ACGIH TLV 0.1 mg/m ³ TWA OSHA PEL (for metal dust and fume)
	Germany	None Established
	United Kingdom	0.1 mg/m ³ TWA UK WEL
	European Union	Belgium: 0.02 mg/m ³
Chromium (as Chromium metal)	United States	0.5 mg/m ³ TWA ACGIH TLV 1 mg/m ³ TWA OSHA PEL
	Germany	2 mg/m ³ TWA, 2 mg/m ³ STEL AGS (Inhalable aerosol) (as chromium and Cr (II); Cr (III) compounds)
	United Kingdom	0.5 mg/m ³ TWA UK WEL (as chromium and Cr (II); Cr (III) compounds)
	European Union	2 mg/m ³ TWA EU OEL (as chromium and Cr (II); Cr (III) compounds)
Molybdenum (as Molybdenum and insoluble compounds, as Mo)	United States	10 mg/m ³ (Inhalable), 3 mg/m ³ (Respirable) TWA ACGIH TLV 15 mg/m ³ TWA OSHA PEL (Total dust)
	Germany	None Established
	United Kingdom	10 mg/m ³ TWA (inhalable), 20 mg/m ³ STEL (Inhalable) UK WEL
	European Union	Belgium: 10 mg/m ³ TWA

Non-Hazardous Ingredients	United States	None Established
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	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Manganese	United States	0.02 mg/m ³ (Respirable), 0.1 mg/m ³ (Inhalable) TWA ACGIH TLV (as Manganese, fume, as Mn) 5 mg/m ³ Ceiling OSHA PEL (as Manganese, fume, as Mn)
	Germany	0.2 mg/m ³ (inhalable), 0.02 mg/m ³ (respirable) TWA DFG MAK 0.16 mg/m ³ (respirable aerosol) STEL DFG MAK
	United Kingdom	0.5 mg/m ³ TWA UK WEL
	European Union	None Established
Nickel	United States	1.5 mg/m ³ TWA ACGIH TLV (Inhalable) 1 mg/m ³ TWA OSHA PEL
	Germany	None Established
	United Kingdom	None Established
	European Union	Belgium: 1 mg/m ³ TWA

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.

8.2 Exposure Controls:

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

Individual Protection Measures (PPE):



Specific Eye/face Protection: Wear safety glasses with side-shields or tight fitting goggles or other eye protection consistent with industrial safety practice for the process being performed.

Specific Skin Protection: None normally required for handling product. If processing generates dust, rubber or other impervious gloves are recommended.

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
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Metallic, solid pieces	Explosive limits:	LEL: Not applicable UEL: Not applicable
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Odor:	Odorless	Vapor pressure (mmHg):	Not applicable
Odor threshold:	Not applicable	Vapor density:	Not applicable
pH:	Not applicable	Relative density:	Not determined
Melting/freezing point:	2375 - 2500°F (1300 - 1370°C)	Solubility(ies):	Not soluble in water
Initial boiling point and boiling 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 determined
Flammability (solid, gas):	Not combustible in solid form.	Viscosity:	Not applicable
Explosive Properties:	Fine dust may present an explosion hazard.	Oxidizing Properties:	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Not reactive.

10.2 Chemical Stability: Stable under normal conditions.

10.3 Possibility of Hazardous Reactions: If nickel powder comes into contact with bromine pentafluoride at ambient or slightly elevated temperatures, ignition will probably occur. Powdered cobalt and nickel may react violently or explosively with fused ammonium nitrate below 200°C.

10.4 Conditions to Avoid: None known.

10.5 Incompatible materials: Acids, ammonium nitrate, oxidizers, lithium, hydrogen peroxides, chlorine trifluoride, fluorine, lead oxide, nitric acid, sulfuric acids.

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

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Contact with dust or fumes may cause mechanical irritation. Dust particles may cause abrasive injury to the eyes.

Skin: Dust generated from processing may cause abrasive irritation. May cause allergic skin reaction (sensitization).

Ingestion: No adverse effects expected. Ingestion of large amounts of dust may cause gastrointestinal irritation, anemia, headache, fever, nausea, abdominal pain, and liver damage.

Inhalation: Dust generated from processing may cause respiratory irritation and an 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, and fatigue and muscle pain. Symptoms generally resolve in 24-48 hours.

Chronic Health Effects: Prolonged inhalation of nickel dust or fumes may cause perforation of the nasal septum and lung damage. Inhalation of cobalt particles results in disposition in the upper and lower respiratory tract and may lead to an interstitial lung disease generally referred to as hard metal lung disease.

Irritation: No data available. This product is not expected to be irritating.

Corrosivity: No data available. This product is not expected to be corrosive.

Sensitization: Nickel sensitivity was positive in human patch tests. Cobalt: Potential skin sensitizer in mouse local lymphnode assay and sensitizing in guinea pig maximization test.

Carcinogenicity: Nickel compounds are classified by IARC as known human carcinogens (Group 1) and by NTP as known human carcinogens. Metallic nickel is classified by IARC as possibly carcinogenic to humans (Group 2B) and by NTP as reasonably anticipated to be a carcinogen. 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 CLP.

Mutagenicity: Nickel: Nickel alters macromolecular synthesis but no convincing evidence has been provided of its ability to produce gene mutations or structural chromosome aberrations in mammalian cells. 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. This product is not expected to present a risk of genetic damage.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing skin and respiratory disorders may be at increased risk from exposure.

Acute Toxicity Data:

Cobalt: Oral rat LD50- 6174 mg/kg

Chromium: No toxicity data available

Molybdenum: Oral rat LD50->2000 mg/kg, Inhalation rat LC50- >3.92 mg/L/4hr (no mortality), Skin rat LD50->2000 mg/kg

Non-Hazardous Ingredients: No toxicity data available

Manganese: Oral rat LD50- >2000 mg/kg; Inhalation rat LC50 - >5.14 mg/L/4hr

Nickel: Oral rat LD50->9000 mg/kg

Reproductive Toxicity Data: Cobalt: In a 15 gestation study, rats were given 25, 50 and 100 mg/kg of cobalt powder. It was concluded that cobalt administered by gavage up to 100 mg/kg was not embryotoxic or teratogenic. Nickel: Metallic nickel may upset the hormonal balance of the mother and can impair the development of the preimplantation embryo. The metal can cross the fetomaternal barrier and enter the fetus. In addition to an increase in prenatal and neonatal mortality, nickel can produce different types of malformations in the surviving embryos and cause teratogenic effects.

Specific Target Organ Toxicity (STOT):

Single Exposure: Cobalt: Cobalt has been shown to cause dermatitis in humans. Manganese: Inhalation of manganese dust or fumes may cause metal fume fever 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

12.1 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

Nickel: 96 hr LC50 Rainbow trout- 15.3 mg/L

This product is classified as may cause long lasting harmful effects to aquatic life. Releases to the environment should be avoided.

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

12.3 Bio-accumulative Potential: Cobalt and nickel do not bio-accumulate in organic organisms. The potential to bio-accumulate in aquatic organism is low.

12.4 Mobility in Soil: No data available.

12.5 Results of PBT and vPvB Assessment: Not required

12.6 Other Adverse Effects: None known.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	None	Not Regulated	None	None	Not applicable

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): Fine particulates of this product have a Reportable Quantity (RQ) of 14,285 lbs. (based on the RQ for Chromium of 5,000 lbs present at <35%). 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. No reporting of the solid form is required if the mean diameter of the pieces of the solid metal released is greater than 100 micrometers (0.004 inches).

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

Clean Water Act (CWA): This material contains chromium, copper and nickel which are regulated under the Clean Water

Act.

Clean Air Act (CAA): This material contains nickel, cobalt, and chromium which are 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	<35%
Manganese	7439-96-5	0-1%
Nickel	7440-02-0	0-0.1%

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 (as Cobalt metal powder)	7440-48-4	<70%
Nickel	7440-02-0	0-0.1%

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: 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.

Philippine Inventory of Chemicals and 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.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 2* Flammability – 2 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:

Carc. Cat 3 Carcinogen Category 3

T Toxic

Xn Harmful

R40 Limited evidence of a carcinogenic effect.

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

R43 May cause sensitization by skin contact.

R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Aquatic Chronic 3 Aquatic Chronic Toxicity Category 3

Aquatic Chronic 4 Aquatic Chronic Toxicity Category 4

Carc 2 Carcinogen Category 2

Resp. Sens. 1 Respiratory Sensitization Category 1

Skin Sens. 1 Skin Sensitization Category 1

STOT RE 1 Specific Target Organ Toxicity Repeated Exposure Category 1

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H351 Suspected of causing cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

H412 Harmful to aquatic life with long lasting effects.

H413 May cause long lasting harmful effects to aquatic life.

Supersedes: 24 May 2013

Revision Summary: Converted SDS to Reach SDS. Updated 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.