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Material safety data sheet for BionMet T2 / T4 /T5

SDS004ENa Rev.: 01.07.2022	In conformity with: Regulation (EC) No 1907/2006

1. COMMERCIAL PRODUCT NAME AND SUPPLIER

1.1 Commercial product name	BionMet T2 / T4 / T5
1.2 Application / use	Production of dental restorations
1.3 Uses advised against	No additional information available
1.4 Description	Metal disc
1.5 Manufacturer	Bionah srl, Via J.G. Mahl 40, I – 39031 Brunico
1.6 Supplier	Bionah srl, Via J.G. Mahl 40, I – 39031 Brunico
1.7 Emergency number	+39 0474 370 350 (Mon. – Fri. 8 am – 6 pm)

2. HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture	The mixture is not classified as dangerous within the meaning of Regulation (EC) No. 1272/2008 The product falls within the scope of EEC Directive 93/42 for medical devices.
2.2 Label elements	Not dangerous
2.3 Other hazards	Titanium dust is combustible.
2.4 Additional information	Avoid grinding dust (see 8.3.1).

3. COMPOSITION

3.1 Chemical Characterization	BionMet T2 and T4 contains: titanium (CAS Nr. 7440-32-6) T5 (Titanium 6AL4V) contains: titanium (CAS Nr. 7440-32-6), aluminum (CAS Nr.7429-90-5), vanadium (CAS Nr. 7740-62-2).
3.2 Hazardous ingredients	Aluminum (CAS 7429-90-5): • Flam. Sol 1- H228 • Water-react 2 - H261
3.3 Additional information	None

4. FIRST AID MEASURES

4.1 Eye contact	Open eyes as wide as possible and rinse with large quantities of running water. If complaints persist, consult a physician.
4.2 Skin contact	Wash thoroughly with warm water. Take off contaminated clothing and wash before reuse. If complaints persist, consult a physician.
4.3 Ingestion	Do not induce vomiting. Rinse mouth with water. If troubles persist, contact a physician.
4.4 Inhalation	Provide sufficient ventilation. Leave the emission area and provide fresh air supply. Supply oxygen when inhaling gases from thermal decomposition. If troubles persist, contact a physician.
4.5 Most important symptoms and effects	None known.
4.6 Additional information	None

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5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing device	Special powder for metal fires, sand.
5.2 Unsuitable extinguishing device	Water.
5.3 Additional information	Dust may form explosive mixtures with air. In case of fire, dangerous smoke gases are produced: Carbon oxides and metal oxides. A self-contained breathing apparatus and full protective clothing should be worn. The disposal of burnt material and contaminated extinguishing water should be carried out in accordance with local regulations.

6. ACCIDENTAL RELEASE MEASURES

6.1 Individual protection	Avoid dust formation. Do not breathe dust. Keep away from sources of ignition. Ventilate room sufficiently. Use personal protective equipment.
6.2 Environmental protection	Damp down dust with water spray. Collect contaminated water separately. Do not discharge into soils, sewerage systems, surface water and groundwater.
6.3 Cleansing	Clean up mechanically.
6.4 Additional information	Safe handling: see section 7. Personal protective equipment: see section 8. Disposal: see section 13

7. HANDLING AND STORAGE

7.1 Handling	Only adequately trained personnel should handle this product. Keep out of reach of children. Avoid dust formation. Ensure adequate ventilation.
7.2 Industrial hygiene	Usual hygienic measures are necessary. When using, do not eat or drink or smoke. Wash hands with soap before and after breaks and at the end of work.
7.3 Storage	Store in a dry place and protected from heat sources. Do not expose to heavy shocks or vibrations. Blocks must not come into contact with liquids. Protect the products from dirt. Avoid any exposure to humidity. Avoid the formation and deposition of dust.
7.4 Information about storage in one common storage facility	Not required.
7.5 Fire and Explosion protection	Dust may form explosive mixtures with air. Avoid static charges. Keep away from sources of ignition.
7.6 Indications for safe handling	Provide adequate local ventilation or suction unit, especially in case of dust exposure.
7.7 Additional information	None.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Technical equipment	See point 7
8.2 Control of threshold limits	Aluminum CAS-Nr. 7429-90-5 | Inhalative (longtime) | 3,72 mg/m^3
8.3 Personal protective equipment	
8.3.1 Respiratory protection	Respiratory protection if dust is generated. For intensive or prolonged exposure, use self-contained breathing apparatus.
8.3.2 Hand protection	Protective gloves
8.3.3 Eye protection	Safety goggles.

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8.3.4 General measures	Do not breathe dust.
8.4 Directives of exposure / threshold	/
8.5 Additional information	None

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Form	Solid
9.2 Colour	Silver-grey
9.3 Odour	Odourless
9.4 Changes in physical state	
9.4.1 Freezing Point	Not applicable
9.4.2 Melting point	1160 °C
9.4.3 Boiling point	3290 °C
9.5 Density	~ 4.5 g/cm³
9.6 Solubility	Insoluble in water. Organic solvents 0,0%
9.7 pH-Value	Not applicable.
9.8 Flash point	Not specified.
9.9 Ignition point	Not specified.
9.10 Explosion limits	Not specified.
9.11 Solids content / viscosity	100% solid
9.12 Additional information	None

10. STABILITY AND REACTIVITY

10.1 Reactivity	Dust is combustible.
10.2 Chemical stability	Stable when handled and stored according to instructions.
10.3 Hazardous reactions	No dangerous reactions known.
10.4 Conditions to avoid	Dust producing.
10.5 Incompatible materials	Acids.
10.6 Hazardous decomposition products	No hazardous decomposition products known.
10.7 Additional information	None

11. TOXICOLOGICAL INFORMATION

11.1 Acute Toxicity	<table><tr><th>Chemical description</th><th>CAS No.</th><th>LD50 oral</th></tr><tr><td>Titanium</td><td>7440-32-6</td><td>5000 mg/kg (rat)</td></tr><tr><td>Aluminum</td><td>7429-90-5</td><td>15900 mg/kg (rat)</td></tr><tr><td>Vanadium</td><td>7440-62-2</td><td>2000 mg/kg (rat)</td></tr></table>
11.2 Skin	None.
11.3 Eyes	None.
11.4 Sensitization	Sensitisation possible through inhalation and skin contact.
11.5 Additional information	None.

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12. ECOLOGICAL INFORMATION

12.1 Toxicity

Avoid discharge into drains or surface water.

Composition	Aquat. Toxicity	Dose	Time
Titanium CAS-Nr. 7440-32-6	Fish	LC50 10 mg/L	48 h
	Invertebrates	EC50 1 g/L	48 h
	Algae	EC50 16 – 10000 mg/L	72 h
Aluminum CAS-Nr. 7429-90-5	Fish	LC50 10 – 19,3 mg/L	72 h
	Fish	NOEL 88 – 350 µg/L	60 d
	Invertebrates	EC50 1,5 – 2,56 mg/L	48 h
	Invertebrates	NOEL 232,6 – 453,8 µg/L	42 d
	Algae	EC50 16,9 – 4980 µg/L	72 h
Vanadium CAS-Nr. 7440-62-2	Fish	LC50 9,005 – 44 mg/L	24 h
	Fish	NOEL 480 µg/L	70 d
	Invertebrates	LC50 1,52 – 13,3 mg/L	48 h
	Invertebrates	560 – 1000 µg/L	3 months
	Algae	EC50 989,4 – 2907 µg/L	72 h

12.2 Persistence and degradability	Not specified.
12.3 Bioaccumulative potential	Not specified.
12.4 Mobility in soil	Not specified.
12.5 Results of PBT and vPvB assessment	Not specified.
12.6 Other harmful effects	The product has not been tested as such.

13. DISPOSAL CONSIDERATIONS

13.1 Product	Dispose of according to local regulations
13.1.1 EC-Waste key	The classification of waste has to comply with the European Waste Catalogue (EWC).
13.2 Container	Dispose contaminated and non-contaminated containers of according to local regulations
13.3 Additional information	None

14. TRANSPORT INFORMATION

14.1 Transport at land (ADR/RIG/GGVSE)	
14.1.1 Classification	No dangerous good according to these transport regulations.
14.1.2 Hazard label	No dangerous good according to these transport regulations.
14.1.3 UN – NO.	Not specified.
14.1.4 Kemler number	No dangerous good according to these transport regulations.
14.1.5 Packing Group	No dangerous good according to these transport regulations.
14.1.6 Classification code	No dangerous good according to these transport regulations.
14.1.7 Warning sign	No dangerous good according to these transport regulations.
14.1.8 Packing Code	No dangerous good according to these transport regulations.

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14.1.9 Volume or Mass	No dangerous good according to these transport regulations.
14.1.10 Correct technical Term	No dangerous good according to these transport regulations.
14.1.11 Limited quantity	No dangerous good according to these transport regulations.
14.2 Transport at sea (IMDG-Code/GGVSEE)	
14.2.1 Classification	No dangerous good according to these transport regulations.
14.2.2 UN – NO.	Not specified.
14.2.3 Packing Group	No dangerous good according to these transport regulations.
14.2.4 EMS	No dangerous good according to these transport regulations.
14.2.5 Marine pollutant	No dangerous good according to these transport regulations.
14.2.6 Additional danger	No dangerous good according to these transport regulations.
14.3 Air Transport (ICAO-Code/GGVSEE)	
14.3.1 Classification	No dangerous good according to these transport regulations.
14.3.2 UN – NO.	Not specified.
14.3.3 Packing Group	No dangerous good according to these transport regulations.
14.3.4 Subsidiary risk (subsidiary risk)	No dangerous good according to these transport regulations.
14.4 Transport in bulk	Not applicable.
14.5 Additional information	The product is not classified for any type of transport.

15. REGULATORY INFORMATION

15.1 Regulations according to EC regulations	The product falls within the scope of EEC Directive 93/42 for medical devices.
15.2 National regulations	The user is responsible for compliance with national regulations.
15.3 Technical guidelines air	Not specified.
15.4 Water hazard class	Water hazard class 1: slightly hazardous to water.
15.5 Chemical safety assessment	A Chemical Safety Assessment has not been carried out.

16. ADDITIONAL INFORMATION

16.1 General information	The above mentioned data correspond to our present state of knowledge and experience. The safety data sheet serves as description of the products in regard to necessary safety measures. The indications do not have the meaning of guarantees on properties. The user of our products is responsible for compliance with applicable laws and regulations.
16.2 Relevant phrases	Flam. Sol 1- Flammable Solids, category 1 Water-react 2 – Water reactive substances, category 2 H228 Flammable solid H261 In contact with water releases flammable gas
16.3 Indications of Changes	Acute toxicity values were added in chapter 11, some other minor updates were done.
16.4 Abbreviations and acronyms	ADR European Agreement concerning the International Carriage of Dangerous Goods by Road (Accord européen relatif au transport international des marchandises Dangereuses par Route) ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises Dangereuses par voie de Navigation intérieure)

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	RID: Regulation on the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport International ferroviaire de marchandises Dangereuses) ICAO-TI: International Civil Aviation Organisation – Technical Instructions for the Safe Transportation of Dangerous Goods by Air IATA-DGR: International Air Transport Association – Dangerous Goods Regulations AGW: Occupational Exposure Limit PBT/vPvB: Persistent, Bioaccumulative and Toxic/very Persistent and very Bioaccumulative BGW: Biological Limit Value CAS: Chemical Abstracts Service CLP: Classification, Labelling and Packaging EWC: European Waste Catalogue GHS: Globally Harmonized System of Classification and Labelling of Chemicals IATA: International Air Transport Association ICAO: International Civil Aviation Organization IMDG: International Maritime Code for Dangerous Goods IOELV: Indicative Occupational Exposure Limit Value LD50: Lethal Dose 50