

Material safety data sheet for BionZ

SDS002ENa Rev.: 01.07.2022	In conformity with: Regulation (EC) No 1907/2006
1. COMMERCIAL PRODUCT NAME AND SUPPLIER	
1.1 Commercial product name	BionZ
1.2 Application / use	Production of dental restorations
1.3 Uses advised against	No additional information available
1.4 Description	Porous zirconia block
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	When used as indicated: none.
2.4 Additional information	Avoid grinding dust (see 8.3.1).
3. COMPOSITION	
3.1 Chemical Characterization	Ceramic corpus containing: Aluminium oxide (CAS Number 1344-28-1), Zirconium oxide (CAS Number 1314-23-4), Erbium oxide (CAS Number 12061-16-4), Yttrium oxide (CAS Number 1314-36-9) and other oxides in not health relevant concentrations (< 1%)
3.2 Hazardous ingredients	None
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
5. FIRE FIGHTING MEASURES	

5.1 Suitable extinguishing device	Carbon dioxide, dry chemicals or water fog. Suitable extinguishing media depend on environment.
5.2 Unsuitable extinguishing device	Water with full jet.
5.3 Additional information	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 zirconia discs 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	No special measures required.
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	Components with necessary airborne concentration control: Zirconium oxide (CAS: 1314-23-4) MAK: 5E mg/m ³ ; 25; (DFG)
8.3 Personal protective equipment	
8.3.1 Respiratory protection	Respiratory protection if dust is generated.
8.3.2 Hand protection	Protective gloves
8.3.3 Eye protection	Safety goggles.
8.3.4 General measures	None
8.4 Directives of exposure / threshold	/

8.5 Additional information	None												
9. PHYSICAL AND CHEMICAL PROPERTIES													
9.1 Form	Solid												
9.2 Colour	White or tooth colour												
9.3 Odour	Odourless												
9.4 Changes in physical state													
9.4.1 Freezing Point	Not applicable												
9.4.2 Melting point	Not determined												
9.4.3 Boiling point	Not determined												
9.5 Density	3,0 g/cm ³												
9.6 Solubility	Insoluble in water. Organic solvents 0,0%												
9.7 pH-Value	Not applicable.												
9.8 Flash point	Not applicable.												
9.9 Ignition point	Not applicable.												
9.10 Explosion limits	Not applicable.												
9.11 Solids content / viscosity	100% solid												
9.12 Additional information	None												
10. STABILITY AND REACTIVITY													
10.1 Reactivity	None if properly used.												
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	Not specified.												
10.5 Incompatible materials	None known.												
10.6 Hazardous decomposition products	No hazardous decomposition products known.												
10.7 Additional information	None												
11. TOXICOLOGICAL INFORMATION													
11.1 Acute Toxicity	<table border="1"> <thead> <tr> <th>Chemical description</th> <th>LD50 oral</th> <th>LC50 inhalation</th> </tr> </thead> <tbody> <tr> <td>Zirconia</td> <td>> 5000 mg/kg bw (rat)</td> <td>> 4.3 mg/l (rat) 4h</td> </tr> <tr> <td>Yttrium oxide</td> <td>> 5000 mg/kg bw (rat)</td> <td>> 5.09 mg/l (rat) 4h</td> </tr> <tr> <td>Aluminium oxide</td> <td>> 10000 mg/kg bw (rat)</td> <td>7.6 mg/l (rat) 1h > 2.3 mg/l (rat) 4h</td> </tr> </tbody> </table>	Chemical description	LD50 oral	LC50 inhalation	Zirconia	> 5000 mg/kg bw (rat)	> 4.3 mg/l (rat) 4h	Yttrium oxide	> 5000 mg/kg bw (rat)	> 5.09 mg/l (rat) 4h	Aluminium oxide	> 10000 mg/kg bw (rat)	7.6 mg/l (rat) 1h > 2.3 mg/l (rat) 4h
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11.2 Skin	Low irritant effect.												
11.3 Eyes	Dust can lead to mechanical irritation.												
11.4 Sensitization	No sensitizing effects known.												
11.5 Additional information	This product does not require classification according to the last-released EEC criteria. According to our knowledge and the information												

	at our disposal, no damage to health or environment will occur, if the product is properly handled and used for what it has been designed for.
12. ECOLOGICAL INFORMATION	
12.1 Toxicity	Avoid discharge into drains or surface water. Toxicology for fish: Zirconia LC50: > 100 mg/L 96h static (<i>Brachydanio rerio</i>) Yttrium oxide LC50: > 100 mg/L 96h static; (<i>Brachydanio rerio</i>)
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.
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	Product is not classified for any mode of transportation.
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	Not specified.
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	None
16.3 Indications of Changes	Relevant toxicological data added in chapter 11 and other not risk relevant minor changes were made.
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) 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
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