EU Safety Data Sheet

BioUniversal E



Date of issue / Reference 22.09.2005 hot

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Company Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan Principality of Liechtenstein

Commercial product name and supplier

1.1 Commercial product name / BioUniversal E

Designation

1.2 Application / Use Universal alloy

1.3 Producer Ivoclar Vivadent, Inc.

175 Pineview Drive, Amherst NY 14228, USA

1.4 Supplier

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1.5 TOX emergency number Emergency-Call USA: (716) 691-0010

Emergency-Call LI: +423 / 235 35 35 or 373 40 40

2 Composition

2.1 Chemical characterization Dental alloy made of:

Ag 52.2 % (7440-22-4), Pd 40.0 % (7440-05-3), In 1.4 % (7440-74-

6), Sn 5.5 % (7440-31-5), < 1.0 % Re, Ru, Zn

2.2 Hazardous components

2.3 Further information None.

3 Hazards identification Avoid breathing of grinding dust and vapours.

Melted material may cause burns.

4 First aid measures

4.1 Eye contact Flush eyes with plenty of water (10-15 min.). Call a physician if

irritation persists.

4.2 Skin contact Melted material presents a special hazard of deep thermal burns. If

burn occurs, treat as any thermal burn.

4.3 Ingestion Call a physician immediately.

4.4 Inhalation Remove to fresh air.

4.5 Further information None.

5 Fire-fighting measures

5.1 Suitable extinguishing media Not required, not flammable.

5.2 Extinguishing media to avoid Do not use direct water stream.

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5.3	Further information	None.					
6	Accidental release measures	Clean up mechanically. Clean and reuse					
7	Handling and storage						
7.1	Handling	Only adequately trained personnel should handle this product. Keep out of reach of children.					
7.2	Industrial hygiene	Usual hygienic measures for dental practice.					
7.3	Storage	No specific requirements.					
7.4	Place of storage						
7.5	Fire- and explosion-protection	No specific requirements.					
8	Exposure controls / Personal protection						
8.1	Technical measures	Provide adequate local ventilation. Control airborne concentration below the exposure guideline.					
8.2	Control of threshold limits	Dust and vap	oors: MAK 0.1 mg/m³				
8.3	Personal protective equipment						
8.3.1	Respiratory protection	In dusty atmospheres, use an approved dust respirator P2. If metal fumes are present, use an approved high-efficiency particulate respirator (P3).					
8.3.2	Hand protection	Gloves.					
8.3.3	Eye protection	Safety goggle	es.				
8.3.4	Other	Use only with	h adequate ventilation.				
9	Physical and chemical properties						
9.1	Appearance	solid					
9.2	Colour	white					
9.3	Odour	odourless					
9.4	Change of physical state			Test method:			
	Melting range	1100-1150 °C					
		1000 1000 00					

1200-1260 °C

not applicable

not applicable

10.7 g/cm³

Casting temperature

9.5 Density

9.7 Viscosity

9.6 Vapour pressure

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9.8	Solubility					
	Solubility in	non soluble				
9.9	пН	not applicable				
9.10 Flash point		*FF				
		not applicable				
9.11 Ignition temperature9.12 Explosion limits		not applicable				
		Lower: Upper: not applicable				
9.13	Further information	Complies with ISO 8891, ISO 9693				
10	Stability and reactivity					
10.1	Thermal decomposition	None, if used in accordance to instructions.				
10.2	Hazardous decomposition products	None, if used in accordance to instructions.				
10.3	Hazardous reactions	None, if used in accordance to instructions.				
10.4	Further information	None.				
11	Toxicological information					
11.1	Acute toxicity	Alloy: non-cytotoxic, non-mutagenic, non-irritant, non-sensitizer				
11.2	Subacute / Chronic toxicity	Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.				
11.3	Further information	None.				
12	Ecological information	No ecological problems to be anticipated if properly handled and used. nearly insoluble				

Transport information

Disposal considerations

13.1 EU waste key

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Recycling

17 04 07

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UN Number Kemler Number **Packing Group** Proper shipping name 14.2 Transport at sea **ADNR IMDG** UN Number **EMS MFAG** Packing Group Proper shipping name ICAO / IATA-DGR 14.3 Air transport UN Number Proper shipping name Subsidiary Risk Labels Packing Group Passenger airplane **Packing Instructions** max. Cargo Airplane **Packing Instructions** max. 14.4 Further information Product is not classified for any mode of transportation. 15 The product is a medical device according to the EC-directive **Regulatory information** 93/42. 15.1 UN number National regulations 15.2 15.3 EU number 15.4 Hazard symbols 15.5 Hazard designation 15.6 Risk phrases 15.7 Safety phrases 15.8 MAK value $0.1 \text{ ml/m}^3 \text{ (ppm)}$ 15.9 BVD classification (CH) 15.10 VbF (D) 15.11 Further information None.

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16 Other information

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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.

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