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Safety data sheet according to 1907/2006/EC, Article 31

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Version number 5

Revision: 17.03.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier • Trade name: IPS e.max ZirCAD (Block/Disc) · CAS Number: 66402-68-4 • EC number: 266-340-9 · 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available. · Application of the substance / the mixture Manufacture of dental prothesis Yttrium-stabilized zirconium oxide block for the CAD/CAM technology Yttrium-stabilized zirconium oxide disc for the CAD/CAM technology · 1.3 Details of the supplier of the safety data sheet · Manufacturer/Supplier: Ivoclar Vivadent AG Bendererstrasse 2 FL-9494 Schaan PRINCIPALITY OF LIECHTENSTEIN Tel: +423 235 35 35 Fax: +423 235 33 60 • Further information obtainable from: Regulatory Affairs sds@ivoclarvivadent.com · 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein) **SECTION 2: Hazards identification** · 2.1 Classification of the substance or mixture · Classification according to Regulation (EC) No 1272/2008 The substance is not classified according to the CLP regulation. · 2.2 Label elements · Labelling according to Regulation (EC) No 1272/2008 Void · Hazard pictograms Void · Signal word Void · Hazard statements Void · 2.3 Other hazards Avoid breathing sanding dust /swarf. · Results of PBT and vPvB assessment · **PBT:** Not applicable. · vPvB: Not applicable. **SECTION 3: Composition/information on ingredients** · 3.1 Chemical characterisation: Substances · CAS No. Description 66402-68-4 ceramic materials

- · Identification number(s) ---
- · EC number: 266-340-9

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SECTION 4: First aid measures

• 4.1 Description of first aid measures

· General information: No special measures required.

• After inhalation: Grinding dust: Supply fresh air; consult doctor in case of complaints.

• After skin contact: Generally the product does not irritate the skin.

• After eye contact:

Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

Mechanical effects only.

• After swallowing:

Grinding dust: Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.

• 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

• 5.1 Extinguishing media

• Suitable extinguishing agents: The product is not flammable.

- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures Not required.

- · 6.2 Environmental precautions: No special measures required.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Only adequately trained personnel should handle this product. For use in dentistry only.

• Information about fire - and explosion protection: No special measures required.

· 7.2 Conditions for safe storage, including any incompatibilities

• Storage:

• *Requirements to be met by storerooms and receptacles:* Store only in the original receptacle.

- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: None.
- 7.3 Specific end use(s) No further relevant information available.

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Additional information about desig	n of technical facilities: No further data; see item 7.
8.1 Control parameters	
	equire monitoring at the workplace: Not required.
	ilid during the making were used as basis.
·	
8.2 Exposure controls	
Personal protective equipment: General protective and hygienic me	
Usual hygienic measures for dental	
Keep away from foodstuffs, beverage	
Wash hands before breaks and at the	
Respiratory protection:	
Mechanical processing:	
Use respiratory protective device ag	ainst the effects of dust.
Recommended filter device for shor	
Protection of hands:	
	worn during mechanical and thermal processing.
After use of gloves apply skin-cleant	
Material of gloves	
Mechanical processing:	
Leather gloves	
Strong material gloves	
Penetration time of glove material	
The exact break through time has to	be found out by the manufacturer of the protective gloves and has to be
The exact break through time has to observed.	be found out by the manufacturer of the protective gloves and has to be
The exact break through time has to observed. Eye protection:	
The exact break through time has to observed. Eye protection:	be found out by the manufacturer of the protective gloves and has to be nechanical processing (grinding, sawing /cutting, drilling, milling).
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The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch	nechanical processing (grinding, sawing /cutting, drilling, milling). D <mark>emical properties</mark>
The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch 9.1 Information on basic physical a	nechanical processing (grinding, sawing /cutting, drilling, milling). D <mark>emical properties</mark>
The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch 9.1 Information on basic physical a General Information	nechanical processing (grinding, sawing /cutting, drilling, milling). D <mark>emical properties</mark>
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The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch 9.1 Information on basic physical a General Information Appearance: Form: Colour: Odour:	nechanical processing (grinding, sawing /cutting, drilling, milling). nemical properties and chemical properties Solid According to product specification Odourless
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The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch 9.1 Information on basic physical a General Information Appearance: Form: Colour: Odour: Odour: pH-value:	nechanical processing (grinding, sawing /cutting, drilling, milling). nemical properties and chemical properties Solid According to product specification Odourless
The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch 9.1 Information on basic physical a General Information Appearance: Form: Colour: Odour: Odour: Dour threshold: pH-value: Change in condition	nechanical processing (grinding, sawing /cutting, drilling, milling). temical properties und chemical properties Solid According to product specification Odourless Not determined. Not applicable.
The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch 9.1 Information on basic physical a General Information Appearance: Form: Colour: Odour: Odour: Odour: pH-value: Change in condition Melting point/Melting range:	nechanical processing (grinding, sawing /cutting, drilling, milling).
The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch 9.1 Information on basic physical a General Information Appearance: Form: Colour: Odour: Odour: Dour threshold: pH-value: Change in condition	nechanical processing (grinding, sawing /cutting, drilling, milling). temical properties und chemical properties Solid According to product specification Odourless Not determined. Not applicable.
The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch 9.1 Information on basic physical a General Information Appearance: Form: Colour: Odour: Odour: Odour: pH-value: Change in condition Melting point/Melting range: Boiling point/Boiling range:	nechanical processing (grinding, sawing /cutting, drilling, milling).
The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch 9.1 Information on basic physical a General Information Appearance: Form: Colour: Odour: Odour: Odour: Dur threshold: pH-value: Change in condition Melting point/Melting range: Boiling point/Boiling range: Flash point:	nechanical processing (grinding, sawing /cutting, drilling, milling). emical properties and chemical properties Solid According to product specification Odourless Not determined. Not applicable. Undetermined. Undetermined.
The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch 9.1 Information on basic physical a General Information Appearance: Form: Colour: Odour: Odour: Odour: Odour: PH-value: Change in condition Melting point/Melting range: Boiling point/Boiling range: Flash point: Flammability (solid, gaseous):	nechanical processing (grinding, sawing /cutting, drilling, milling).
The exact break through time has to observed. Eye protection: Always wear safety goggles during r SECTION 9: Physical and ch 9.1 Information on basic physical a General Information Appearance: Form: Colour: Odour: Odour: PH-value: Change in condition Melting point/Melting range:	nechanical processing (grinding, sawing /cutting, drilling, milling).
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Upper:	Not determined.	
· Vapour pressure:	Not applicable.	
· Density:	Not determined.	
· Relative density	Not determined.	
· Vapour density	Not applicable.	
· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
water:	Insoluble.	
· Partition coefficient (n-octano	l/water): Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
• 9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability Stable under normal handling and storage conditions.

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

- Acute toxicity Based on available data, the classification criteria are not met.
- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Additional toxicological information: No further relevant information available.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· 12.1 Toxicity

- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- General notes: Generally not hazardous for water

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· 12.5 Results of PBT and vPvB assessment

• *PBT:* Not applicable.

• **vPvB:** Not applicable.

• 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

· Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information	on
· 14.1 UN-Number · ADR,RID,ADN, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR,RID,ADN, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR,RID,ADN, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR,RID,ADN, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Anne: Marpol and the IBC Code	x II of Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN ''Model Regulation'':	Void

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· National regulations:

· Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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· Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

• * Data compared to the previous version altered.