

*** SECTION 1: Identification of the substance/mixture and of the company/undertaking**

· 1.1 Product identifier

· Trade name: *IPS e.max ZirCAD*

· 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

· 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

· Description: Yttrium-stabilized zirconium oxide block

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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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SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
 - **General protective and hygienic measures:** Usual hygienic measures for dental practice.
 - **Respiratory protection:** Use respiratory protective device against the effects of dust.
 - **Protection of hands:** Not required.
 - **Material of gloves** -
 - **Penetration time of glove material** -
 - **Eye protection:**
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties
· General Information
· Appearance:
Form: Solid
Colour: According to product specification
Odour: Odourless
Odour threshold: Not determined.
· pH-value: Not applicable.
· Change in condition
Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.
· Flash point: Not applicable.
· Flammability (solid, gaseous): Product is not flammable.
· Self-igniting: Not determined.
· Danger of explosion: Product does not present an explosion hazard.
· Explosion limits:
Lower: Not determined.
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-octanol/water): Not determined.
· Viscosity:
Dynamic: Not applicable.

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Kinematic:	<i>Not applicable.</i>
9.2 Other information	<i>No further relevant information available.</i>

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.*

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SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** *No irritant effect.*
- **on the eye:** *No irritating effect.*
- **Sensitisation:** *No sensitising effects known.*
- **Additional toxicological information:** *No further relevant information available.*

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*
- **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.*

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SECTION 14: Transport information	
· 14.1 UN-Number	
· ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name	
· ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR, 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 Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	-

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.	
· 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)	
· * Data compared to the previous version altered.	

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