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

Printing date 08.11.2012

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Version number 4

Revision: 08.11.2012

1 Identification of the substance/mixture and of the company/undertaking · Product identifier · Trade name: IPS e.max Press · CAS Number: 66402-68-4 · EC number: 266-340-9 · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available. · Application of the substance / the preparation Manufacture of dental prothesis Lithium disilicate glass-ceramic ingot for the PRESS technology · 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** msds@ivoclarvivadent.com · Emergency telephone number: +423/2353313 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein) **2** Hazards identification · Classification of the substance or mixture · Classification according to Regulation (EC) No 1272/2008

The substance is not classified according to the CLP regulation.

· Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.

· Information concerning particular hazards for human and environment: Not applicable.

· Label elements

- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards Avoid breathing sanding dust /swarf.
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description
- 66402-68-4 ceramic materials
- Identification number(s) ---
- EC number: 266-340-9

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Trade name: IPS e.max Press

· Description: Lithium disilicate glass-ceramic ingot

4 First aid measures

· 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.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Firefighting measures

- · Extinguishing media
- Suitable extinguishing agents: The product is not flammable.
- Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up: Pick up mechanically.
- · 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.

7 Handling and storage

· Handling:

- · 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.
- · 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.

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• Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

• Additional information about design of technical facilities: No further data; see item 7.

- · Ingredients with limit values that require monitoring at the workplace: Not required.
- Additional information: The lists valid during the making were used as basis.
- · 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).

9 Physical and chemical properties

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.	

[·] Control parameters

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· Partition coefficient (n-octanol/water): Not determined.

Viscosity:

Dynamic:

Kinematic: • Other information Not applicable. Not applicable. No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.

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

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · Primary irritant effect:
- on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The substance is not subject to classification according to the latest version of the EU lists.

12 Ecological information

- · Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Generally not hazardous for water
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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

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· Uncleaned packaging:

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

UN-Number ADR, ADN, IMDG, IATA	Void
UN proper shipping name ADR, ADN, IMDG, IATA	Void
Transport hazard class(es)	
ADR, ADN, IMDG, IATA Class	Void
Packing group ADR, IMDG, IATA	Void
Environmental hazards: Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex II og MARPOL73/78 and the IBC Code	r Not applicable.
· UN ''Model Regulation'':	-

15 Regulatory information

· 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 EC-directive 93/42/EEC.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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 Organization
- 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 Harmonized 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)