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

- **1.1 Product identifier**
  - **Trade name:** IPS e.max ZirPress
  - **CAS Number:** 66402-68-4
  - **EC number:** 266-340-9

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
  - **Application of the substance / the mixture**
    - Manufacture of dental prothesis
    - Fluorapatite glass-ceramic ingot for the PRESS-ON technology

- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Ivoclar Vivadent AG
    - Bendererstrasse 2
    - 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, 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:** Fluorapatite glass-ceramic ingot

(Contd. on page 2)
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.
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 and dental laboratories.
    - Respiratory protection: Use respiratory protective device against the effects of dust.
    - Protection of hands: Not required.
    - Material of gloves: Not required.
    - Penetration time of glove material: Not required.
    - 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/freezing point: Undetermined.
    - Initial boiling point and boiling range: Undetermined.
  - Flash point: Not applicable.
  - Flammability (solid, gas): Product is not flammable.
  - Auto-ignition temperature: Not determined.
  - Explosive properties: 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.
SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability Stable under normal handling and storage conditions.
- 10.3 Possibility of hazardous reactions No decomposition if used according to specifications.
- 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.
  - Persistence and degradability No further relevant information available.
  - Bioaccumulative potential No further relevant information available.
  - Mobility in soil No further relevant information available.
  - Additional ecological information:
    - General notes: Not hazardous for water.
    - 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.
### SECTION 14: Transport information

<table>
<thead>
<tr>
<th>14.1 UN-Number</th>
<th>Void</th>
</tr>
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<tbody>
<tr>
<td>14.2 UN proper shipping name</td>
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</tr>
<tr>
<td>14.3 Transport hazard class(es)</td>
<td>Void</td>
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<tr>
<td>14.4 Packing group</td>
<td>Void</td>
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<tr>
<td>14.5 Environmental hazards:</td>
<td>No</td>
</tr>
<tr>
<td>14.6 Special precautions for user</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Transport/Additional information:</td>
<td>Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).</td>
</tr>
<tr>
<td>UN &quot;Model Regulation&quot;:</td>
<td>Void</td>
</tr>
</tbody>
</table>

### 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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.