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
- 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

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
- 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.
  - vPoB: 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
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.
      Keep away from foodstuffs, beverages and feed.
      Wash hands before breaks and at the end of work.
    - **Respiratory protection:**
      Mechanical processing:
      Use respiratory protective device against the effects of dust.
    - **Recommended filter device for short term use:** Filter P1
    - **Protection of hands:**
      Protective gloves should always be worn during mechanical and thermal processing.
      After use of gloves apply skin-cleaning agents and skin cosmetics.
    - **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 observed.
    - **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. (Contd. on page 4)
43.0.9

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
<td>Upper:</td>
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<tr>
<td>Vapour pressure:</td>
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<tr>
<td>Density:</td>
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<td>Relative density:</td>
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<td>Vapour density:</td>
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<tr>
<td>Evaporation rate:</td>
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<td>Solubility in / Miscibility with water:</td>
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<td>Partition coefficient (n-octanol/water):</td>
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<td>Viscosity:</td>
<td>Dynamic: Not applicable.</td>
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<td></td>
<td>Kinematic: Not applicable.</td>
</tr>
<tr>
<td>9.2 Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

**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 Thermal decomposition / conditions to be avoided: 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.
- 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.

SECTION 14: Transport information

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 Annex II of Marpol 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": 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.
Trade name: IPS e.max ZirCAD (Block/Disc)

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.