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

- 1.1 Product identifier
  - Trade name: IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal, Transpa, Essence, Gingiva, Margin, Intensive Margin, Add-On, Special Enamel, Light Reflector, Light Absorber, Power Dentin
  - 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 prosthesis

- 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
  - Dust generation
    Particular danger of slipping on leaked/spilled product.
  - 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
43.0.9

· 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:
    Supply fresh air; consult doctor in case of complaints.
    In case of unconsciousness place patient stably in side position for transportation.
  · After skin contact:
    Rinse with water.
    Generally the product does not irritate the skin.
  · After eye contact:
    Rinse opened eye for several minutes under running water.
    If symptoms persist, consult a doctor.
    Mechanical effects only.
  · After swallowing:
    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
  Particular danger of slipping on leaked/spilled product.

· 6.2 Environmental precautions
  No special measures required.

· 6.3 Methods and material for containment and cleaning up:
  Pick up mechanically.
  Ensure adequate ventilation.

· 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.
Prevent formation of dust.
 Ensure good ventilation/exhaustion at the workplace.

- **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:**
      - Keep container tightly sealed.
      - Store in dry conditions.

- **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:**
      - Vacuum clean contaminated clothing. Do not blow or brush off contamination.
      - Keep away from foodstuffs, beverages and feed.
      - Wash hands before breaks and at the end of work.
      - Usual hygienic measures for dental practice and dental laboratories.
    - **Respiratory protection:** Not required.
    - **Recommended filter device for short term use:** Filter P2
    - **Protection of hands:**
      - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
      - Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
      - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
    - **Material of gloves**
      - The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
    - **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:** Not required.

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:**
    - **Form:** Powder
**Trade name:** IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal, Transpa, Essence, Gingiva, Margin, Intensive Margin, Add-On, Special Enamel, Light Reflector, Light Absorber, Power Dentin

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>According to product specification</td>
</tr>
<tr>
<td>Odour</td>
<td>Odourless</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not determined</td>
</tr>
<tr>
<td>pH-value</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Change in condition</td>
<td></td>
</tr>
<tr>
<td>Melting point/Melting range</td>
<td>Undetermined</td>
</tr>
<tr>
<td>Boiling point/Boiling range</td>
<td>Undetermined</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gaseous)</td>
<td>Product is not flammable</td>
</tr>
<tr>
<td>Self-igniting</td>
<td>Not determined</td>
</tr>
<tr>
<td>Danger of explosion</td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td>Explosion limits</td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>Not determined</td>
</tr>
<tr>
<td>Upper</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Density</td>
<td>Not determined</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
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</tr>
<tr>
<td>Solubility in / Miscibility with water</td>
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</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
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<tr>
<td>Viscosity</td>
<td></td>
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<tr>
<td>Dynamic</td>
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</tr>
<tr>
<td>Kinematic</td>
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<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.
- **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** Mechanical effects only.
Trade name: IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal, Transpa, Essence, Gingiva, Margin, Intensive Margin, Add-On, Special Enamel, Light Reflector, Light Absorber, Power Dentin

- 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.
- European waste catalogue
  - 08 02 99 wastes not otherwise specified

- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

- 14.1 UN-Number: Void
- 14.2 UN proper shipping name: Void
- 14.3 Transport hazard class(es): Void
- 14.4 Packing group: 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).

14.8 Other information: 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.

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.