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

1.1 Product identifier

Trade name: IPS InLine System Opaquer, Intensive Opaquer, Opaquer F

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

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 product is not classified according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: dental ceramic

Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS:</th>
<th>Substance</th>
<th>Workplace exposure limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Glycerol substance with a Community workplace exposure limit &lt;10%</td>
<td></td>
</tr>
</tbody>
</table>

Additional information: For the wording of the listed risk phrases refer to section 16.

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.

(Contd. on page 2)
### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
  - Suitable extinguishing agents: CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- **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:** Do not allow to enter sewers/surface or ground water.

- **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.

- **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:
      - This product is hygroscopic.
      - 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:

- 56-81-5 glycerol
  - WEL Long-term value: 10 mg/m³

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.
    - Wash hands before breaks and at the end of work.
    - Keep away from foodstuffs, beverages and feed.
  - Respiratory protection:
    - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
  - 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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
  - 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: Safety glasses

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

- Appearance:
  - Form: Pasty
  - Colour: According to product specification
  - Odour: Characteristic
  - Odour threshold: Not determined.
- pH-value: Not determined.
- Change in condition
  - Melting point/Melting range: Undetermined.
  - Boiling point/Boiling range: Undetermined.
- Flash point: Undetermined.
- Flammability (solid, gaseous): Not applicable.
- Self-igniting: Product is not selfigniting.
- Danger of explosion: Product does not present an explosion hazard.
Trade name: IPS InLine System Opaquer, Intensive Opaquer, Opaquer F

- Explosion limits:
  - Lower: Not determined.
  - Upper: Not determined.

- Vapour pressure: Not determined.

- Density:
  - Not determined.
  - Relative density: Not determined.
  - Vapour density: Not determined.
  - Evaporation rate: Not determined.

- Solubility in / Miscibility with water: Not miscible or difficult to mix.

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

- Viscosity:
  - Dynamic: Not determined.
  - Kinematic: Not determined.

- 9.2 Other information
  - No further relevant information available.

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:
    - 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:
    - Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
    - Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

(Contd. on page 5)
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**

- **Recommendation** Disposal must be made according to official regulations.

<table>
<thead>
<tr>
<th>European waste catalogue</th>
</tr>
</thead>
<tbody>
<tr>
<td>08 02 99</td>
</tr>
<tr>
<td>wastes not otherwise specified</td>
</tr>
</tbody>
</table>

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

**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** 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 MARPOL 73/78 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
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)

* Data compared to the previous version altered.