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

1.1 Product identifier

Trade name: IPS e.max Press Opaquer

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

No further relevant information available.

Application of the substance / the mixture: Auxiliary for 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 product 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

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>Community workplace exposure limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5</td>
<td>200-289-5</td>
<td>&lt;10%</td>
</tr>
</tbody>
</table>

Glycerol substance with a Community workplace exposure limit 3-<10%

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)
40.1.5

· 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:
  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.
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:
  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.
    - Keep away from foodstuffs, beverages and feed.
    - Wash hands before breaks and at the end of work.
  - **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.
    - After use of gloves apply skin-cleaning agents and skin cosmetics.
  - **Material of gloves**
    - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
  - **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 applicable.
  - **Change in condition**
    - Melting point/Melting range: Undetermined.
    - Boiling point/Boiling range: Undetermined.
  - **Flash point:** Undetermined.
  - **Flammability (solid, gaseous):** Not determined.
  - **Self-igniting:** Product is not selfigniting.
  - **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.
 Trade name: **IPS e.max Press Opaquer**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>
<td>Not applicable.</td>
</tr>
<tr>
<td>Solubility in / Miscibility with water</td>
<td>Partly soluble.</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Viscosity:</td>
<td></td>
</tr>
<tr>
<td>Dynamic</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Kinematic</td>
<td>Not applicable.</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:
  - 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.
- **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
  - 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.

- UN "Model Regulation": UN-,-

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)
Trade name: IPS e.max Press Opaquer

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
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)

* Data compared to the previous version altered.