1 Identification

- **Product identifier**
- **Trade name:** IPS e.max Press Opaquer
- **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
- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Ivoclar Vivadent Inc.
    175 Pineview Drive, Amherst, N.Y. 14228
    USA
    Tel. +1 800 533 6825
    Fax +1 716 691 2285
  - Ivoclar Vivadent Inc.
    1-6600 Dixie Road
    Mississauga, Ontario
    L5T 2Y2
    Canada
    Phone: +1 905 670 8499
    Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
  - 24 Hour Emergency Assistance:
    Emergency-Call USA - Infotrac: 1-800-535-5053
    Emergency-Call Canada - Canutec: 1-613-996-6666
  - General SDS Assistance:
    US: 1-800-533-6825
    Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
  The product is not classified according to the Globally Harmonized System (GHS).
- **Label elements**
  - **GHS label elements** Void
  - **Hazard pictograms** Void
  - **Signal word** Void
  - **Hazard statements** Void
  - **Classification system:**
    - **NFPA ratings (scale 0 - 4)**
      Health = 0
      Fire = 0
      Reactivity = 0
    - **HMIS-ratings (scale 0 - 4)**
      Health = 0
      Fire = 0
      Reactivity = 0

(Contd. on page 2)
Material Safety Data Sheet  
acc. to ISO 11014  

Trade name: IPS e.max Press Opaquer

* Other hazards  
Results of PBT and vPvB assessment  
PBT: Not applicable.  
vPvB: Not applicable.

<table>
<thead>
<tr>
<th>3 Composition/information on ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical characterization: Mixtures</td>
</tr>
<tr>
<td>Description: dental ceramic</td>
</tr>
<tr>
<td>Dangerous components:</td>
</tr>
<tr>
<td>56-81-5 glycerol 5-&lt;10%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4 First-aid measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of first aid measures</td>
</tr>
<tr>
<td>General information: No special measures required.</td>
</tr>
<tr>
<td>After inhalation:</td>
</tr>
<tr>
<td>Supply fresh air; consult doctor in case of complaints.</td>
</tr>
<tr>
<td>In case of unconsciousness place patient stably in side position for transportation.</td>
</tr>
<tr>
<td>After skin contact:</td>
</tr>
<tr>
<td>Rinse with water. Generally the product does not irritate the skin.</td>
</tr>
<tr>
<td>After eye contact:</td>
</tr>
<tr>
<td>Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor. Mechanical effects only.</td>
</tr>
<tr>
<td>After swallowing:</td>
</tr>
<tr>
<td>Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.</td>
</tr>
<tr>
<td>Information for doctor:</td>
</tr>
<tr>
<td>Most important symptoms and effects, both acute and delayed No further relevant information available.</td>
</tr>
<tr>
<td>Indication of any immediate medical attention and special treatment needed</td>
</tr>
<tr>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5 Fire-fighting measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extinguishing media</td>
</tr>
<tr>
<td>Suitable extinguishing agents:</td>
</tr>
<tr>
<td>CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.</td>
</tr>
<tr>
<td>Special hazards arising from the substance or mixture No further relevant information available.</td>
</tr>
<tr>
<td>Advice for firefighters</td>
</tr>
<tr>
<td>Protective equipment: No special measures required.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6 Accidental release measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal precautions, protective equipment and emergency procedures Not required.</td>
</tr>
<tr>
<td>Environmental precautions: Do not allow to enter sewers/ surface or ground water.</td>
</tr>
<tr>
<td>Methods and material for containment and cleaning up: Pick up mechanically.</td>
</tr>
<tr>
<td>Reference to other sections</td>
</tr>
<tr>
<td>See Section 7 for information on safe handling.</td>
</tr>
<tr>
<td>See Section 8 for information on personal protection equipment.</td>
</tr>
</tbody>
</table>

(Contd. on page 1)
Trade name: **IPS e.max Press Opaquer**

See Section 13 for disposal information.

### 7 Handling and storage

- **Handling:**
  - **Precautions for safe handling**
    Only adequately trained personnel should handle this product.
    For use in dentistry only.
  - **Information about protection against explosions and fires:** No special measures required.

- **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 receptacle tightly sealed.
  - Store in dry conditions.

- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

- **Control parameters**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5 glycerol</td>
<td>EL Long-term value: 10* 3** mg/m³</td>
<td>*mist; **mist, respirable</td>
</tr>
<tr>
<td></td>
<td>EV Long-term value: 10 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

- **Additional information:** The lists that were valid during the creation were used as basis.

- **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.

- **Breathing equipment:**
  - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

- **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
### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - Form: Pasty
      - Color: According to product specification
      - Odor: 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.
    - **Auto igniting:** Product is not selfigniting.
    - **Danger of explosion:** Product does not present an explosion hazard.
    - **Explosion limits:**
      - Lower: Not determined.
      - Upper: Not determined.
    - **Vapor pressure:** Not applicable.
    - **Density:** Not determined.
    - **Relative density:** Not determined.
    - **Vapour density:** Not applicable.
    - **Evaporation rate:** Not applicable.
  - **Solubility in / Miscibility with**
    - Water: Partly soluble.
  - **Partition coefficient (n-octanol/water):** Not determined.
  - **Viscosity:**
    - Dynamic: Not applicable.
    - Kinematic: Not applicable.
  - **Other information**
    - No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.
**11 Toxicological information**

- **Information on toxicological effects**
  - **Acute toxicity:**
  - **Primary irritant effect:**
    - on the skin: No irritant effect.
    - on the eye: No irritating effect.
  - **Sensitization:** No sensitizing effects known.
  - **Additional toxicological information:** No further relevant information available.

- **Carcinogenic categories**
  - NTP (National Toxicology Program)
    None of the ingredients is listed.
  - OSHA-Ca (Occupational Safety & Health Administration)
    None of the ingredients is listed.

**12 Ecological information**

- **Toxicity**
  - Aquatic toxicity: No further relevant information available.
  - Persistence and degradability: No further relevant information available.
  - Behavior in environmental systems:
    - Bioaccumulative potential: No further relevant information available.
    - Mobility in soil: No further relevant information available.
  - Additional ecological information:
    - **General notes:**
      Water hazard class 1 (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.
    - Results of PBT and vPvB assessment
      - PBT: Not applicable.
      - vPvB: Not applicable.
    - Other adverse effects: No further relevant information available.

**13 Disposal considerations**

- **Waste treatment methods**
  - **Recommendation:**
    Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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

**14 Transport information**

- **UN-Number**
  - DOT, TDG, ADN, IMDG, IATA: Void

- **UN proper shipping name**
  - DOT, TDG, ADN, IMDG, IATA: Void
### Transport hazard class(es)
- DOT, TDG, ADN, IMDG, IATA
- Class: Void
- Packing group: DOT, TDG, IMDG, IATA
- Void

### Environmental hazards:
- Marine pollutant: No

### Special precautions for user
- Not applicable.

### Transport in bulk according to Annex II of MARPOL73/78 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": UN-, -

### 15 Regulatory information

#### Safety, health and environmental regulations/legislation specific for the substance or mixture

- **Sara**
  - Section 355 (extremely hazardous substances):
    - None of the ingredients is listed.
  - Section 313 (Specific toxic chemical listings):
    - None of the ingredients is listed.
  - TSCA (Toxic Substances Control Act):
    - All ingredients are listed.

- **Proposition 65**
  - Chemicals known to cause cancer:
    - None of the ingredients is listed.
  - Chemicals known to cause reproductive toxicity for females:
    - None of the ingredients is listed.
  - Chemicals known to cause reproductive toxicity for males:
    - None of the ingredients is listed.
  - Chemicals known to cause developmental toxicity:
    - None of the ingredients is listed.

- **Carcinogenic categories**
  - EPA (Environmental Protection Agency)
    - None of the ingredients is listed.
  - TLV (Threshold Limit Value established by ACGIH)
    - None of the ingredients is listed.
  - NIOSH-Ca (National Institute for Occupational Safety and Health)
    - None of the ingredients is listed.

- **GIHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void

(Contd. of page 5)
Trade name: **IPS e.max Press Opaquer**

**Hazard statements** Void

**National regulations:**

**Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

**Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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**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.

**Date of preparation / last revision** 05/18/2015 / 2

**Abbreviations and acronyms:**

- ICAO: International Civil Aviation Organisation
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- ACGIH: American Conference of Governmental Industrial Hygienists
- 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)
- NFPA: National Fire Protection Association (USA)
- HMIS: Hazardous Materials Identification System (USA)

* Data compared to the previous version altered.