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)
Trade name: IPS e.max Press Opaquer

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

3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: dental ceramic
- Dangerous components:
  - 56-81-5 glycerol 2.5-<10%

4 First-aid measures

- 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.
  - Information for doctor:
    - Most important symptoms and effects, both acute and delayed: No further relevant information available.
    - Indication of any immediate medical attention and special treatment needed:
      No further relevant information available.

5 Fire-fighting measures

- Extinguishing media
- Suitable extinguishing agents:
  - CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - Special hazards arising from the substance or mixture: No further relevant information available.
- Advice for firefighters
- Protective equipment: No special measures required.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures: Not required.
- Environmental precautions:
  - Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up: Pick up mechanically.
- Reference to other sections
  - See Section 7 for information on safe handling.
  - See Section 8 for information on personal protection equipment.
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>Components with limit values that require monitoring at the workplace:</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5 glycerol</td>
</tr>
<tr>
<td>PEL</td>
</tr>
<tr>
<td>mist: *total dust **respirable fraction</td>
</tr>
<tr>
<td>TLV TLV withdrawn-insufficient data human occup. exp.</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

- 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, ADR, ADN, IMDG, IATA: Void
- UN proper shipping name
  - DOT, ADR, ADN, IMDG, IATA: Void
### Trade name: IPS e.max Press Opaquer

<table>
<thead>
<tr>
<th>Transport hazard class(es)</th>
<th>DOT, ADR, ADN, IMDG, IATA</th>
<th>Void</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
<td>DOT, ADR, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>Environmental hazards:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marine pollutant:</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Special precautions for user</td>
<td></td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</td>
<td></td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Transport/Additional information:</td>
<td></td>
<td>Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).</td>
</tr>
<tr>
<td>UN &quot;Model Regulation&quot;:</td>
<td>UN-, -</td>
<td></td>
</tr>
</tbody>
</table>

### 15 Regulatory information

<table>
<thead>
<tr>
<th>Safety, health and environmental regulations/legislation specific for the substance or mixture</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sara</td>
<td></td>
</tr>
<tr>
<td>Section 355 (extremely hazardous substances):</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>Section 313 (Specific toxic chemical listings):</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>TSCA (Toxic Substances Control Act):</td>
<td>All ingredients are listed.</td>
</tr>
<tr>
<td>Proposition 65</td>
<td></td>
</tr>
<tr>
<td>Chemicals known to cause cancer:</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>Chemicals known to cause reproductive toxicity for females:</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>Chemicals known to cause reproductive toxicity for males:</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>Chemicals known to cause developmental toxicity:</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>Carcinogenic categories</td>
<td></td>
</tr>
<tr>
<td>EPA (Environmental Protection Agency)</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>TLV (Threshold Limit Value established by ACGIH)</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>NIOSH-Ca (National Institute for Occupational Safety and Health)</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>GHS label elements</td>
<td>Void</td>
</tr>
<tr>
<td>Hazard pictograms</td>
<td>Void</td>
</tr>
<tr>
<td>Signal word</td>
<td>Void</td>
</tr>
</tbody>
</table>
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:**
  - 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
  - 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.