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

- **1.1 Product identifier**
  - Trade name: **IPS Empress Direct Opaque**

- **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
    - 9494 Schaan
    - PRINCIPALITY OF LIECHTENSTEIN
  - Tel: +423 235 35 35
  - Fax: +423 235 33 60

- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

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**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
  - Classification according to Regulation (EC) No 1272/2008
    - **Skin Irrit. 2 H315** Causes skin irritation.
    - **Eye Irrit. 2 H319** Causes serious eye irritation.
    - **Skin Sens. 1 H317** May cause an allergic skin reaction.

- **2.2 Label elements**
  - Labelling according to Regulation (EC) No 1272/2008
    - The product is classified and labelled according to the CLP regulation.
  - **Hazard pictograms**
    - GHS07

- **Signal word** Warning

- **Hazard-determining components of labelling:**
  - urethane dimethacrylate
  - Bis-GMA
  - 1,10-decandiol dimethacrylate

- **Hazard statements**
  - **H315** Causes skin irritation.
  - **H319** Causes serious eye irritation.
  - **H317** May cause an allergic skin reaction.

- **Precautionary statements**
  - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  - P280 Wear protective gloves / eye protection / face protection.
  - P302+P352 IF ON SKIN: Wash with plenty of water.
  - P321 Specific treatment (see on this label).
Trade name: **IPS Empress Direct Opaque**

**SECTION 3: Composition/information on ingredients**

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 72869-86-4 EINECS: 276-957-5</td>
<td>urethane dimethacrylate</td>
</tr>
<tr>
<td>CAS: 36425-15-7 NLP: 500-089-0</td>
<td>Bis-GMA</td>
</tr>
<tr>
<td>CAS: 6701-13-9 EINECS: 229-745-1</td>
<td>1,10-decandiol dimethacrylate</td>
</tr>
<tr>
<td>CAS: 13760-80-0 EINECS: 237-354-2</td>
<td>ytterbium trifluoride</td>
</tr>
</tbody>
</table>

**SECTION 4: First aid measures**

<table>
<thead>
<tr>
<th>Description of first aid measures</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>After inhalation:</td>
<td>Supply fresh air and to be sure call for a doctor.</td>
</tr>
<tr>
<td>After skin contact:</td>
<td>Rinse with water.</td>
</tr>
<tr>
<td>After eye contact:</td>
<td>Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.</td>
</tr>
<tr>
<td>After swallowing:</td>
<td>If symptoms persist consult doctor.</td>
</tr>
</tbody>
</table>

**SECTION 5: Firefighting measures**

<table>
<thead>
<tr>
<th>Extinguishing media</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CO2, powder or water spray.</td>
<td>Fight larger fires with water spray or alcohol resistant foam.</td>
</tr>
</tbody>
</table>

(Contd. on page 3)
Trade name: **IPS Empress Direct Opaque**

### 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:**
    - Protect from exposure to the light.
    - Protect from heat and direct sunlight.
    - Keep container tightly sealed.
- **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:
    - The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
  - **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 and dental laboratories.
      - Wash hands before breaks and at the end of work.
      - Avoid contact with the eyes and skin.
      - Keep away from foodstuffs, beverages and feed.
  - **Respiratory protection:** Not required.
  - **Protection of hands:**
    - **Protective gloves**
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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Not suitable are gloves made of the following materials:**
  Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

- **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/freezing point: Undetermined.
  - Initial boiling point and boiling range: Undetermined.

- **Flash point:** Not applicable.

- **Auto-ignition temperature:**
  - Product is not selfigniting.

- **Explosive properties:**
  - Product does not present an explosion hazard.

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

- **Vapour pressure:**
  - Not determined.

- **Density at 20 °C:**
  - 1.54 g/cm³
  - Relative density: Not determined.
  - Vapour density: Not determined.
  - Evaporation rate: Not determined.

- **Solubility in / Miscibility with water:**
  - Nearly insoluble.

- **Partition coefficient: n-octanol/water:**
  - Not determined.

- **Viscosity:**
  - Dynamic: Not determined.
  - Kinematic: Not determined.
Trade name: IPS Empress Direct Opaque

SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability
  Stable under normal handling and storage conditions.
  Photoreactive (Danger of polymerization).
- 10.3 Possibility of hazardous reactions No decomposition if used according to specifications.
- 10.4 Conditions to avoid
  Protect from exposure to the light.
  Keep away from heat and direct sunlight.
- 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
  Causes skin irritation.
- Serious eye damage/irritation
  Causes serious eye irritation.
- Respiratory or skin sensitisation
  May cause an allergic skin reaction.
- 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:
  Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
  Do not allow product to reach ground water, water course or sewage system.
  Danger to drinking water if even small quantities leak into the ground.
- 12.5 Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.
48.0.6

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.

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

SECTION 14: Transport information

14.1 UN-Number
ADR/RID/ADN, ADN, IMDG, IATA Void

14.2 UN proper shipping name
ADR/RID/ADN, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)
ADR/RID/ADN, ADN, IMDG, IATA Void

14.4 Packing group
ADR/RID/ADN, 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 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": Void

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REGULATION (EC) No 1907/2006 ANNEX XVII
Conditions of restriction: 3

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.

Relevant phrases
H315 Causes skin irritation.
Trade name: **IPS Empress Direct Opaque**

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H412 Harmful to aquatic life with long lasting effects.

**Abbreviations and acronyms:**
- **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)
- **PBT:** Persistent, Bioaccumulative and Toxic
- **vPvB:** very Persistent and very Bioaccumulative
- **Skin Irrit. 2:** Skin corrosion/irritation – Category 2
- **Eye Irrit. 2:** Serious eye damage/eye irritation – Category 2
- **Skin Sens. 1:** Skin sensitisation – Category 1
- **STOT SE 3:** Specific target organ toxicity (single exposure) – Category 3
- **Aquatic Chronic 3:** Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

* Data compared to the previous version altered.