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.

Application of the substance / the mixture

Light-curing opaquer

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

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

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P363 Wash contaminated clothing before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.
Trade name: IPS Empress Direct Opaque

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

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS</th>
<th>Chemical Name</th>
<th>% in mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>72869-86-4</td>
<td>276-957-5</td>
<td>urethane dimethacrylate</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>1565-94-2</td>
<td>237-745-1</td>
<td>Bis-GMA (Bisphenol A Glycidyl Methacrylate)</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>6701-13-9</td>
<td>229-745-1</td>
<td>1,10-decandiol dimethacrylate</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>13760-80-0</td>
<td>237-354-2</td>
<td>ytterbium trifluoride</td>
<td>3-&lt;10%</td>
</tr>
</tbody>
</table>

- **Dangerous components:**
  - CAS: 72869-86-4
  - EINECS: 276-957-5
  - Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412
  - 10-<25%
  - CAS: 1565-94-2
  - EINECS: 237-745-1
  - Bis-GMA
  - Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317
  - 10-<25%
  - CAS: 6701-13-9
  - EINECS: 229-745-1
  - 1,10-decandiol dimethacrylate
  - Eye Irrit. 2, H319; Skin Sens. 1, H317
  - 10-<25%
  - CAS: 13760-80-0
  - EINECS: 237-354-2
  - ytterbium trifluoride
  - Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335
  - 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**
  - **After inhalation:** Supply fresh air and to be sure call for a doctor.
  - **In case of unconsciousness place patient stably in side position for transportation.**
  - **After skin contact:** Rinse with water.
  - **After eye contact:** Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
  - **After swallowing:** 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.
 Trade name: **IPS Empress Direct Opaque**

- **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.
      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 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**: 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**: Not applicable.
  - **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 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.
  - **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.

- **Photoreactive (Danger of polymerization)**
  - **Thermal decomposition / conditions to be avoided**: No decomposition if used according to specifications.
  - **10.3 Possibility of hazardous reactions**
    No dangerous reactions known.
**SECTION 11: Toxicological information**

- **11.1 Information on toxicological effects**
  - Acute toxicity:
  - Primary irritant effect:
    - on the skin: Irritant to skin and mucous membranes.
    - on the eye: Irritating effect.
  - Sensitisation: Sensitisation possible through skin contact.
- **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 2 (German Regulation) (Self-assessment): 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.
- **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
Trade name: **IPS Empress Direct Opaque**

- **14.3 Transport hazard class(es)**
  - ADR, ADN, IMDG, IATA
  - Class: 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 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":**
  - -

---

**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.

- **Relevant phrases**
  - H315 Causes skin irritation.
  - 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)
  - Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
  - Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
  - Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
  - STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
  - Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

- * Data compared to the previous version altered.