

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 10.09.2012


Version number 1

Revision: 10.09.2012

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

- **Product identifier**
- **Trade name: *IPS Empress Direct Color***
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** *Light-curing characterization material*
- **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  
msds@ivoclarvivadent.com*
- **Emergency telephone number:** *+423 / 235 33 13*

**2 Hazards identification**

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
*Xi; Irritant*  
*R36/38: Irritating to eyes and skin.*
- **Xi; Sensitising**  
*R43: May cause sensitisation by skin contact.*
- **R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.**
- **Classification system:**  
*The classification is according to the latest editions of the EU-lists, and extended by company and literature data.*
- **Label elements**
- **Labelling according to EU guidelines:**  
*Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/ EWG usually if they are in the finished state and intended for the final user.*
- **Code letter and hazard designation of product:**  
 *Xi Irritant*
- **Hazard-determining components of labelling:**  
*urethane dimethacrylate  
triethyleneglycol dimethacrylate*
- **Risk phrases:**  
*36/38 Irritating to eyes and skin.  
43 May cause sensitisation by skin contact.  
52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.*

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- **Safety phrases:**
  - 24 Avoid contact with skin.
  - 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
  - 37 Wear suitable gloves.
  - 60 This material and its container must be disposed of as hazardous waste.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 1565-94-2	Bis-GMA	Xi R36/38	25-50%
CAS: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate	Xi R36; Xi R43 R52/53	25-50%
CAS: 109-16-0	triethyleneglycol dimethacrylate	Xi R36/37/38; Xi R43	10-25%

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

### 4 First aid measures

- **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.
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
  - CO<sub>2</sub>, 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.

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- **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.

## 7 Handling and storage

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

## 8 Exposure controls/personal protection

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

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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

### 9 Physical and chemical properties

· **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/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:** 1.18 g/cm<sup>3</sup>

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

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

· **Segregation coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

· **Dynamic:** Not determined.

· **Kinematic:** Not determined.

· **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.

Photoreactive (Danger of polymerization).

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

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- **Conditions to avoid**  
Protect from exposure to the light.  
Keep away from heat and direct sunlight.
- **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:** Irritant to skin and mucous membranes.
  - **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
Irritant

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour 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 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.
- **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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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### 14 Transport information

· <b>UN-Number</b> · <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>UN proper shipping name</b> · <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>Packing group</b> · <b>ADR, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

### 15 Regulatory information

- **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 EC-directive 93/42/EEC.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 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**
  - R36 Irritating to eyes.
  - R36/37/38 Irritating to eyes, respiratory system and skin.
  - R36/38 Irritating to eyes and skin.
  - R43 May cause sensitisation by skin contact.
  - R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.