

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

Printing date 20.04.2015

Version number 3

Revision: 01.04.2015

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

- **1.1 Product identifier**
- **Trade name: *IPS Empress Direct***
- **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 resin-based dental restorative material
- **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
- **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.

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· **Additional information:**

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 Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

|                   |   |         |
|-------------------|---|---------|
| CAS: 72869-86-4   | urethane dimethacrylate   | 10-<25% |
| EINECS: 276-957-5 | Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412 |         |
| CAS: 13760-80-0   | ytterbium trifluoride   | 3-<10%  |
| EINECS: 237-354-2 | Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335        |         |
| CAS: 43048-08-4   | tricyclodocane dimethanol dimethacrylate                        | 3-<10%  |
| EINECS: 256-062-6 | Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335        |         |
| CAS: 1565-94-2    | Bis-GMA   | 2.5-<3% |
|                   | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317     |         |

· **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:**

CO<sub>2</sub>, 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.

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- **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

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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:**

|                           |                                    |
|---------------------------|------------------------------------|
| · <b>Form:</b>            | Pasty                              |
| · <b>Colour:</b>          | According to product specification |
| · <b>Odour:</b>           | Characteristic                     |
| · <b>Odour threshold:</b> | Not determined.                    |

· **pH-value:** Not determined.· **Change in condition**

|                                       |               |
|---------------------------------------|---------------|
| · <b>Melting point/Melting range:</b> | Undetermined. |
| · <b>Boiling point/Boiling range:</b> | Undetermined. |

· **Flash point:** Not applicable.· **Self-igniting:** Product is not selfigniting.· **Danger of explosion:** Product does not present an explosion hazard.· **Explosion limits:**

|                 |                 |
|-----------------|-----------------|
| · <b>Lower:</b> | Not determined. |
| · <b>Upper:</b> | Not determined. |

· **Vapour pressure:** Not determined.

|                            |                        |
|----------------------------|------------------------|
| · <b>Density at 20 °C:</b> | 1.94 g/cm <sup>3</sup> |
| · <b>Relative density</b>  | Not determined.        |
| · <b>Vapour density</b>    | Not determined.        |
| · <b>Evaporation rate</b>  | Not determined.        |

· **Solubility in / Miscibility with water:** Nearly insoluble.· **Partition coefficient (n-octanol/water):** Not determined.· **Viscosity:**

|                     |                 |
|---------------------|-----------------|
| · <b>Dynamic:</b>   | Not determined. |
| · <b>Kinematic:</b> | 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.

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- **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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **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 3 (German Regulation) (Self-assessment): extremely 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**

- |                                       |      |
|---------------------------------------|------|
| · <b>14.1 UN-Number</b>               |      |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void |
| · <b>14.2 UN proper shipping name</b> |      |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void |

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|   |  |
|---|--|
| · <b>14.3 Transport hazard class(es)</b>  |  |
| · <b>ADR, ADN, IMDG, IATA</b>   |  |
| · <b>Class</b>  | Void   |
| · <b>14.4 Packing group</b>   |  |
| · <b>ADR, IMDG, IATA</b>  | Void   |
| · <b>14.5 Environmental hazards:</b>  |  |
| · <b>Marine pollutant:</b>  | No   |
| · <b>14.6 Special precautions for user</b>  | Not applicable.  |
| · <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable.  |
| · <b>Transport/Additional information:</b>  | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>   | -  |

### 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.**