




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

- **Product identifier**
- **Trade name:** **IPS Empress Direct Flow**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Light-curing, flowable, resin-based dental restorative
- **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:** Irritating to eyes.
-  Xi; Sensitising
- **R43:** May cause sensitisation by skin contact.
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
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- **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  
decamethylene dimethacrylate
- **Risk phrases:**  
36 Irritating to eyes.  
43 May cause sensitisation by skin contact.
- **Safety phrases:**  
24 Avoid contact with skin.  
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
37/39 Wear suitable gloves and eye/face protection.  
60 This material and its container must be disposed of as hazardous waste.

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- **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: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate	☒ Xi R36; ☒ Xi R43 R52/53	2.5-25%
CAS: 6701-13-9	decamethylene dimethacrylate	☒ Xi R36; ☒ Xi R43	2.5-10%
CAS: 43048-08-4 EINECS: 256-062-6	Tricyclodocandimethanoldimethacrylat	☒ Xi R38-41	0-10%
CAS: 1565-94-2	Bis-GMA	☒ Xi R36/38	0.5-10%

- **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.
- **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.

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### 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 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.*

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Trade name: **IPS Empress Direct Flow**· **Eye protection:** Safety glasses

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### 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:** 1.42 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.· **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.

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### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **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
- **Sensitisation** May cause sensitisation by skin contact.

### 12 Ecological information

- **Toxicity**
- **Acquatic 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 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.
- **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.

### 14 Transport information

- **Land transport ADR/RID (cross-border)**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

- **Special precautions for user** Not applicable.

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· *Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code 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.

R36/38 Irritating to eyes and skin.

R38 Irritating to skin.

R41 Risk of serious damage to eyes.

R43 May cause sensitisation by skin contact.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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