

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:**
 - CO₂, 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/cm³

· **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

· UN-Number · ADR, ADN, IMDG, IATA	Void
· UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Void
· Packing group · ADR, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· 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.
 - R36/37/38 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.

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

- **Product identifier**
- **Trade name:** ***IPS Empress Direct Opaque***
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** *Light-curing opaquer*
- **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.
 - **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
decamethylene dimethacrylate*
 - **Risk phrases:**
*36/38 Irritating to eyes and skin.
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.*

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- 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: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate	Xi R36; Xi R43 R52/53	10-25%
CAS: 1565-94-2	Bis-GMA	Xi R36/38	10-25%
CAS: 6701-13-9	decamethylene dimethacrylate	Xi R36; 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:**
CO₂, 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.

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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.

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Trade name: IPS Empress Direct Opaque

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- **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:** 1.54 g/cm³
- **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

· UN-Number · ADR, ADN, IMDG, IATA	Void
· UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Void
· Packing group · ADR, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· 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.
R43 May cause sensitisation by skin contact.
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.