

EU Safety Data Sheet

IPS Empress Direct



Date of issue / Reference 25.11.2008 liprt / Version 1
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Date of printing 15.04.2009 **Sheet No. 1767** Version 1 Page 1 of 5
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Company Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan
Fürstentum Liechtenstein

1 Commercial product name and supplier

- 1.1 Commercial product name / Designation **IPS Empress Direct**
- 1.2 Application / Use Light-curing restorative
- 1.3 Producer Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan
Fürstentum Liechtenstein
msds@ivoclarvivadent.com
- Supplier
- 1.4 TOX emergency number
Official Emergency-Call: +423 / 235 35 35
Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein

2 Hazards identification

Uncured material: Direct contact can cause eye and skin irritation. The material is contraindicated if a person is known to be allergic to any of the ingredients of the product.

3 Composition

- 3.1 Chemical characterization Paste of dimethacrylates, inorganic fillers, copolymer, ytterbiumtrifluoride, initiators, stabilizers and pigments
- 3.2 Hazardous components < 22 % Dimethacrylates (CAS No. 1565-94-2 und 72869-86-4)
R36: Irritating to eyes. R38: Irritating to skin.
- 3.3 Further information None.

4 First aid measures

- 4.1 Eye contact Flush with plenty of water. Consult a physician if irritation persists.
- 4.2 Skin contact Wash thoroughly with water.
- 4.3 Ingestion No hazards anticipated from swallowing small amounts incidentally to normal handling.
- 4.4 Inhalation Remove to fresh air.
- 4.5 Further information If you feel unwell, seek medical advice (show this safety data sheet).

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5 Fire-fighting measures

- | | | |
|-----|------------------------------|---|
| 5.1 | Suitable extinguishing media | Water fog, carbon dioxide, foam, dry chemicals. |
| 5.2 | Extinguishing media to avoid | None known |
| 5.3 | Further information | None. |

6 Accidental release measures

Clean up mechanically.
Dispose of according to local and national regulations.

7 Handling and storage

- | | | |
|-----|--------------------------------|---|
| 7.1 | Handling | Only adequately trained personnel should handle this product.
Keep out of reach of children. |
| 7.2 | Industrial hygiene | Usual hygienic measures for dental practice.
When using, do not eat, drink or smoke. |
| 7.3 | Storage | Store at 2-28 °C / 36-82 °F |
| 7.4 | Place of storage | Avoid exposure to light. |
| 7.5 | Fire- and explosion-protection | Not required. |

8 Exposure controls / Personal protection

- | | | |
|-------|---------------------------------|--|
| 8.1 | Exposure controls | Good general ventilation should be sufficient. |
| 8.2 | Exposure limit values | None established. |
| 8.3 | Occupational exposure controls | |
| 8.3.1 | Respiratory protection | Not required. |
| 8.3.2 | Hand protection | Gloves.
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
Avoid direct and indirect skin contact. |
| 8.3.3 | Eye protection | Safety goggles. |
| 8.3.4 | Other | None. |
| 8.4 | Environmental exposure controls | |
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9 Physical and chemical properties

9.1	Appearance	Paste	
9.2	Colour	off-white to cream	
9.3	Odour	practically odourless	
9.4	Change of physical state	---	Test method:
9.5	Density		
9.6	Vapour pressure	not applicable	
9.7	Viscosity	not determined	
9.8	Solubility		
	Solubility in water	< 0.1 %	
9.9	pH	Not determined.	
9.10	Flash point		
9.11	Ignition temperature	not determined	
9.12	Explosion limits	Lower: Upper: not applicable	
9.13	Further information		
	Part. coeff. n-octanol/water		
	Evaporat. rate	None.	

10 Stability and reactivity

10.1	Thermal decomposition	None, if used in accordance to instructions.
10.2	Hazardous decomposition products	None under normal conditions of storage and use.
10.3	Conditions / materials to avoid	None.
10.4	Further information	Avoid exposure of product to light.

11 Toxicological information

11.1	Acute toxicity	Oral LD50 for rats: > 5000 mg/kg
11.2	Subacute / Chronic toxicity	Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions.

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11.3 Further information No hazards anticipated from swallowing small amounts incidentally to normal handling.

12 Ecological information

12.1 Ecotoxicity No data available.

12.2 Mobility No data available.

12.3 Persistence and degradability No data available.

12.4 Bioaccumulative potential No data available.

12.5 Further information No ecological problems to be anticipated if properly handled and used.
nearly insoluble

13 Disposal considerations

Take to a waste incineration plant, under conditions approved by the local authority.

13.1 EU waste key 20 01 39

14 Transport information

14.1 Transport at land ADR --- RID ---

UN Number --- Kemler Number

Packing Group ---

Proper shipping name

14.2 Transport at sea ADNR --- IMDG ---

UN Number ---

EMS --- MFAG ---

Packing Group

Proper shipping name ---

Marine pollutant

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14.3	Air transport	ICAO / IATA-DGR	---
		UN Number	---
		Proper shipping name	---
		Subsidiary Risk	---
		Labels	---
		Packing Group	---
	Passenger airplane	Packing Instructions	---
		max.	---
	Cargo Airplane	Packing Instructions	---
		max.	---
14.4	Further information	Product is not classified as a dangerous good for transport.	

15 Regulatory information

The product is a medical device according to the EC-directive 93/42/EEC.
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

15.1	UN number	---
15.2	National regulations	
15.3	EINECS/ELINCS number	---
15.4	Hazard symbols	
15.5	Hazard designation	
15.6	Risk phrases	
15.7	Safety phrases	
15.8	AGW value	
15.9	BVD classification (CH)	
15.10	VbF (D)	
15.11	Further information	None.

16 Other information

The above mentioned data correspond to our present state of knowledge and experience. The safety data sheet serves as description of the products in regard to necessary safety measures. The indications do not have the meaning of guarantees on properties.