

EU Safety Data Sheet

4 Seasons



Date of issue / Reference

08.04.2005 hot

Replaces version of

24.07.2003

Date of printing

08.04.2005 **Sheet No. 1494**

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Company

Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan
Principality of Liechtenstein

1 Commercial product name and supplier

- 1.1 Commercial product name / Designation **4 Seasons**
- 1.2 Application / Use Resin-based dental restorative material
- 1.3 Producer Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan
Fürstentum Liechtenstein
- 1.4 Supplier
- 1.5 TOX emergency number Emergency-Call: +423 / 235 35 35 or 373 40 40
Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein

2 Composition

- 2.1 Chemical characterization Paste of dimethacrylates, inorganic fillers, ytterbiumtrifluoride, initiators, stabilizers and pigments
- 2.2 Hazardous components
- | | |
|--------------------|---|
| CAS No. 1565-94-2 | 7-9 % Bis-GMA
Xi: Irritant. R36: Irritating to eyes. R38: Irritating to skin. |
| CAS No. 109-16-0 | 3-4 % Triethylene glycoldimethacrylate
Xi: Irritant. R36/37/38: Irritating to eyes, respiratory system and skin. |
| CAS No. 72869-86-4 | 9-11 % Urethanedimethacrylate
Xi: Irritant. R36: Irritating to eyes. R38: Irritating to skin. |
- 2.3 Further information None.

3 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.

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 | Technical measures | Good general ventilation should be sufficient. |
| 8.2 | Control of threshold limits | None established. |
| 8.3 | Personal protective equipment | |
| 8.3.1 | Respiratory protection | Not required. |
| 8.3.2 | Hand protection | Gloves.
Avoid direct and indirect skin contact.
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates. |
| 8.3.3 | Eye protection | Safety goggles. |
| 8.3.4 | Other | None. |

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 | 2.05-2.25 g/cm ³ (20°C) |

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9.6	Vapour pressure	not applicable
9.7	Viscosity	not determined
9.8	Solubility	
	Solubility in	< 0.1 %
9.9	pH	not determined
9.10	Flash point	> 150 °C
9.11	Ignition temperature	not determined
9.12	Explosion limits	Lower: Upper: not applicable
9.13	Further information	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	Hazardous reactions	None.
10.4	Further information	Avoid exposure of product to light.

11 Toxicological information

11.1	Acute toxicity	The oral LD-50 for rats is > 5'000 mg/kg.
11.2	Subacute / Chronic toxicity	Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions in some individuals.
11.3	Further information	No hazards anticipated from swallowing small amounts incidentally to normal handling.

12 Ecological information

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

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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 ---

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 for any mode of transportation.

15 Regulatory information

The product is a medical device according to the EC-directive 93/42.

This product does not require classification according to the criteria of the EC.

15.1 UN number

15.2 National regulations

15.3 EU number

15.4 Hazard symbols

15.5 Hazard designation

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15.6 Risk phrases
15.7 Safety phrases
15.8 MAK value
15.9 BVD classification (CH)
15.10 VbF (D)
15.11 Further information

None.

16 Other information

Version: 3
Changes: 13.1

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.

This safety data sheet has been generated with the safety database 'ChemManager'.
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