

EU Safety Data Sheet

Vivaglass Liner



Date of issue / Reference 18.03.2005 hot
Replaces version of 19.01.2001
Date of printing 18.03.2005 **Sheet No. 1161**

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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 **Vivaglass Liner**
- 1.2 Application / Use Glass ionomer cement
- 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 Powder: Mixture of inorganic fillers, catalysts and pigments
Liquid: Mixture of water, polyacrylic acid, HEMA (hydroxyethyl methacrylate) and dimethacrylates
- 2.2 Hazardous components Powder none
Liquid
CAS No. 9003-01-4 < 30 % Polyacrylic acid
Xi: Irritant. R36/37/38: Irritating to eyes, respiratory system and skin.
CAS No. 868-77-7 < 40 % HEMA
Xi: Irritant. R43: May cause sensitisation by skin contact. R36/38: Irritating to eyes and skin.
- 2.3 Further information None.

3 Hazards identification

Powder: none
Liquid: Irritating to eyes, respiratory system and skin. Liquid and uncured material may cause slight, reversible irritation. May cause sensitization by skin contact.

4 First aid measures

- 4.1 Eye contact Flush eyes with plenty of water (10-15 min.). Call a physician.
- 4.2 Skin contact Wash thoroughly with soap and 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

Wash the area with soap and water.
Dispose of according to local and national regulations.
Clean up mechanically.

7 Handling and storage

- | | | |
|-----|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7.1 | Handling | Only adequately trained personnel should handle this product.
Keep out of reach of children.
This product is intended for use in dentistry only. |
| 7.2 | Industrial hygiene | When using, do not eat, drink or smoke.
Usual hygienic measures for dental practice. |
| 7.3 | Storage | Store at 12-28 °C / 54-82 °F. |
| 7.4 | Place of storage | |
| 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 | Respiratory Protection. |
| 8.3.2 | Hand protection | Gloves. |
| 8.3.3 | Eye protection | Safety goggles (patient). |
| 8.3.4 | Other | None. |

9 Physical and chemical properties

- | | | |
|-----|--------------------------|---------------------------------|
| 9.1 | Appearance | Paste (mixed powder and liquid) |
| 9.2 | Colour | off-white to cream - yellowish |
| 9.3 | Odour | Practically odourless |
| 9.4 | Change of physical state | not applicable |

Test method:

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9.5 Density	not determined
9.6 Vapour pressure	not applicable
9.7 Viscosity	not determined
9.8 Solubility	
Solubility in	< 0.5 %
9.9 pH	< 2 (Liquid and uncured material)
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	None.

11 Toxicological information

11.1 Acute toxicity	Oral LD50 for rats: >5000 mg/kg Liquid and uncured material: Direct contact may cause eye irritation. Skin: repeated or prolonged exposure may cause slight irritations. Vivaglass Liner possesses no cytotoxic potential.
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.

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12 Ecological information

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

Do not discharge the liquid to sewers or natural waters.
nearly insoluble

13 Disposal considerations

Take to a special waste incineration plant, in line with local regulations.

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

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15.3 EU number ---

15.4 Hazard symbols

Xi



15.5 Hazard designation

15.6 Risk phrases

R: 43-36/37/38

43 May cause sensitisation by skin contact.

36/37/38 Irritating to eyes, respiratory system and skin.

15.7 Safety phrases

15.8 MAK value --- ml/m³ (ppm)

15.9 BVD classification (CH) ---

15.10 VbF (D)

15.11 Further information None.

16 Other information

Version: 3

Changes: 2.2 / 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.