

EU Safety Data Sheet

System.inlay / System.onlay



Date of issue / Reference

18.03.2005 hot

Replaces version of

19.01.2001

Date of printing

18.03.2005 **Sheet No. 1150**

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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 **System.inlay / System.onlay**
- 1.2 Application / Use Temporary 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 polyesterurethanedimethacrylate, silicon dioxide, copolymer, triclosan, initiators and stabilizers
- 2.2 Hazardous components
- System.inlay and System.onlay
- CAS No. 76558-74-2 < 50 % Paste of polyesterurethanedimethacrylate
- System.inlay
- CAS No. 39670-09-2 < 8 % Ethyltriglycolmethacrylate
- 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 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

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. |
| 8.3.3 | Eye protection | Safety goggles. |
| 8.3.4 | Other | None. |

9 Physical and chemical properties

- | | | |
|-----|--------------------------|--------------------------------------|
| 9.1 | Appearance | Paste |
| 9.2 | Colour | white to pale yellow |
| 9.3 | Odour | Practically odourless |
| 9.4 | Change of physical state | Test method:
not applicable |
| 9.5 | Density | 1.32 - 1.33 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

< 0.5 %

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 > 5000 mg/kg.
Primary eye irritation test acc. to EEC Directive (Rabbit eye): not irritant

11.2 Subacute / Chronic toxicity

Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions in some individuals.
Skin: repeated or prolonged exposure may cause slight irritations.

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

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

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

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 --- ml/m³ (ppm)
15.9 BVD classification (CH) ---
15.10 VbF (D)
15.11 Further information None.

16 Other information Version: 2
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.

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