

EU Safety Data Sheet

Callisto Implant 78



Date of issue / Reference

17.10.2006 casa

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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

Callisto Implant 78

1.2 Application / Use

Ceramic alloy

1.3 Producer

Ivoclar Vivadent, Inc.
175 Pineview Drive, Amherst NY 14228, USA

1.4 Supplier

1.5 TOX emergency number

Emergency-Call USA: (716) 691-0010
Emergency-Call LI: +423 / 235 35 35 or 373 40 40

2 Composition

2.1 Chemical characterization

Dental alloy made of: Au 78.6 % (CAS No. 7440-57-5), Pt 9.7 % (7440-06-4), Pd 7.9 % (7440-05-3), In 3.4 % (7440-74-6), < 1.0 % Fe, Re, Rh, Ru

2.2 Hazardous components

2.3 Further information

None.

3 Hazards identification

Avoid breathing of grinding dust and vapours.
Melted material may cause burns.

4 First aid measures

4.1 Eye contact

Flush eyes with plenty of water. Call a physician if irritation persists.

4.2 Skin contact

Melted material presents a special hazard of deep thermal burns. If burn occurs, treat as any thermal burn.

4.3 Ingestion

Call a physician immediately.

4.4 Inhalation

Remove to fresh air.

4.5 Further information

None.

5 Fire-fighting measures

5.1 Suitable extinguishing media

Not required.
not combustible

5.2 Extinguishing media to avoid

None.

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5.3 Further information None.

6 Accidental release measures
Clean up mechanically.
Clean and reuse

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.

7.3 Storage No specific requirements.

7.4 Place of storage

7.5 Fire- and explosion-protection Not required.

8 Exposure controls / Personal protection

8.1 Technical measures Provide adequate local ventilation. Control airborne concentration below the exposure guideline.

8.2 Control of threshold limits Dust and vapors: MAK 0.1 mg/m³

8.3 Personal protective equipment

8.3.1 Respiratory protection If metal fumes are present, use an approved high-efficiency particulate respirator (P3).
In dusty atmospheres, use an approved dust respirator P2.

8.3.2 Hand protection Gloves.

8.3.3 Eye protection Safety goggles.

8.3.4 Other Use only with adequate ventilation.

9 Physical and chemical properties

9.1 Appearance solid

9.2 Colour white

9.3 Odour odourless

9.4 Change of physical state Test method:

Melting range 1135-1250 °C 2075-2200 °F

Casting temperature 1305-1365 °C 2380-2485 °F

9.5 Density 17.6 g/cm³ (20°C)

9.6 Vapour pressure
not applicable

9.7 Viscosity
not applicable

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9.8 Solubility

Solubility in

non soluble

9.9 pH

not applicable

9.10 Flash point

not applicable

9.11 Ignition temperature

not applicable

9.12 Explosion limits

Lower:
Upper:
not applicable

9.13 Further information

Complies with ISO 9693

10 Stability and reactivity

10.1 Thermal decomposition

None, if used in accordance to instructions.

10.2 Hazardous decomposition products

None, if used in accordance to instructions.

10.3 Hazardous reactions

None, if used in accordance to instructions.

10.4 Further information

None.

11 Toxicological information

11.1 Acute toxicity

Alloy: non-cytotoxic, non-mutagenic, non-irritant, non-sensitizer

11.2 Subacute / Chronic toxicity

Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

11.3 Further information

None.

12 Ecological information

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

13 Disposal considerations

Recycling

13.1 EU waste key

17 04 07

14 Transport information

14.1 Transport at land

ADR

RID

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| | | | | |
|------|----------------------|--|---------------|------|
| | UN Number | --- | Kemler Number | --- |
| | Packing Group | --- | | |
| | Proper shipping name | #Fehler | | |
| 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 as a dangerous good for transport. | | |

15 Regulatory information

This product does not require classification as Dangerous Goods. 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 | EU number | --- |
| 15.4 | Hazard symbols | |
| 15.5 | Hazard designation | |
| 15.6 | Risk phrases | |
| 15.7 | Safety phrases | |
| 15.8 | MAK value | 0.1 mg/m ³ |
| 15.9 | BVD classification (CH) | --- |
| 15.10 | VbF (D) | --- |
| 15.11 | Further information | None. |

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16 Other information

Version: 1

Changes: 0

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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91/155/EEC