

Safety Data Sheet in accordance with HSNO

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** ***Callisto Implant 78***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Manufacture of dental prothesis
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285
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- **Importer:**
Ivoclar Vivadent Ltd
12 Omega St, Rosedale, Auckland
New Zealand
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **Emergency telephone number:** 0800 764 766 (National Poison Centre - 24 hours / 7 days)

2 Hazards identification

- **Classification of the substance or mixture**
Ox. Sol. 2 H272 May intensify fire; oxidiser.
- **Label elements**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**



GHS03

- **Signal word** Danger
- **Hazard statements**
May intensify fire; oxidiser.
- **Precautionary statements**
Keep away from heat. - No smoking.
Keep/Store away from clothing/combustible materials.
Take any precaution to avoid mixing with combustibles.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of fire: Use CO2, powder or water spray to extinguish.
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**
Alloys do not require a label, providing they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market.

(Contd. on page 2)

Safety Data Sheet in accordance with HSNO

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

Trade name: **Callisto Implant 78**

(Contd. of page 1)

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/Information on ingredients

- **Chemical characterisation:** Mixtures
- **Description:** Dental alloy

- **Dangerous components:**

CAS: 7440-06-4 EINECS: 231-116-1	platinum	Ox. Sol. 2, H272	2.5-10%
CAS: 7440-74-6 EINECS: 231-180-0	indium		2.5-10%
CAS: 7439-89-6 EINECS: 231-096-4	iron	Acute Tox. 2, H300	<2.5%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**
Grinding dust: Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** After contact with the molten product, cool rapidly with cold water.
- **After eye contact:**
Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
Mechanical effects only.
- **After swallowing:** Seek medical treatment.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** The product is not flammable.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Do not inhale explosion gases or combustion gases.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling.

(Contd. on page 3)

Safety Data Sheet in accordance with HSNO

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

Trade name: Callisto Implant 78

(Contd. of page 2)

See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Extractors are required on all machines used for thermal processing or splinter removal processes.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 7440-06-4 platinum

WES Long-term value: 1* 0.002** mg/m³
*metal; **soluble salts, as Pt: dsen

CAS: 7440-74-6 indium

WES Long-term value: 0.1 mg/m³
as In

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
- **Respiratory protection:** Use respiratory protective device against the effects of fumes/dust/aerosol.
- **Protection of hands:**
Protective gloves should always be worn during mechanical and thermal processing.
After use of gloves apply skin-cleaning agents and skin cosmetics.
- **Material of gloves**
Mechanical processing:
Leather gloves
Strong material gloves
Thermal processing:
Heat protection gloves
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

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(Contd. on page 4)

Safety Data Sheet in accordance with HSNO

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

Trade name: **Callisto Implant 78**

(Contd. of page 3)

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Solid

Colour: White

· **Odour:** Odourless

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/freezing point: 1135–1250 °C

Initial boiling point and boiling range: Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

· **Vapour pressure:** Not applicable.

· **Density at 20 °C:** 17.6 g/cm³

· **Relative density** Not determined.

· **Vapour density** Not applicable.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with water:**

Insoluble.

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

Dynamic: Not applicable.

Kinematic: Not applicable.

· **Solvent content:**

Solids content: 100 %

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability** Stable under normal handling and storage conditions.

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** None under normal conditions of storage and use.

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(Contd. on page 5)

Safety Data Sheet in accordance with HSNO

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

Trade name: **Callisto Implant 78**

(Contd. of page 4)

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
- **Specific symptoms in biological assay:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:**
Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|------|
| <ul style="list-style-type: none"> · UN-Number · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · UN proper shipping name · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADR/RID/ADN, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · Packing group · ADR/RID/ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: | No |

(Contd. on page 6)

Safety Data Sheet in accordance with HSNO

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Version number 4

Revision: 29.08.2022

Trade name: **Callisto Implant 78**

(Contd. of page 5)

· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **New Zealand Inventory of Chemicals**

All ingredients are listed.

· **HSNO Approval numbers**

CAS: 7440-74-6 indium

HSR003007

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS03

· **Signal word** Danger

· **Hazard statements**

May intensify fire; oxidiser.

· **Precautionary statements**

Keep away from heat. - No smoking.

Keep/Store away from clothing/combustible materials.

Take any precaution to avoid mixing with combustibles.

Wear protective gloves/protective clothing/eye protection/face protection.

In case of fire: Use CO₂, powder or water spray to extinguish.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category P8** OXIDISING LIQUIDS AND SOLIDS

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H272 May intensify fire; oxidiser.

(Contd. on page 7)

Safety Data Sheet
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Revision: 29.08.2022

Trade name: Callisto Implant 78

(Contd. of page 6)

H300 Fatal if swallowed.

· **Contact:**

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Ox. Sol. 2: Oxidizing solids – Category 2

Acute Tox. 2: Acute toxicity – Category 2

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