

Safety Data Sheet according to WHS Regulations

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **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 prosthesis
- **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
- **Importer:**
Ivoclar Vivadent Pty. Ltd.
1- 5 Overseas Drive
Noble Park North VIC 3174
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) 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.

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· **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.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**

· **Description:** Dental alloy

· **Dangerous components:**

CAS: 7440-06-4	platinum	Ox. Sol. 2, H272	2.5-10%
CAS: 7440-05-3	palladium	Ox. Sol. 2, H272	2.5-10%
CAS: 7440-74-6	indium		2.5-10%
CAS: 7439-89-6	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.

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- **Reference to other sections**
See Section 7 for information on safe handling.
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 and 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 mg/m ³
CAS: 7440-74-6 indium	
WES	Long-term value: 0.1 mg/m ³ 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.

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· **Eye protection:**

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

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/cm ³
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.

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- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

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

- | | |
|-------------------------------------|------|
| · UN-Number | |
| · ADG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · ADG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · ADG, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · ADG, IMDG, IATA | Void |

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· Environmental hazards:	
· Marine pollutant:	No
· 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**

· **Australian Inventory of Industrial Chemicals**

CAS: 7440-57-5 Gold

CAS: 7440-22-4 silver

CAS: 7440-50-8 copper

CAS: 7440-06-4 platinum

CAS: 7440-74-6 indium

CAS: 7439-88-5 iridium

· **Standard for the Uniform Scheduling of Medicines and Poisons**

CAS: 7440-22-4 silver

S2

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **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

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- **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.
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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