

## 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 60**

· **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.

Skin Irrit. 2      H315 Causes skin irritation.

Eye Irritation 2A      H319 Causes serious eye irritation.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS03      GHS07

· **Signal word** Danger

· **Hazard statements**

May intensify fire; oxidiser.

Causes skin irritation.

Causes serious eye irritation.

· **Precautionary statements**

Keep away from heat. - No smoking.

Keep/Store away from clothing/combustible materials.

Take any precaution to avoid mixing with combustibles.

(Contd. on page 2)

## Safety Data Sheet

### according to WHS Regulations

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

**Trade name: Callisto Implant 60**

(Contd. of page 1)

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

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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.

· **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: 7440-05-3 | palladium | Ox. Sol. 2, H272    | 50-100% |
| CAS: 7440-22-4 | silver    |                     | 25-50%  |
| CAS: 7440-31-5 | tin       |                     | 2.5-10% |
| CAS: 7440-74-6 | indium    |                     | <2.5%   |
| CAS: 7440-55-3 | gallium   | Skin Corr. 1B, H314 | <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.

AU

(Contd. on page 3)

## Safety Data Sheet according to WHS Regulations

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

Trade name: **Callisto Implant 60**

(Contd. of page 2)

### 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.  
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: 7440-22-4 silver

WES Long-term value: 0.1 mg/m<sup>3</sup>

CAS: 7440-31-5 tin

WES Long-term value: 2 mg/m<sup>3</sup>

CAS: 7440-74-6 indium

WES Long-term value: 0.1 mg/m<sup>3</sup>  
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

(Contd. on page 4)

## Safety Data Sheet

### according to WHS Regulations

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

**Trade name: Callisto Implant 60**

(Contd. of page 3)

**· 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).

### 9 Physical and Chemical Properties

**· Information on basic physical and chemical properties**
**· General Information**
**· Appearance:**

|                         |                 |
|-------------------------|-----------------|
| <b>Form:</b>            | Solid           |
| <b>Colour:</b>          | White           |
| <b>Odour:</b>           | Odourless       |
| <b>Odour threshold:</b> | Not determined. |

**· pH-value:** Not applicable.

**· Change in condition**

|   |               |
|---|---------------|
| <b>Melting point/freezing point:</b>            | 1100–1260 °C  |
| <b>Initial boiling point and boiling range:</b> | 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:**

|               |                 |
|---------------|-----------------|
| <b>Lower:</b> | Not determined. |
| <b>Upper:</b> | Not determined. |

**· Vapour pressure:** Not applicable.

|                            |                        |
|----------------------------|------------------------|
| <b>· Density at 20 °C:</b> | 10.8 g/cm <sup>3</sup> |
| <b>· Relative density</b>  | Not determined.        |
| <b>· Vapour density</b>    | Not applicable.        |
| <b>· Evaporation rate</b>  | Not applicable.        |

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

Insoluble.

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

**· Viscosity:**

|                   |                 |
|-------------------|-----------------|
| <b>Dynamic:</b>   | Not applicable. |
| <b>Kinematic:</b> | 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.

(Contd. on page 5)

## Safety Data Sheet according to WHS Regulations

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

Trade name: **Callisto Implant 60**

(Contd. of page 4)

- **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.

### 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

- |                                  |      |
|----------------------------------|------|
| · <b>UN-Number</b>               |      |
| · <b>ADG, ADN, IMDG, IATA</b>    | Void |
| · <b>UN proper shipping name</b> |      |
| · <b>ADG, ADN, IMDG, IATA</b>    | Void |

(Contd. on page 6)

-AU-

## Safety Data Sheet

### according to WHS Regulations

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

Trade name: **Callisto Implant 60**

(Contd. of page 5)

|   |  |
|---|--|
| · <b>Transport hazard class(es)</b>   |  |
| · <b>ADG, ADN, IMDG, IATA</b>   |  |
| · <b>Class</b>  | Void   |
| · <b>Packing group</b>  |  |
| · <b>ADG, IMDG, IATA</b>  | Void   |
| · <b>Environmental hazards:</b>   |  |
| · <b>Marine pollutant:</b>  | No   |
| · <b>Special precautions for user</b>                                       | Not applicable.  |
| · <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable.  |
| · <b>Transport/Additional information:</b>                                  | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>   | 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    GHS07

· **Signal word** Danger

· **Hazard statements**

May intensify fire; oxidiser.

Causes skin irritation.

Causes serious eye irritation.

· **Precautionary statements**

Keep away from heat. - No smoking.

Keep/Store away from clothing/combustible materials.

Take any precaution to avoid mixing with combustibles.

(Contd. on page 7)

## Safety Data Sheet

### according to WHS Regulations

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

**Trade name: Callisto Implant 60**

(Contd. of page 6)

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

*IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*

*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.  
H314 Causes severe skin burns and eye damage.
- **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  
Skin Corr. 1B: Skin corrosion/irritation – Category 1B  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

-AU-