

# Safety Data Sheet

## acc. to ISO/DIS 11014

Printing date 12/19/2012


Version number 3

Reviewed on 12/19/2012

### 1 Identification of the substance/mixture and of the company/undertaking

- **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 preparation** *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*
- 
- Ivoclar Vivadent Inc.*  
*1-6600 Dixie Road*  
*Mississauga, Ontario*  
*L5T 2Y2*  
*Canada*  
*Phone: +1 905 670 8499*  
*Fax: +1 905 670 3102*
- **Information department:** *Quality Assurance / Regulatory Affairs*
- **Emergency telephone number:**  
*24 Hour Emergency Assistance:*  
*Emergency-Call USA - Infotrac: 1-800-535-5053*  
*Emergency-Call Canada - Canutec: 1-613-996-6666*
- 
- General MSDS Assistance:*  
*US: 1-800-533-6825*  
*Canada: 1-800-263-8182*

### 2 Hazards identification

- **Classification of the substance or mixture**  
*Ox. Sol. 2 H272 May intensify fire; oxidizer.*
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
*Oxidizing*  
*Contact with combustible material may cause fire.*
- **Information concerning particular hazards for human and environment:**  
*Avoid breathing of grinding dust and vapours. Melted material may cause burns.*
- **Classification system:**  
*The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.*
- **Label elements**
- **GHS label elements**  
*The product is classified and labelled according to the Globally Harmonized System (GHS).*
- **Hazard pictograms**
- 
- GHS03**
- **Signal word** *Danger*

(Contd. on page 2)

USA

## Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/19/2012

Version number 3

Reviewed on 12/19/2012

**Trade name: Callisto Implant 78**

(Contd. of page 1)

- **Hazard statements**

May intensify fire; oxidizer.

- **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Take any precaution to avoid mixing with combustibles.

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

Keep/Store away from clothing/combustible materials.

In case of fire: Use for extinction: CO<sub>2</sub>, powder or water spray.

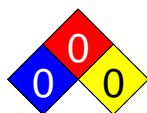
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

· **Description:** Dental alloy

- **Dangerous components:**

7440-06-4	platinum	1-<10%
7440-05-3	palladium	1-<10%
7440-74-6	indium	1-<10%

### 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.

(Contd. on page 3)

## Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/19/2012

Version number 3

Reviewed on 12/19/2012

**Trade name: Callisto Implant 78**

(Contd. of page 2)

- **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 Firefighting 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.  
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 protection against explosions and fires:** 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 systems:** No further data; see item 7.
- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

#### 7440-06-4 platinum

PEL	0.002 mg/m <sup>3</sup> soluble salts, as Pt
REL	1* 0.002** mg/m <sup>3</sup> *Metal **soluble salts, as Pt
TLV	1* 0.002** mg/m <sup>3</sup> *metal **soluble salts, as Pt

(Contd. on page 4)

## Safety Data Sheet

### acc. to ISO/DIS 11014

Printing date 12/19/2012

Version number 3

Reviewed on 12/19/2012

**Trade name: Callisto Implant 78**

(Contd. of page 3)

#### 7440-74-6 indium

REL	0.1 mg/m <sup>3</sup> and compounds, as In
TLV	0.1 mg/m <sup>3</sup>

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Usual hygienic measures for dental practice.
- **Breathing equipment:** 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 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).

## 9 Physical and chemical properties

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

Form:	Solid
Color:	White
Odor:	Odorless
Odour threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/Melting range:	1135–1250 °C (2075–2282 °F)
Boiling point/Boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not determined.
- **Auto igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapor pressure:** Not applicable.
- **Density at 20 °C (68 °F):** 17.6 g/cm<sup>3</sup> (146.872 lbs/gal)
- **Relative density** Not determined.

(Contd. on page 5)

USA

## Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/19/2012

Version number 3

Reviewed on 12/19/2012

**Trade name: Callisto Implant 78**

(Contd. of page 4)

· <b>Vapour density</b>	<i>Not applicable.</i>
· <b>Evaporation rate</b>	<i>Not applicable.</i>
· <b>Solubility in / Miscibility with Water:</b>	<i>Insoluble.</i>
· <b>Partition coefficient (n-octanol/water):</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
<b>Dynamic:</b>	<i>Not applicable.</i>
<b>Kinematic:</b>	<i>Not applicable.</i>
· <b>Solvent content:</b>	
<b>Solids content:</b>	<i>100 %</i>
· <b>Other information</b>	<i>No further relevant information available.</i>

### 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.*

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** *No irritant effect.*
- **on the eye:** *No irritating effect.*
- **Sensitization:** *No sensitizing effects known.*
- **Additional toxicological information:**  
*Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.*
- **Carcinogenic categories**

- **NTP (National Toxicology Program)**

*None of the ingredients is listed.*

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*
- **Behavior in environmental systems:**
- **Bioaccumulative potential** *No further relevant information available.*
- **Mobility in soil** *No further relevant information available.*
- **Additional ecological information:**
- **General notes:** *Generally not hazardous for water*

(Contd. on page 6)

## Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/19/2012

Version number 3

Reviewed on 12/19/2012

**Trade name: Callisto Implant 78**

(Contd. of page 5)

- **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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |  |  |
|--|--|
| · <b>UN-Number</b>   |  |
| · <b>DOT</b>   | NA3077   |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void   |
| · <b>UN proper shipping name</b>   |  |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void   |
| · <b>Transport hazard class(es)</b>  |  |
| · <b>DOT</b>   |  |
| · <b>Class</b>   | 9 Miscellaneous dangerous substances and articles. |
| · <b>Label</b>   | 9  |
| · <b>ADR, ADN, IMDG, IATA</b>  |  |
| · <b>Class</b>   | Void   |
| · <b>Packing group</b>   |  |
| · <b>DOT</b>   | III  |
| · <b>ADR, 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 MARPOL73/78 and the IBC Code</b> | Not applicable.                                    |
| · <b>UN "Model Regulation":</b>  | -  |

### 15 Regulatory information

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

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

(Contd. on page 7)

## Safety Data Sheet

acc. to ISO/DIS 11014

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Version number 3

Reviewed on 12/19/2012

**Trade name: Callisto Implant 78**

(Contd. of page 6)

· **Section 313 (Specific toxic chemical listings):**

7440-22-4 silver

7440-50-8 copper

· **TSCA (Toxic Substances Control Act):**

7440-57-5 Gold

7440-22-4 silver

7440-50-8 copper

7440-06-4 platinum

7440-74-6 indium

7439-88-5 iridium

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

7440-22-4 silver

D

7440-50-8 copper

D

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **GHS label elements**

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

· **Hazard pictograms**



GHS03

· **Signal word Danger**

· **Hazard statements**

May intensify fire; oxidizer.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Take any precaution to avoid mixing with combustibles.

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

Keep/Store away from clothing/combustible materials.

(Contd. on page 8)

## Safety Data Sheet

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Version number 3

Reviewed on 12/19/2012

**Trade name: Callisto Implant 78**

(Contd. of page 7)

*In case of fire: Use for extinction: CO<sub>2</sub>, powder or water spray.*

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

· **National regulations:**

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

*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.*

· **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.*

· **Abbreviations and acronyms:**

*ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

*IMDG: International Maritime Code for Dangerous Goods*

*DOT: US Department of Transportation*

*IATA: International Air Transport Association*

*ACGIH: American Conference of Governmental Industrial Hygienists*

*NFPA: National Fire Protection Association (USA)*

*HMIS: Hazardous Materials Identification System (USA)*

USA