

Material Safety Data Sheet
acc. to ISO 11014

Printing date 06/23/2015

Version number 4

Reviewed on 05/07/2015

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 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 SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
Ox. Sol. 2 H272 May intensify fire; oxidizer.

 - **Label elements**
 - **GHS label elements**
The product is classified and labeled 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.
Take any precaution to avoid mixing with combustibles.
Wear protective gloves / eye protection / face protection.
Keep/Store away from clothing/combustible materials.

(Contd. on page 2)

Material Safety Data Sheet

acc. to ISO 11014

Printing date 06/23/2015

Version number 4

Reviewed on 05/07/2015

Trade name: **Callisto Implant 78**

(Contd. of page 1)

In case of fire: Use for extinction: CO₂, powder or water spray.

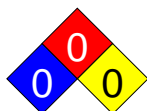
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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	5-<10%
7440-05-3	palladium	5-<10%
7440-74-6	indium	3-5%

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.

CA

(Contd. on page 3)

Material Safety Data Sheet

acc. to ISO 11014

Printing date 06/23/2015

Version number 4

Reviewed on 05/07/2015

Trade name: **Callisto Implant 78**

(Contd. of page 2)

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.
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

EL Long-term value: 1* 0.002** mg/m³
 *metal; **soluble salts (as Pt): S

EV Long-term value: 1* 0.002** mg/m³
 *metal; **water-soluble compounds (as Pt)

7440-74-6 indium

EL Long-term value: 0.1 mg/m³
 as In; ACGIH 2B

EV Long-term value: 0.1 mg/m³
 as indium

- **Additional information:** *The lists that were valid during the creation were used as basis.*

(Contd. on page 4)

CA

Material Safety Data Sheet

acc. to ISO 11014

Printing date 06/23/2015

Version number 4

Reviewed on 05/07/2015

Trade name: Callisto Implant 78

(Contd. of page 3)

- **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 |
| 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: | 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. | |

(Contd. on page 5)

CA

Material Safety Data Sheet

acc. to ISO 11014

Printing date 06/23/2015

Version number 4

Reviewed on 05/07/2015

Trade name: Callisto Implant 78

(Contd. of page 4)

- | | |
|----------------------------|---|
| · Viscosity: | |
| <i>Dynamic:</i> | <i>Not applicable.</i> |
| <i>Kinematic:</i> | <i>Not applicable.</i> |
| · Solvent content: | |
| <i>Solids content:</i> | <i>100 %</i> |
| · Other information | <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)
--

<i>None of the ingredients is listed.</i>

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

<i>None of the ingredients is listed.</i>

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

(Contd. on page 6)

CA

Material Safety Data Sheet

acc. to ISO 11014

Printing date 06/23/2015

Version number 4

Reviewed on 05/07/2015

Trade name: Callisto Implant 78

(Contd. of page 5)

· **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

- **UN-Number**
- **DOT** NA3077
- **TDG, ADN, IMDG, IATA** Void
- **UN proper shipping name**
- **TDG, ADN, IMDG, IATA** Void
- **Transport hazard class(es)**
- **DOT**
- **Class** 9 Miscellaneous dangerous substances and articles
- **Label** 9
- **TDG, ADN, IMDG, IATA**
- **Class** Void
- **Packing group**
- **DOT** III
- **TDG, IMDG, IATA** Void
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 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":** -

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.

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

7440-22-4 silver

7440-50-8 copper

(Contd. on page 7)

CA

Material Safety Data Sheet

acc. to ISO 11014

Printing date 06/23/2015

Version number 4

Reviewed on 05/07/2015

Trade name: Callisto Implant 78

(Contd. of page 6)

· **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.

· **GHS label elements**

The product is classified and labeled 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.

Take any precaution to avoid mixing with combustibles.

Wear protective gloves / eye protection / face protection.

Keep/Store away from clothing/combustible materials.

In case of fire: Use for extinction: CO₂, 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 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.

(Contd. on page 8)

Material Safety Data Sheet
acc. to ISO 11014

Printing date 06/23/2015

Version number 4

Reviewed on 05/07/2015

Trade name: **Callisto Implant 78**

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

(Contd. of page 7)

* **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.

· **Date of preparation / last revision** 06/23/2015 / 3

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

Ox. Sol. 2: Oxidising Solids, Hazard Category 2

· *** Data compared to the previous version altered.**

CA