

Safety Data Sheet
acc. to OSHA HCS

Printing date 06/23/2015

Version number 3

Reviewed on 05/07/2015

1 Identification


- **Product identifier**
- **Trade name:** ***Callisto Implant 33***
- **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

- 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**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Dam. 1 H318 Causes serious eye damage.

 - **Label elements**
 - **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
 - **Hazard pictograms**
- 

GHS05
- **Signal word** *Danger*
 - **Hazard-determining components of labeling:**
gallium
 - **Hazard statements**
Causes skin irritation.
Causes serious eye damage.

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· **Precautionary statements**

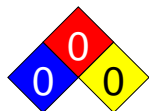
- Wear protective gloves.
- Wear eye protection / face protection.
- Wash thoroughly after handling.
- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- Immediately call a poison center/doctor.
- Specific treatment (see on this label).
- If skin irritation occurs: Get medical advice/attention.
- If on skin: Wash with plenty of water.
- Take off contaminated clothing and wash it before reuse.

· **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 Health = 0
FIRE 0 Fire = 0
REACTIVITY 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:**

7440-05-3	palladium	50-100%
7440-22-4	silver	2.5-<10%
7440-55-3	gallium	2.5-<10%
7440-31-5	tin	1-<2.5%

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.

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- *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.
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:**

7440-22-4 silver

PEL Long-term value: 0.01 mg/m³

REL Long-term value: 0.01 mg/m³

TLV Long-term value: 0.1 mg/m³
metal: dust and fume

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7440-31-5 tin

PEL	Long-term value: 2 mg/m ³ metal
REL	Long-term value: 2 mg/m ³
TLV	Long-term value: 2 mg/m ³ metal

- **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:	1115–1305 °C (2039–2381 °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):** 12.6 g/cm³ (105.147 lbs/gal)

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· Relative density	<i>Not determined.</i>
· Vapour density	<i>Not applicable.</i>
· Evaporation rate	<i>Not applicable.</i>
· Solubility in / Miscibility with Water:	<i>Insoluble.</i>
· Partition coefficient (n-octanol/water):	<i>Not determined.</i>
· Viscosity:	
Dynamic:	<i>Not applicable.</i>
Kinematic:	<i>Not applicable.</i>
· Solvent content:	
Solids content:	<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)**

None of the ingredients is listed.

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

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.*

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- **Additional ecological information:**
- **General notes:** Generally 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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---|--|
| <ul style="list-style-type: none"> · UN-Number · DOT · ADR, ADN, IMDG, IATA | <ul style="list-style-type: none"> NA3077 Void |
| <ul style="list-style-type: none"> · UN proper shipping name · ADR, ADN, IMDG, IATA | <ul style="list-style-type: none"> Void |
| <ul style="list-style-type: none"> · Transport hazard class(es) · DOT · Class · Label | <ul style="list-style-type: none"> 9 Miscellaneous dangerous substances and articles 9 |
| <ul style="list-style-type: none"> · ADR, ADN, IMDG, IATA · Class | <ul style="list-style-type: none"> Void |
| <ul style="list-style-type: none"> · Packing group · DOT · ADR, IMDG, IATA | <ul style="list-style-type: none"> III Void |
| <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: | <ul style="list-style-type: none"> No |
| <ul style="list-style-type: none"> · Special precautions for user | <ul style="list-style-type: none"> Not applicable. |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | <ul style="list-style-type: none"> Not applicable. |
| <ul style="list-style-type: none"> · Transport/Additional information: | <ul style="list-style-type: none"> Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| <ul style="list-style-type: none"> · UN "Model Regulation": | <ul style="list-style-type: none"> - |

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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

· **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**



GHS05

· **Signal word Danger**

· **Hazard-determining components of labeling:**

gallium

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- **Hazard statements**

- Causes skin irritation.

- Causes serious eye damage.

- **Precautionary statements**

- Wear protective gloves.

- Wear eye protection / face protection.

- Wash thoroughly after handling.

- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

- Continue rinsing.

- Immediately call a poison center/doctor.

- Specific treatment (see on this label).

- If skin irritation occurs: Get medical advice/attention.

- If on skin: Wash with plenty of water.

- Take off contaminated clothing and wash it before reuse.

- **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.

- **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.

- **Date of preparation / last revision** 06/23/2015 / 2

- **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

- 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)

- Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

- Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

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