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)
Trade name: Callisto Implant 78

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 2.5-<10%
  - 7440-05-3 palladium 2.5-<10%
  - 7440-74-6 indium 2.5-<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.
- 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.
Trade name: **Callisto Implant 78**

### 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**
      - **PEL**: Long-term value: 0.002 mg/m³
      - **REL**: Long-term value: 1 * 0.002** mg/m³
        - **Metal**: soluble salts, as Pt
        - ****soluble salts, as Pt
      - **TLV**: Long-term value: 1 * 0.002** mg/m³
        - **Metal**: soluble salts, as Pt
  - **7440-74-6 indium**
    - **REL**: Long-term value: 0.1 mg/m³
      - as In
    - **TLV**: Long-term value: 0.1 mg/m³
      - as In
- **Additional information**: The lists that were valid during the creation were used as basis.
40.1.5 · 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:
  · Odor 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/cm³ (146.872 lbs/gal)
· Relative density: Not determined.
· Vapor density: Not applicable.
· Evaporation rate: Not applicable.
· Solubility in / Miscibility with Water: Insoluble.
· Partition coefficient (n-octanol/water): Not determined.
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**:
    - **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.
  - **Additional ecological information**:
    - **General notes**: Generally not hazardous for water
    - **Results of PBT and vPvB assessment**:
      - **PBT**: Not applicable.
      - **vPvB**: Not applicable.
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: NA3077
- DOT: Void
- ADR, ADN, IMDG, IATA: Void
- UN proper shipping name: Void
- Transport hazard class(es)
  - DOT
    - Class: 9 Miscellaneous dangerous substances and articles
  - ADR, ADN, IMDG, IATA: Void
  - Class: 9
- Packing group
  - DOT: III
  - ADR, IMDG, IATA: Void
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user: Not applicable.
- Transport in bulk according to Annex II of MARPOL 73/78 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

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Trade name: Callisto Implant 78

<table>
<thead>
<tr>
<th>TSCA (Toxic Substances Control Act):</th>
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</thead>
<tbody>
<tr>
<td>7440-57-5 Gold</td>
</tr>
<tr>
<td>7440-22-4 silver</td>
</tr>
<tr>
<td>7440-50-8 copper</td>
</tr>
<tr>
<td>7440-06-4 platinum</td>
</tr>
<tr>
<td>7440-74-6 indium</td>
</tr>
<tr>
<td>7439-88-5 iridium</td>
</tr>
</tbody>
</table>

- 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.
### Trade name: Callisto Implant 78

**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 / 3
- **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)
  - Ox. Sol. 2: Oxidising Solids, Hazard Category 2
- **Data compared to the previous version altered.**