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 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 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
3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: Dental alloy

- Dangerous components:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-06-4</td>
<td>platinum</td>
</tr>
<tr>
<td>7440-05-3</td>
<td>palladium</td>
</tr>
<tr>
<td>7440-74-6</td>
<td>indium</td>
</tr>
</tbody>
</table>

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.
Trade name: Callisto Implant 78

- 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/m³
      - REL: 1* 0.002** mg/m³
        - Metal **soluble salts, as Pt
      - TLV: 1* 0.002** mg/m³
        - *metal **soluble salts, as Pt

(Contd. on page 4)
7440-74-6 indium

REL 0.1 mg/m³
and compounds, as In
TLV 0.1 mg/m³

· 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/cm³ (146.872 lbs/gal)
· Relative density Not determined.
Trade name: Callisto Implant 78

- Vapour density: Not applicable.
- Evaporation rate: Not applicable.
- Solubility in / Miscibility with Water: Insoluble.
- Partition coefficient (n-octanol/water): Not determined.
- Viscosity:
  - Dynamic: Not applicable.
  - Kinematic: 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.
- 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)
Trade name: Callisto Implant 78

- 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

- UN-Number
  - DOT
  - ADR, ADN, IMDG, IATA NA3077 Void

- UN proper shipping name
  - ADR, ADN, IMDG, IATA Void

- Transport hazard class(es)
  - DOT
  - Class 9 Miscellaneous dangerous substances and articles.
  - Label 9

- ADR, ADN, IMDG, IATA
  - Class Void

- 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 MARPOL73/78 and the IBC Code Not applicable.

- 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.
Trade name: **Callisto Implant 78**

### 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.
  - Keep any precaution to avoid mixing with combustibles.
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - Keep/Store away from clothing/combustible materials.

(Contd. of page 8)
Trade name: Callisto Implant 78

(Contd. of page 7)

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 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)