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

- **Product identifier**
  - **Trade name:** Callisto 75 Pd

- **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)
Trade name: Callisto 75 Pd

- **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: 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

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Chemical characteristic</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pd</td>
<td>palladium</td>
<td>25-100%</td>
</tr>
<tr>
<td>Sn</td>
<td>tin</td>
<td>1-&lt;10%</td>
</tr>
<tr>
<td>Ag</td>
<td>silver</td>
<td>1-&lt;10%</td>
</tr>
<tr>
<td>Ga</td>
<td>gallium</td>
<td>1-&lt;2.5%</td>
</tr>
<tr>
<td>In</td>
<td>indium</td>
<td>0.1-&lt;0.25%</td>
</tr>
<tr>
<td>Zn</td>
<td>Zink</td>
<td></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.
Trade name: Callisto 75 Pd

- After eye contact:
  Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
  Mechanical effects only.
- 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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-31-5 tin</td>
<td>PEL: 2 mg/m³ metal</td>
</tr>
</tbody>
</table>
Trade name: Callisto 75 Pd

<table>
<thead>
<tr>
<th>Substance</th>
<th>REL</th>
<th>TLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>7440-74-6 indium</td>
<td>0.01 mg/m³</td>
<td>0.01 mg/m³</td>
</tr>
<tr>
<td></td>
<td>0.1 mg/m³</td>
<td>0.1 mg/m³</td>
</tr>
</tbody>
</table>

- **REL** and **TLV** values are for metal and soluble compounds (as Ag) and metal: dust and fume respectively.

**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:** 1130–1296 °C (2066–2365 °F)
    - **Boiling point/Boiling range:** Undetermined.
- **Flash point:** Not applicable.
### 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.
35.0.51

· 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.
  · 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: NA3077

· ADR, ADN, IMDG, IATA: Void

· UN proper shipping name
  · ADR, ADN, IMDG, IATA: Void

· Transport hazard class(es)
  · DOT: Void
  · 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
### 35.0.51 Special precautions for user
- Not applicable.

### 35.0.52 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.

- **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.
  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)