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

- Product identifier
- Trade name: **Callisto Implant 60**
- 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)
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.

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>Palladium</td>
<td>25-100%</td>
</tr>
<tr>
<td>Silver</td>
<td>25-50%</td>
</tr>
<tr>
<td>Tin</td>
<td>1-10%</td>
</tr>
<tr>
<td>Indium</td>
<td>1-2.5%</td>
</tr>
<tr>
<td>Gallium</td>
<td>1-2.5%</td>
</tr>
</tbody>
</table>

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.
35.0.51

- 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:
    7440-22-4 silver
    PEL 0.01 mg/m³
    metal and soluble compounds (as Ag)

(Contd. on page 2)
Trade name: Callisto Implant 60

REL 0.01 mg/m³
TLV 0.1 mg/m³
metal: dust and fume

7440-31-5 tin

PEL 2 mg/m³
metal
REL 2 mg/m³
TLV 2 mg/m³
metal

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: 1100–1260 °C (2012–2300 °F)
      Boiling point/Boiling range: Undetermined.

    · Flash point: Not applicable.
Trade name: Callisto Implant 60

- 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): 10.8 g/cm³ (90.126 lbs/gal)
- 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.
- 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.
Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 12/19/2012
Version number 3
Reviewed on 12/19/2012

Trade name: Callisto Implant 60

(Contd. of page 5)

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
    - Class 9 Miscellaneous dangerous substances and articles.
    - Label 9
  - ADR, ADN, IMDG, IATA Void
  - Class Void
- Packing group
  - DOT
    - ADR, IMDG, IATA III Void
  - Environmental hazards:
    - Marine pollutant: No

(Contd. on page 7)
Trade name: Callisto Implant 60

- 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.
  - 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).
Trade name: Callisto Implant 60

· **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)