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

- **Product identifier**
- **Trade name:** Leo
- **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:**
  Ivoclav Vivadent Inc.
  175 Pineview Drive, Amherst, N.Y. 14228
  USA
  Tel. +1 800 533 6825
  Fax +1 716 691 2285

  Ivoclav 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 - Canute: 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).
  - **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: Health = 0
    FIRE: Fire = 0
    REACTIVITY: 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:

<table>
<thead>
<tr>
<th>Chemical Formula</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-05-3</td>
<td>Palladium</td>
<td>25-50%</td>
</tr>
<tr>
<td>7440-22-4</td>
<td>Silver</td>
<td>1-10%</td>
</tr>
<tr>
<td>7440-74-6</td>
<td>Indium</td>
<td>1-10%</td>
</tr>
<tr>
<td>7440-31-5</td>
<td>Tin</td>
<td>1-2.5%</td>
</tr>
<tr>
<td>7440-55-3</td>
<td>Gallium</td>
<td>1-2.5%</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.

(Contd. on page 3)
Safety Data Sheet
acc. to ISO/DIS 11014

Trade name: Leo

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.
· 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 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>7440-22-4 silver</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEL ( ) 0.01 mg/m³ metal and soluble compounds (as Ag)</td>
</tr>
</tbody>
</table>

(Contd. on page 4)
## Trade name: Leo

<table>
<thead>
<tr>
<th>REL ()</th>
<th>0.01 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLV ()</td>
<td>0.1 mg/m³</td>
</tr>
</tbody>
</table>

### Metal: dust and fume

**7440-74-6 indium**

<table>
<thead>
<tr>
<th>REL ()</th>
<th>0.1 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLV ()</td>
<td>0.1 mg/m³</td>
</tr>
</tbody>
</table>

**7440-31-5 tin**

<table>
<thead>
<tr>
<th>PEL ()</th>
<th>2 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>REL ()</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>TLV ()</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

### 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 breakthrough 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:** 1225–1315 °C (2237–2399 °F)
- **Boiling point/Boiling range:** Undetermined.

#### Flash point: Not applicable.
35.0.51

- **Flammability (solid, gaseous):** Not determined.
- **Auto igniting:** Product is not self-igniting.
- **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):** 13.3 g/cm³ (110.989 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.

### 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.

### 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.
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
- ADR, ADN, IMDG, IATA
- UN proper shipping name
- ADR, ADN, IMDG, IATA
- Transport hazard class(es)
  - DOT
  - Class
  - Label
- ADR, ADN, IMDG, IATA
- Class
- Packing group
  - DOT
  - ADR, IMDG, IATA
- Environmental hazards:
  - Marine pollutant: No
Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 12/19/2012
Reviewed on 12/19/2012
Version number 6

Trade name: Leo

- 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: Leo

- **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)