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

- **Product identifier**
- **Trade name:** IS-64

- **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

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: IS-64

- **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 extinguition: 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>Dangerous components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-05-3 palladium</td>
<td>25-100%</td>
</tr>
<tr>
<td>7440-22-4 silver</td>
<td>25-50%</td>
</tr>
<tr>
<td>7440-31-5 tin</td>
<td>1-&lt;10%</td>
</tr>
<tr>
<td>7440-55-3 gallium</td>
<td>1-&lt;2.5%</td>
</tr>
<tr>
<td>7440-74-6 indium</td>
<td>1-&lt;2.5%</td>
</tr>
<tr>
<td>7440-06-4 platinum</td>
<td>1-&lt;2.5%</td>
</tr>
</tbody>
</table>

### 4 First aid measures

- **Description of first aid measures**
  
  - **General information:** No special measures required.
  
  - **After inhalation:**
    Grind 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)
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:
  7440-22-4 silver
  PEL 0.01 mg/m³ metal and soluble compounds (as Ag)

(Contd. of page 2)
Trade name: IS-64

<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**

**7440-31-5 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>

**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>

**7440-06-4 platinum**

<table>
<thead>
<tr>
<th>PEL</th>
<th>0.002 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>REL</td>
<td>1* 0.002** mg/m³</td>
</tr>
<tr>
<td>TLV</td>
<td>1* 0.002** mg/m³</td>
</tr>
</tbody>
</table>

*metal **soluble salts, as Pt

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- **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).

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**9 Physical and chemical properties**

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
  - Form: Solid
  - Color: White
  - Odor: Odorless
### Trade name: IS-64

- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**
  - Melting point/Melting range: 1150–1280 °C (2102–2336 °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):** 11.2 g/cm³ (93.464 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.

(Contd. on page 6)
Trade name: IS-64

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
    - Class: Void
- Packing group
  - DOT
    - ADR, IMDG, IATA: III
  - ADR, IMDG, IATA: Void
# 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.
**Trade name: IS-64**

- **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](image)

- **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.

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**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)