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

- **1.1 Product identifier**
  - Trade name: **Euro 33 Implant**

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.
  - Application of the substance / the mixture:
    - Dental alloy
    - Manufacture of dental prothesis

- **1.3 Details of the supplier of the safety data sheet**
  - Manufacturer/Supplier:
    - Ivoclar Vivadent AG
    - Bendererstrasse 2
    - FL-9494 Schaan
    - PRINCIPALITY OF LIECHTENSTEIN
  - Tel: +423 235 35 35
  - Fax: +423 235 33 60
  - Further information obtainable from:
    - Regulatory Affairs
    - sds@ivoclarvivadent.com
  - **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
  - Classification according to Regulation (EC) No 1272/2008:
    - The product is not classified according to the CLP regulation.

- **2.2 Label elements**
  - Labelling according to Regulation (EC) No 1272/2008:
    - Void

- **2.3 Other hazards**
  - Avoid breathing of grinding dust and vapours. Melted material may cause burns.
  - Results of PBT and vPvB assessment:
    - PBT: Not applicable.
    - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
  - Description: Dental alloy

  Dangerous components:
  - CAS: 7440-22-4 EINECS: 231-131-3 silver substance with a Community workplace exposure limit 10-<25%
**Trade name: Euro 33 Implant**

CAS: 7440-74-6  |  indium  |  substance with a Community workplace exposure limit  |  2.5-<10%  
EINECS: 231-180-0

*Additional information: For the wording of the listed hazard phrases refer to section 16.*

---

## SECTION 4: First aid measures

4.1 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.

- **After swallowing:** Seek medical treatment.

4.2 Most important symptoms and effects, both acute and delayed

- No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

- No further relevant information available.

---

## SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing agents: The product is not flammable.

5.2 Special hazards arising from the substance or mixture

- No further relevant information available.

5.3 Advice for firefighters

- **Protective equipment:** No special measures required.

---

## SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Not required.

6.2 Environmental precautions:

- No special measures required.

- Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up:

- Pick up mechanically.

6.4 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.

---

## SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Only adequately trained personnel should handle this product.

- For use in dentistry only.

- Extractors are required on all machines used for thermal processing or splinter removal processes.

- **Information about fire- and explosion protection:** No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

- Storage:
  - **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
  - **Information about storage in one common storage facility:** Not required.
Trade name: Euro 33 Implant

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

- Additional information about design of technical facilities: No further data; see item 7.

Ingredients with limit values that require monitoring at the workplace:

<table>
<thead>
<tr>
<th>CAS</th>
<th>WEL</th>
<th>Long-term value:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4</td>
<td>silver</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>7440-74-6</td>
<td>indium</td>
<td>0.3 mg/m³</td>
</tr>
</tbody>
</table>

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

- Personal protective equipment:
  - General protective and hygienic measures:
    Usual hygienic measures for dental practice and dental laboratories.
    Keep away from foodstuffs, beverages and feed.
    Wash hands before breaks and at the end of work.
  - Respiratory protection: 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.
  - Material of 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).

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- General Information
  - Appearance:
    Form: Solid
    Colour: White
    Odour: Odourless
    Odour threshold: Not determined.
  - pH-value: Not applicable.
  - Change in condition
    Melting point/freezing point: 1215 - 1290 °C
    Initial boiling point and boiling range: Undetermined.
  - Flash point: Not applicable.
  - Flammability (solid, gas): Not determined.
## Trade name: Euro 33 Implant

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto-ignition temperature</td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td>Explosion limits:</td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Upper</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Density at 20 °C:</td>
<td>12.5 g/cm³</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Solubility in / Miscibility with water</td>
<td>Insoluble.</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Dynamic</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Kinematic</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Solvent content</td>
<td></td>
</tr>
<tr>
<td>Solids content</td>
<td>100 %</td>
</tr>
</tbody>
</table>

## SECTION 10: Stability and reactivity

- **10.1 Reactivity**: No further relevant information available.
- **10.2 Chemical stability**: Stable under normal handling and storage conditions.
- **10.3 Thermal decomposition / conditions to be avoided**: No decomposition if used according to specifications.
- **10.4 Conditions to avoid**: No further relevant information available.
- **10.5 Incompatible materials**: No further relevant information available.
- **10.6 Hazardous decomposition products**: None under normal conditions of storage and use.

## SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
  - **Acute toxicity**: Based on available data, the classification criteria are not met.
  - **Skin corrosion/irritation**: Based on available data, the classification criteria are not met.
  - **Serious eye damage/irritation**: Based on available data, the classification criteria are not met.
  - **Respiratory or skin sensitisation**: Based on available data, the classification criteria are not met.
  - **Additional toxicological information**: Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.
  - **Germ cell mutagenicity**: Based on available data, the classification criteria are not met.
  - **Carcinogenicity**: Based on available data, the classification criteria are not met.
  - **Reproductive toxicity**: Based on available data, the classification criteria are not met.
  - **STOT-single exposure**: Based on available data, the classification criteria are not met.
  - **STOT-repeated exposure**: Based on available data, the classification criteria are not met.
  - **Aspiration hazard**: Based on available data, the classification criteria are not met.
SECTION 12: Ecological information

12.1 Toxicity
- Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability: No further relevant information available.

12.3 Bioaccumulative potential: No further relevant information available.

12.4 Mobility in soil: No further relevant information available.

Additional ecological information:
- General notes: Generally not hazardous for water

12.5 Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
- Recommendation
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN-Number
- ADR/RID/ADN, ADN, IMDG, IATA: Void

14.2 UN proper shipping name
- ADR/RID/ADN, ADN, IMDG, IATA: Void

14.3 Transport hazard class(es)
- ADR/RID/ADN, ADN, IMDG, IATA Class: Void

14.4 Packing group
- ADR/RID/ADN, IMDG, IATA: Void

14.5 Environmental hazards:
- Not applicable.

14.6 Special precautions for user
- Not applicable.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
- Not applicable.

Transport/Additional information:
- Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

UN "Model Regulation":
- Void
SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- National regulations:
  - Other regulations, limitations and prohibitive regulations
    The product is a medical device according to the Directive 93/42/EEC.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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.

Relevant phrases
H272 May intensify fire; oxidiser.

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
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Ox. Sol. 2: Oxidizing solids – Category 2