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

- **1.1 Product identifier**
  - Trade name: Spartan

- **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** Manufacture of dental prothesis

- **1.3 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

- **Further information obtainable from:**
  - Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein
  - 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**
    - Ox. Sol. 2 H272 May intensify fire; oxidiser.

- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**
    - The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms**
  - ![GHS03](image)

- **Signal word** Danger

- **Hazard statements**
  - H272 May intensify fire; oxidiser.

- **Precautionary statements**
  - P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  - P221 Take any precaution to avoid mixing with combustibles.
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
  - P220 Keep/Store away from clothing/combustible materials.
  - P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.
  - P501 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.

- **2.3 Other hazards**
  - **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures
· Description: Dental alloy

· Dangerous components:

<table>
<thead>
<tr>
<th>CAS: 7440-05-3</th>
<th>EINECS: 231-115-6</th>
<th>palladium</th>
<th>Self-heat. 2, H252; Ox. Sol. 2, H272</th>
<th>50-100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 7440-50-8</td>
<td>EINECS: 231-159-6</td>
<td>copper</td>
<td>substance with a Community workplace exposure limit</td>
<td>≤10%</td>
</tr>
</tbody>
</table>

· Additional information: For the wording of the listed risk 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.
  Mechanical effects only.
· 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: Do not inhale explosion gases or combustion gases.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures Not required.
· 6.2 Environmental precautions: No special measures required.
· 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
  Extractors are required on all machines used for thermal processing or splinter removal processes.
- 7.2 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.
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Limit values</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-50-8 copper</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WEL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term value:</td>
<td>2** mg/m³</td>
<td></td>
</tr>
<tr>
<td>Long-term value:</td>
<td>0.2* 1** mg/m³</td>
<td></td>
</tr>
<tr>
<td>*fume **dusts and mists (as Cu)</td>
<td></td>
<td></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.
    - 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.
      - After use of gloves apply skin-cleaning agents and skin cosmetics.
  - Material of gloves
    - Mechanical processing:
      - Leather gloves
    - Strong material 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
### SECTION 10: Stability and reactivity

- **10.1 Reactivity**: No further relevant information available.
- **10.2 Chemical stability**: Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided**: No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**: No dangerous reactions known.
- **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:
  - Primary irritant effect:
    - on the skin: No irritant effect.
    - on the eye: No irritating effect.
  - Sensitisation: No sensitising effects known.

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(Contd. of page 3)
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.
- European waste catalogue
  - 20 01 40 metals
- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

*SECTION 14: Transport information

14.1 UN-Number
- ADR, ADN, IMDG, IATA Void
- 14.2 UN proper shipping name
- ADR, ADN, IMDG, IATA Void
- 14.3 Transport hazard class(es)
- ADR, ADN, IMDG, IATA Void
- 14.4 Packing group
- ADR, IMDG, IATA Void
- 14.5 Environmental hazards:
  - Marine pollutant: No
- 14.6 Special precautions for user
  - Not applicable.
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
  - Not applicable.
- Transport/Additional information:
  - Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

(Contd. on page 6)
Trade name: **Spartan**

(Contd. of page 5)

- **UN "Model Regulation":** -

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **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**
  H252 Self-heating in large quantities; may catch fire.
  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)
  Self-heat. 2: Self-Heating Substances and Mixtures, Hazard Category 2
  Ox. Sol. 2: Oxidising Solids, Hazard Category 2

- **Data compared to the previous version altered.**