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

- **Product identifier**
- **Trade name:** BioUniversal PdF
- **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

- **Further information obtainable from:**
  Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein
  Regulatory Affairs
  msds@ivoclarvivadent.com

- **Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
  Ox. Sol. 2 H272 May intensify fire; oxidiser.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
  O: Oxidising

- **Classification system:**
  The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **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/sparks/open flames/hot surfaces. - 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.

(Contd. on page 2)
Trade name: BioUniversal PdF

- Additional information: Void
- Information concerning particular hazards for human and environment:
  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.
- Other hazards
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: Mixture of substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance</th>
<th>Community workplace exposure limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 7440-22-4</td>
<td>silver</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>EINECS: 231-131-3</td>
<td>substance with a Community workplace exposure limit</td>
<td></td>
</tr>
<tr>
<td>CAS: 7440-06-4</td>
<td>platinum</td>
<td>3-&lt;10%</td>
</tr>
<tr>
<td>EINECS: 231-116-1</td>
<td>O R8</td>
<td></td>
</tr>
<tr>
<td>Ox. Sol. 2, H272</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS: 7440-50-8</td>
<td>copper</td>
<td>3-&lt;10%</td>
</tr>
<tr>
<td>EINECS: 231-159-6</td>
<td>substance with a Community workplace exposure limit</td>
<td></td>
</tr>
<tr>
<td>CAS: 7440-28-0</td>
<td>thallium</td>
<td>0.1-&lt;0.3%</td>
</tr>
<tr>
<td>EINECS: 231-138-1</td>
<td>T+ R26/28</td>
<td></td>
</tr>
<tr>
<td>R33-53</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Tox. 2, H300; Acute Tox. 2, H330; STOT RE 2, H373; Aquatic Chronic 4, H413</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Additional information: For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- Description of first aid measures
  - After inhalation: Grinding dust: Supply fresh air; consult doctor in case of complaints.
  - 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.
- 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.
Trade name: BioUniversal PdF

- Advice for firefighters
- Protective equipment: Do not inhale explosion gases or combustion gases.

### 6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
  Wear protective equipment. Keep unprotected persons away.
- 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.
  Only adequately trained personnel should handle this product.
  For use in dentistry only.
- Information about fire- and explosion protection: Keep ignition sources away - Do not smoke.
- 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.
  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 facilities: No further data; see item 7.
- Control parameters

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>WEL Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>Long-term value: 0.1 mg/m³</td>
</tr>
<tr>
<td>7440-06-4 platinum</td>
<td>Long-term value: 5 mg/m³</td>
</tr>
<tr>
<td>7440-50-8 copper</td>
<td>Short-term value: 2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Long-term value: 0.2 mg/m³</td>
</tr>
</tbody>
</table>

*Additional information: The lists valid during the making were used as basis.
- Exposure controls
- Personal protective equipment:
  General protective and hygienic measures:
  Wash hands before breaks and at the end of work.
  Usual hygienic measures for dental practice.
- Respiratory protection: Use respiratory protective device against the effects of fumes/dust/aerosol.
Trade name: BioUniversal PdF

- 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).

9 Physical and chemical properties

- Information on basic physical and chemical properties
- General Information
- Appearance:
  Form: Solid
  Colour: Yellow
- Odour: Odourless
- Odour threshold: Not determined.
- pH-value: Not applicable.

- Change in condition
  Melting point/Melting range: 910 – 970 °C
  Boiling point/Boiling range: Undetermined.

- Flash point: Not applicable.

- Flammability (solid, gaseous):
  Contact with combustible material may cause fire.

- Self-igniting:
  Product is not selfigniting.

- Danger of explosion:
  Not determined.

- Explosion limits:
  Lower: Not determined.
  Upper: Not determined.

- Vapour pressure: Not applicable.

- Density at 20 °C: 16.2 g/cm³
- 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.
36.0.5
· Solvent content:
  Organic solvents: 0.0 %
· Solids content: 100.0 %
· 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.

12 Ecological information
· Toxicity
  · Aquatic toxicity:
    No further relevant information available.
  · Persistence and degradability:
    No further relevant information available.
· Behaviour 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
  Must not be disposed together with household garbage. Do not allow product to reach sewage system.
  Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

(Contd. of page 4)
### 14 Transport information

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN-Number</td>
<td>Void</td>
</tr>
<tr>
<td>UN proper shipping name</td>
<td>Void</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td>Void</td>
</tr>
<tr>
<td>Packing group</td>
<td>Void</td>
</tr>
<tr>
<td>Environmental hazards</td>
<td>Yes</td>
</tr>
<tr>
<td>Special precautions for user</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>UN &quot;Model Regulation&quot;</td>
<td>-</td>
</tr>
</tbody>
</table>

### 15 Regulatory information

- 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 EC-directive 93/42/EEC.
- 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.

**Relevant phrases**

- **H272** May intensify fire; oxidiser.
- **H300** Fatal if swallowed.
- **H330** Fatal if inhaled.
- **H373** May cause damage to organs through prolonged or repeated exposure.
- **H413** May cause long lasting harmful effects to aquatic life.
- **R26/28** Very toxic by inhalation and if swallowed.
- **R33** Danger of cumulative effects.
- **R53** May cause long-term adverse effects in the aquatic environment.
- **R8** Contact with combustible material may cause fire.
Trade name: BioUniversal PdF

- **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 Harmonized System of Classification and Labelling of Chemicals

- *Data compared to the previous version altered.*