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

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

- **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:
  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
  R8: 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 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.
Trade name: BioUniversal PKF

- 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.
- Dangerous components:

<table>
<thead>
<tr>
<th>CAS:</th>
<th>EINECS:</th>
<th>Substance</th>
<th>Exposure limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4</td>
<td>231-131-3</td>
<td>silver with a Community workplace exposure limit</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>7440-06-4</td>
<td>231-116-1</td>
<td>platinum</td>
<td>3-&lt;10%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ox. Sol. 2, H272</td>
<td></td>
</tr>
<tr>
<td>7440-28-0</td>
<td>231-138-1</td>
<td>thallium</td>
<td>0.3-&lt;1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute Tox. 2, H300; Acute Tox. 2, H330; STOT RE 2, H373; Aquatic Chronic 4, H413</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.
  - 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:
  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
- Ingredients with limit values that require monitoring at the workplace:
  7440-22-4 silver
  WEL (L) Long-term value: 0.1 mg/m³
  7440-06-4 platinum
  WEL (L) Long-term value: 5 mg/m³
- 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.
  - 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:
### Trade name: BioUniversal PKF

(Contd. of page 3)

- **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:** Solid
    - **Colour:** Yellow
    - **Odour:** Odourless
    - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.
  - **Change in condition**
    - Melting point/Melting range: 945–1035 °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:** 16.8 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.
  - **Solvent content:**
    - Organic solvents: 0.0 %
  - **Solids content:** 100.0 %
  - **Other information**
    - No further relevant information available.

(Contd. on page 5)
## 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.
- **European waste catalogue**
  - 20 01 40 metals
- **Uncleaned packaging**
- **Recommendation**: Disposal must be made according to official regulations.
14 Transport information

- UN-Number
  - ADR, ADN, IMDG, IATA: Void
- UN proper shipping name
  - ADR, ADN, IMDG, IATA: Void
- Transport hazard class(es)
  - ADR, ADN, IMDG, IATA: Void
  - Class: Void
- Packing group
  - ADR, IMDG, IATA: Void
- Environmental hazards:
  - Marine pollutant: No
- 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
- 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.

- 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.