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

  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

2 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
36.0.5

- **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.

- **Additional information:** Void

- **Information pertaining to particular dangers for man 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.

- **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:** Mixture of the substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
<th>Dangerous components</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>10.0-&lt;25%</td>
</tr>
<tr>
<td>7440-06-4 platinum</td>
<td>1.0-&lt;10%</td>
</tr>
<tr>
<td>7440-28-0 thallium</td>
<td>0.1-&lt;1%</td>
</tr>
</tbody>
</table>

### 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.

(Contd. on page 3)
Trade name: BioUniversal PKF

- 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:
- 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 protection against explosions and fires: 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 systems: No further data; see item 7.
- Control parameters
  - Components with limit values that require monitoring at the workplace:

<table>
<thead>
<tr>
<th></th>
<th>PEL (mg/m³)</th>
<th>REL (mg/m³)</th>
<th>TLV (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>0.01</td>
<td>0.01</td>
<td>0.1</td>
</tr>
</tbody>
</table>
  metal and soluble compounds (as Ag) |
  metal: dust and fume |
Trade name: BioUniversal PKF

**7440-06-4 platinum**

<table>
<thead>
<tr>
<th></th>
<th>PEL ( )</th>
<th>REL ( )</th>
<th>TLV ( )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.002 mg/m³</td>
<td>1* 0.002** mg/m³</td>
<td>1* 0.002** mg/m³</td>
</tr>
<tr>
<td>soluble salts, as Pt</td>
<td>*Metal **soluble salts, as Pt</td>
<td>*metal **soluble salts, as Pt</td>
<td></td>
</tr>
</tbody>
</table>

**7440-28-0 thallium**

<table>
<thead>
<tr>
<th></th>
<th>PEL ( )</th>
<th>REL ( )</th>
<th>TLV ( )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.1 mg/m³</td>
<td>0.1 mg/m³</td>
<td>0.02* mg/m³</td>
</tr>
<tr>
<td>&amp; soluble compounds, as TI; Skin</td>
<td>&amp; soluble compounds, as Ti; Skin</td>
<td>&amp; soluble compounds, as Ti; *inh. fraction; Skin</td>
<td></td>
</tr>
</tbody>
</table>

- **Additional information:** The lists that were valid during the creation 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.
    - **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 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).

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**9 Physical and chemical properties**

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - Form: Solid
      - Color: Yellow
  - **Odor:** Odorless
  - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.

  - **Change in condition**
    - Melting point/Melting range: 945–1035 °C (1733–1895 °F)
    - Boiling point/Boiling range: Undetermined.
36.0.5

- Flash point: Not applicable.
- Flammability (solid, gaseous): Contact with combustible material may cause fire.
- Auto igniting: Product is not selfigniting.
- Danger of explosion: Not determined.
- Explosion limits:
  - Lower: Not determined.
  - Upper: Not determined.
- Vapor pressure: Not applicable.
- Density at 20 °C (68 °F): 16.8 g/cm³ (140.196 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:
  - 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.

(Contd. on page 6)
Trade name: BioUniversal PKF

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:
    - Must not be disposed of 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.
  - Uncleaned packagings:
    - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - DOT, ADR, ADN, IMDG, IATA Void

- UN proper shipping name
  - DOT, ADR, ADN, IMDG, IATA Void

- Transport hazard class(es)
  - DOT, ADR, ADN, IMDG, IATA Void
  - Class Void

- Packing group
  - DOT, 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.
Trade name: BioUniversal PKF

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
  - TSCA (Toxic Substances Control Act):
    - 7440-57-3 Gold
    - 7440-22-4 silver
    - 7440-06-4 platinum
    - 7440-16-6 rhodium
    - 7440-25-7 tantalum
    - 7439-89-6 iron
    - 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
    - TLV (Threshold Limit Value established by ACGIH)
      - 7440-16-6 rhodium A4
    - NIOSH-Ca (National Institute for Occupational Safety and Health)
      None of the ingredients is listed.
    - 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

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.

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)

* Data compared to the previous version altered.