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 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

(Contd. on page 2)
Safety Data Sheet
acc. to OSHA HCS

Trade name: BioUniversal PdF

- 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.
- Dangerous components:
  7440-22-4 silver 10-<25%
  7440-06-4 platinum 1-<10%
  7440-50-8 copper 1-<10%
  7440-74-6 indium 1-<2.5%
  7440-28-0 thallium 0.1-<1%

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.

(Contd. on page 3)
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>Component</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>PEL ( ) 0.01 mg/m³ metal and soluble compounds (as Ag)</td>
</tr>
</tbody>
</table>

*
### Safety Data Sheet

**Trade name:** BioUniversal PdF

<table>
<thead>
<tr>
<th>Substance</th>
<th>REL</th>
<th>TLV</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-06-4 platinum</td>
<td>0.01 mg/m³</td>
<td>0.1 mg/m³</td>
<td>metal: dust and fume</td>
</tr>
<tr>
<td>7440-50-8 copper</td>
<td>0.002 mg/m³</td>
<td>1* 0.1** mg/m³</td>
<td>soluble salts, as Pt</td>
</tr>
<tr>
<td>7440-74-6 indium</td>
<td>0.1 mg/m³</td>
<td>0.02* mg/m³</td>
<td>and compounds, as In</td>
</tr>
<tr>
<td>7440-28-0 thallium</td>
<td>0.1 mg/m³</td>
<td>0.1 mg/m³</td>
<td>&amp; soluble compounds, as Ti; Skin</td>
</tr>
</tbody>
</table>

- **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.
9 Physical and chemical properties

- Information on basic physical and chemical properties
- General Information
  - Appearance: Solid
  - Form: Solid
  - Color: Yellow
  - Odor: Odorless
  - Odour threshold: Not determined.
- pH-value: Not applicable.
- Change in condition
  - Melting point/Melting range: 910 – 970 °C (1670 – 1778 °F)
  - Boiling point/Boiling range: Undetermined.
- 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): 16.2 g/cm³ (135.189 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.
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.
  - Carcinogenic categories
    - NTP (National Toxicology Program)
      None of the ingredients is listed.

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

(Contd. on page 7)
### 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
      - 7440-50-8 copper
    - **TSCA (Toxic Substances Control Act):**
      - 7440-57-5 Gold
      - 7440-22-4 silver
      - 7440-06-4 platinum
      - 7440-50-8 copper
      - 7440-74-6 indium
      - 7440-25-7 tantalum
      - 7439-88-5 iridium
      - 7439-89-6 iron
  - **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.
36.0.5

· Carcinogenic categories
  · EPA (Environmental Protection Agency)
    7440-22-4 silver D
    7440-50-8 copper D
  · TLV (Threshold Limit Value established by ACGIH)
    None of the ingredients is listed.
  · 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.