1 Identification

- **Product identifier**
- **Trade name**: BioUniversal
- **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
- **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 SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
  Ox. Sol. 2 H272 May intensify fire; oxidizer.
- **Label elements**
- **GHS label elements**
The product is classified and labeled 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.
  Take any precaution to avoid mixing with combustibles.
  Wear protective gloves / eye protection / face protection.
  Keep/Store away from clothing/combustible materials.

(Contd. on page 2)
40.1.5 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:
  - 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 Health = 0
    - FIRE Fire = 0
    - REACTIVITY 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: Dental alloy

- Dangerous components:
  - 7440-05-3 palladium 25-50%

4 First-aid measures

- 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.

- 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 Fire-fighting 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

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

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **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.
  - **Information about protection against explosions and fires:** No special measures required.
- **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.
- **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:**
  The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
  - **General protective and hygienic measures:** 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

<table>
<thead>
<tr>
<th>Information on basic physical and chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Information</td>
</tr>
<tr>
<td>Appearance:</td>
</tr>
<tr>
<td><strong>Form:</strong> Solid</td>
</tr>
<tr>
<td><strong>Color:</strong> Yellow</td>
</tr>
<tr>
<td><strong>Odor:</strong> Odorless</td>
</tr>
<tr>
<td><strong>Odour threshold:</strong> Not determined.</td>
</tr>
<tr>
<td><strong>pH-value:</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Change in condition</strong></td>
</tr>
<tr>
<td><strong>Melting point/Melting range:</strong> 1020–1100 °C (1868–2012 °F)</td>
</tr>
<tr>
<td><strong>Boiling point/Boiling range:</strong> Undetermined.</td>
</tr>
<tr>
<td><strong>Flash point:</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Flammability (solid, gaseous):</strong> Not determined.</td>
</tr>
<tr>
<td><strong>Auto igniting:</strong> Product is not selfigniting.</td>
</tr>
<tr>
<td><strong>Danger of explosion:</strong> Product does not present an explosion hazard.</td>
</tr>
<tr>
<td><strong>Explosion limits:</strong></td>
</tr>
<tr>
<td><strong>Lower:</strong> Not determined.</td>
</tr>
<tr>
<td><strong>Upper:</strong> Not determined.</td>
</tr>
<tr>
<td><strong>Vapor pressure:</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Density at 20 °C (68 °F):</strong> 14.5 g/cm³ (121.003 lbs/gal)</td>
</tr>
<tr>
<td><strong>Relative density:</strong> Not determined.</td>
</tr>
<tr>
<td><strong>Vapour density:</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Evaporation rate:</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Solubility in / Miscibility with Water:</strong> Insoluble.</td>
</tr>
<tr>
<td><strong>Partition coefficient (n-octanol/water):</strong> Not determined.</td>
</tr>
<tr>
<td><strong>Viscosity:</strong></td>
</tr>
<tr>
<td><strong>Dynamic:</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Kinematic:</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Solvent content:</strong></td>
</tr>
<tr>
<td><strong>Solids content:</strong> 100 %</td>
</tr>
<tr>
<td><strong>Other information</strong> No further relevant information available.</td>
</tr>
</tbody>
</table>

### 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. |
40.1.5

· 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.

· Carcinogenic categories
  · NTP (National Toxicology Program)
    None of the ingredients is listed.
  · OSHA-Ca (Occupational Safety & Health Administration)
    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:
    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: NA3077
· DOT: Void
· ADR, ADN, IMDG, IATA: Void

(Contd. on page 6)
· **Transport hazard class(es)**
  - **DOT**
  - **Class**: 9 Miscellaneous dangerous substances and articles
  - **Label**: 9

· **ADR, ADN, IMDG, IATA**
  - **Class**: Void

· **Packing group**
  - **DOT**: III
  - **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.

· **Transport/Additional information**: Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

· **UN "Model Regulation"**: -

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**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
  - 7440-50-8 copper
  - 7440-06-4 platinum
  - 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.
40.1.5

- **Chemicals known to cause developmental toxicity:**
  None of the ingredients is listed.

- **Carcinogenic categories**
  
  **EPA (Environmental Protection Agency)**
  - 7440-22-4 silver
  - 7440-50-8 copper
  
  **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.

- **GHS label elements**
  The product is classified and labeled 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.
  Take any precaution to avoid mixing with combustibles.
  Wear protective gloves / 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 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.

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**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.

- **Date of preparation / last revision 06/23/2015 / 4**

  **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
  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)
  NFPA: National Fire Protection Association (USA)
  HMIS: Hazardous Materials Identification System (USA)
Trade name: **BioUniversal**

*Ox. Sol. 2: Oxidising Solids, Hazard Category 2*

* *Data compared to the previous version altered.*