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

- **Product identifier**
- **Trade name:** BioUniversal E
- **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)
Trade name: BioUniversal E

- **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:**
  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 | Fire | Reactivity |
    |--------|------|------------|
    | 0      | 0    | 0          |
  - **HMIS-ratings (scale 0 - 4)**
    | HEALTH | FIRE | REACTIVITY |
    | 0      | 0    | 0          |

- **Other hazards**
  - **Results of PBT and vPvB assessment**
    - PBT: Not applicable.
    - vPvB: Not applicable.

### Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Dental alloy

#### Dangerous components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Chemical</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4</td>
<td>silver</td>
<td>25-100%</td>
</tr>
<tr>
<td>7440-05-3</td>
<td>palladium</td>
<td>25-50%</td>
</tr>
<tr>
<td>7440-31-5</td>
<td>tin</td>
<td>1-&lt;10%</td>
</tr>
<tr>
<td>7440-74-6</td>
<td>indium</td>
<td>1-≤2.5%</td>
</tr>
</tbody>
</table>

### 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.

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

- 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: 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:
    - 7440-22-4 silver
      - PEL: 0.01 mg/m³
        - metal and soluble compounds (as Ag)
      - REL: 0.01 mg/m³
      - TLV: 0.1 mg/m³
        - metal: dust and fume

(Contd. on page 4)
### 7440-31-5 tin

<table>
<thead>
<tr>
<th>Control Limits</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEL</td>
<td>2 mg/m³ metal</td>
</tr>
<tr>
<td>REL</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>TLV</td>
<td>2 mg/m³ metal</td>
</tr>
</tbody>
</table>

### 7440-74-6 indium

<table>
<thead>
<tr>
<th>Control Limits</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>REL</td>
<td>0.1 mg/m³ and compounds, as In</td>
</tr>
<tr>
<td>TLV</td>
<td>0.1 mg/m³</td>
</tr>
</tbody>
</table>

### Additional information:
The lists that were valid during the creation were used as basis.

### Exposure controls

#### General protective and hygienic measures:

- 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 breakthrough 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:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>Whitish</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not determined.</td>
</tr>
</tbody>
</table>

**pH-value:**

Not applicable.

#### Change in condition

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting point/Melting range</td>
<td>1100–1150 °C (2012–2102 °F)</td>
</tr>
<tr>
<td>Boiling point/Boiling range</td>
<td>Undetermined.</td>
</tr>
</tbody>
</table>

#### Flash point:

Not applicable.

#### Flammability (solid, gaseous):

Not determined.

#### Auto igniting:

Product is not selfigniting.

#### Danger of explosion:

Product does not present an explosion hazard.
Trade name: BioUniversal E

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

- Vapor pressure: Not applicable.

- Density at 20 °C (68 °F): 10.7 g/cm³ (89.292 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:
  - Solids content: 100 %

- 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.
- Carcinogenic categories
  - NTP (National Toxicology Program)
    None of the ingredients is listed.

12 Ecological information

- Toxicity
  - Aquatic toxicity: No further relevant information available.
Trade name: BioUniversal E

- **Persistence and degradability**: No further relevant information available.
- **Behavior in environmental systems**: No further relevant information available.
- **Mobility in soil**: No further relevant information available.
- **Bioaccumulative potential**: No further relevant information available.
- **General notes**: Generally not hazardous for water.
- **Results of PBT and vPvB assessment**: 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

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN-Number</td>
<td>NA3077</td>
</tr>
<tr>
<td>DOT</td>
<td>Void</td>
</tr>
<tr>
<td>ADR, ADN, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>UN proper shipping name</td>
<td>Void</td>
</tr>
<tr>
<td>ADR, ADN, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td>9 Miscellaneous dangerous substances and articles.</td>
</tr>
<tr>
<td>DOT has Class</td>
<td>9</td>
</tr>
<tr>
<td>Label</td>
<td></td>
</tr>
<tr>
<td>ADR, ADN, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>Class</td>
<td>III</td>
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<tr>
<td>ADR, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>Packing group</td>
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</tr>
<tr>
<td>DOT</td>
<td>III</td>
</tr>
<tr>
<td>ADR, IMDG, IATA</td>
<td>Void</td>
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<tr>
<td>Environmental hazards:</td>
<td></td>
</tr>
<tr>
<td>Marine pollutant:</td>
<td>No</td>
</tr>
<tr>
<td>Special precautions for user</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Transport in bulk according to Annex II of</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>MARPOL73/78 and the IBC Code</td>
<td></td>
</tr>
<tr>
<td>UN &quot;Model Regulation&quot;:</td>
<td></td>
</tr>
</tbody>
</table>

(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
  7440-50-8 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.

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

- 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)