

**Material Safety Data Sheet**  
acc. to ISO 11014

Printing date 06/23/2015

Version number 4

Reviewed on 05/06/2015


**1 Identification**

- **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 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.

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  - **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.

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In case of fire: Use for extinction: CO<sub>2</sub>, 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)**



· **HMSI-ratings (scale 0 - 4)**

|            |   |                |
|------------|---|----------------|
| HEALTH     | 0 | Health = 0     |
| FIRE       | 0 | Fire = 0       |
| REACTIVITY | 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:** Dental alloy

· **Dangerous components:**

|           |           |        |
|-----------|-----------|--------|
| 7440-22-4 | silver    | 30-60% |
| 7440-05-3 | palladium | 25-40% |
| 7440-31-5 | tin       | 3-7%   |
| 7440-74-6 | indium    | 1-1.5% |

### 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.

· **After swallowing:** Seek medical treatment.

· **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.

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### 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.*
- **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

EL Short-term value: 0.03 mg/m<sup>3</sup>  
 Long-term value: 0.01 mg/m<sup>3</sup>  
 as Ag

EV Long-term value: 0.1 \* 0.01 \*\* mg/m<sup>3</sup>  
 \*metal; \*\*water-soluble compounds (as silver)

#### 7440-31-5 tin

EL Long-term value: 2 mg/m<sup>3</sup>  
 metal

EV Long-term value: 2 \* 0.1 \*\* mg/m<sup>3</sup>  
 \*metal, oxide, inorg. compds.; \*\*org. compds.: Skin

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### 7440-74-6 indium

|    |   |
|----|---|
| EL | Long-term value: 0.1 mg/m <sup>3</sup><br>as In; ACGIH 2B |
| EV | Long-term value: 0.1 mg/m <sup>3</sup><br>as indium       |

- **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.
- **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:**

|                         |                 |
|-------------------------|-----------------|
| <b>Form:</b>            | Solid           |
| <b>Color:</b>           | Whitish         |
| <b>Odor:</b>            | Odorless        |
| <b>Odour threshold:</b> | Not determined. |
- **pH-value:** Not applicable.
- **Change in condition**

|                                     |               |
|-------------------------------------|---------------|
| <b>Melting point/Melting range:</b> | 1100–1150 °C  |
| <b>Boiling point/Boiling range:</b> | Undetermined. |
- **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.
- **Explosion limits:**

|               |                 |
|---------------|-----------------|
| <b>Lower:</b> | Not determined. |
| <b>Upper:</b> | Not determined. |
- **Vapor pressure:** Not applicable.
- **Density at 20 °C:** 10.7 g/cm<sup>3</sup>
- **Relative density** Not determined.

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|   |  |
|---|--|
| · <b>Vapour density</b>                           | Not applicable.                            |
| · <b>Evaporation rate</b>                         | Not applicable.                            |
| · <b>Solubility in / Miscibility with Water:</b>  | Insoluble.                                 |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| · <b>Viscosity:</b>                               |  |
| <b>Dynamic:</b>                                   | Not applicable.                            |
| <b>Kinematic:</b>                                 | Not applicable.                            |
| · <b>Solvent content:</b>                         |  |
| <b>Solids content:</b>                            | 100 %                                      |
| · <b>Other information</b>                        | 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.

#### · **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

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- **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

- |  |  |
|--|--|
| · <b>UN-Number</b>   |  |
| · <b>DOT</b>   | NA3077   |
| · <b>TDG, ADN, IMDG, IATA</b>  | Void   |
| · <b>UN proper shipping name</b>   |  |
| · <b>TDG, ADN, IMDG, IATA</b>  | Void   |
| · <b>Transport hazard class(es)</b>  |  |
| · <b>DOT</b>   |  |
| · <b>Class</b>   | 9 Miscellaneous dangerous substances and articles                              |
| · <b>Label</b>   | 9  |
| · <b>TDG, ADN, IMDG, IATA</b>  |  |
| · <b>Class</b>   | Void   |
| · <b>Packing group</b>   |  |
| · <b>DOT</b>   | III  |
| · <b>TDG, IMDG, IATA</b>   | Void   |
| · <b>Environmental hazards:</b>  |  |
| · <b>Marine pollutant:</b>   | No   |
| · <b>Special precautions for user</b>  | Not applicable.  |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable.  |
| · <b>Transport/Additional information:</b>                                       | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>  | -  |

### 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.

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· **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.

· **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: CO<sub>2</sub>, powder or water spray.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **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.*

**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 / 3
- **Abbreviations and acronyms:**  
*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)  
Ox. Sol. 2: Oxidising Solids, Hazard Category 2*
- **\* Data compared to the previous version altered.**

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