

## Safety Data Sheet according to WHS Regulations

Printing date 29.08.2022

Version number 4

Revision: 29.08.2022

Hazardous according to criteria of Australian Safety and Compensation Council.

### 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 prosthesis
- **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
- **Importer:**  
Ivoclar Vivadent Pty. Ltd.  
1- 5 Overseas Drive  
Noble Park North VIC 3174  
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

### 2 Hazard(s) Identification

- **Classification of the substance or mixture**  
Ox. Sol. 2 H272 May intensify fire; oxidiser.
- **Label elements**
- **GHS label elements**  
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**



GHS03

- **Signal word** *Danger*
- **Hazard statements**  
May intensify fire; oxidiser.
- **Precautionary statements**  
Keep away from heat. - No smoking.  
Keep/Store away from clothing/combustible materials.  
Take any precaution to avoid mixing with combustibles.  
Wear protective gloves/protective clothing/eye protection/face protection.  
In case of fire: Use CO2, powder or water spray to extinguish.  
Dispose of contents/container in accordance with local/regional/national/international regulations.

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· **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.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### 3 Composition and Information on Ingredients

· **Chemical characterisation:** Mixtures

· **Description:** Dental alloy

· **Dangerous components:**

CAS: 7440-22-4	silver		50-100%
CAS: 7440-05-3	palladium	Ox. Sol. 2, H272	25-50%
CAS: 7440-31-5	tin		2.5-10%
CAS: 7440-74-6	indium		<2.5%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 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.

### 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.

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· **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 fire - and explosion protection:** 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 and personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

**CAS: 7440-22-4 silver**

WES Long-term value: 0.1 mg/m<sup>3</sup>

**CAS: 7440-31-5 tin**

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

**CAS: 7440-74-6 indium**

WES Long-term value: 0.1 mg/m<sup>3</sup>  
as In

· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Usual hygienic measures for dental practice and dental laboratories.

· **Respiratory protection:** 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 material 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.

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· **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:**

Form:	Solid
Colour:	Whitish
Odour:	Odourless
Odour threshold:	Not determined.

· **pH-value:** Not applicable.· **Change in condition**

Melting point/freezing point:	1100–1150 °C
Initial boiling point and boiling range:	Undetermined.

· **Flash point:** Not applicable.· **Flammability (solid, gas):** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.· **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

· **Vapour pressure:** Not applicable.

Density at 20 °C:	10.7 g/cm <sup>3</sup>
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 %
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· **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.

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- **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**
- **Specific symptoms in biological assay:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:**  
Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** 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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |  |      |
|--|------|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>ADG, ADN, IMDG, IATA</b></li> </ul>  | Void |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>ADG, ADN, IMDG, IATA</b></li> </ul>                            | Void |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>ADG, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void |
| <ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>ADG, IMDG, IATA</b></li> </ul>   | Void |

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· <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 Marpol 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>	Void

### 15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Industrial Chemicals**

CAS: 7440-57-5 Gold

CAS: 7440-22-4 silver

CAS: 7440-50-8 copper

CAS: 7440-06-4 platinum

CAS: 7440-74-6 indium

CAS: 7439-88-5 iridium

· **Standard for the Uniform Scheduling of Medicines and Poisons**

CAS: 7440-22-4 silver

S2

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS03

· **Signal word** Danger

· **Hazard statements**

May intensify fire; oxidiser.

· **Precautionary statements**

Keep away from heat. - No smoking.

Keep/Store away from clothing/combustible materials.

Take any precaution to avoid mixing with combustibles.

Wear protective gloves/protective clothing/eye protection/face protection.

In case of fire: Use CO2, powder or water spray to extinguish.

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

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category** P8 OXIDISING LIQUIDS AND SOLIDS

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t

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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.*
- **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.*

- **Relevant phrases**  
*H272 May intensify fire; oxidiser.*
- **Contact:**
- **Abbreviations and acronyms:**  
*ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)*  
*IMDG: International Maritime Code for Dangerous Goods*  
*IATA: International Air Transport Association*  
*ELINECS: European Inventory of Existing Commercial Chemical Substances*  
*ELINCS: European List of Notified Chemical Substances*  
*CAS: Chemical Abstracts Service (division of the American Chemical Society)*  
*PBT: Persistent, Bioaccumulative and Toxic*  
*vPvB: very Persistent and very Bioaccumulative*  
*Ox. Sol. 2: Oxidizing solids – Category 2*

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