

# Safety Data Sheet

## acc. to ISO 11014

Printing date 06/12/2013

Version number 5

Reviewed on 06/12/2013

### 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.

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  - **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.

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  - **Label elements**
  - **GHS label elements**  
The product is classified and labelled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms**
- 

GHS03
- **Signal word** Danger

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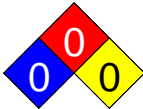
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- **Hazard statements**  
May intensify fire; oxidizer.
  - **Precautionary statements**  
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.  
Take any precaution to avoid mixing with combustibles.  
Wear protective gloves/protective clothing/eye protection/face protection.  
Keep/Store away from clothing/combustible materials.  
In case of fire: Use for extinction: CO<sub>2</sub>, 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 |

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	3-<10%
7440-50-8	copper	3-<10%
7440-74-6	indium	1-<2.5%

### 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.
- **After swallowing:** Seek medical treatment.

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- **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**  
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:**

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
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EV	0.1* 0.01** mg/m <sup>3</sup> *metal; **water-soluble compounds (as silver)
<b>7440-06-4 platinum</b>	
EL	1* 0.002** mg/m <sup>3</sup> *metal; **soluble salts (as Pt): S
EV	1* 0.002** mg/m <sup>3</sup> *metal; **water-soluble compounds (as Pt)
<b>7440-50-8 copper</b>	
EL	1* 0.2** mg/m <sup>3</sup> *dusts and mists; **fume
EV	0.2* 1** mg/m <sup>3</sup> as copper, *fume; **dust and mists
<b>7440-74-6 indium</b>	
EL	0.1 mg/m <sup>3</sup>
EV	0.1 mg/m <sup>3</sup> 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:**

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.

· **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

**Color:** Yellow

· **Odor:** Odorless

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

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· <b>Change in condition</b>	
<i>Melting point/Melting range:</i>	910 – 970 °C
<i>Boiling point/Boiling range:</i>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gaseous):</b>	Contact with combustible material may cause fire.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Not determined.
· <b>Explosion limits:</b>	
<i>Lower:</i>	Not determined.
<i>Upper:</i>	Not determined.
· <b>Vapor pressure:</b>	Not applicable.
· <b>Density at 20 °C:</b>	16.2 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <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>	
<i>Dynamic:</i>	Not applicable.
<i>Kinematic:</i>	Not applicable.
· <b>Solvent content:</b>	
<i>Organic solvents:</i>	0.0 %
<i>Solids content:</i>	100.0 %
· <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.

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- **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

- |                                       |                 |
|---------------------------------------|-----------------|
| · <b>UN-Number</b>                    |                 |
| · <b>DOT, TDG, ADN, IMDG, IATA</b>    | Void            |
| · <b>UN proper shipping name</b>      |                 |
| · <b>DOT, TDG, ADN, IMDG, IATA</b>    | Void            |
| · <b>Transport hazard class(es)</b>   |                 |
| · <b>DOT, TDG, ADN, IMDG, IATA</b>    |                 |
| · <b>Class</b>                        | Void            |
| · <b>Packing group</b>                |                 |
| · <b>DOT, TDG, IMDG, IATA</b>         | Void            |
| · <b>Environmental hazards:</b>       |                 |
| · <b>Marine pollutant:</b>            | Yes             |
| · <b>Special precautions for user</b> | Not applicable. |

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· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**      *Not applicable.*

· **UN "Model Regulation":**      -

### 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.*

· **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.*

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· **Canadian substance listings:**

· **Canadian Domestic Substances List (DSL)**

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

· **Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 1%)**

7440-22-4	silver
7440-06-4	platinum
7440-50-8	copper
7440-74-6	indium

· **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: CO<sub>2</sub>, 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.

· **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:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)

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