

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/13/2013


Version number 5

Reviewed on 02/13/2013

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.
- **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*

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Trade name: **BioUniversal PdF**

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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: CO₂, powder or water spray.

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

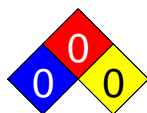
- **Additional information:** Void

- **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 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:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

7440-22-4	silver	10-<25%
7440-06-4	platinum	1-<10%
7440-50-8	copper	1-<10%
7440-74-6	indium	1-≤2.5%
7440-28-0	thallium	0.1-<1%

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.

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- **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 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

PEL ()	0.01 mg/m ³ metal and soluble compounds (as Ag)
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REL ()	0.01 mg/m ³
TLV ()	0.1 mg/m ³ metal: dust and fume
7440-06-4 platinum	
PEL ()	0.002 mg/m ³ soluble salts, as Pt
REL ()	1* 0.002** mg/m ³ *Metal **soluble salts, as Pt
TLV ()	1* 0.002** mg/m ³ *metal **soluble salts, as Pt
7440-50-8 copper	
PEL ()	1* 0.1** mg/m ³ as Cu *dusts and mists **fume
REL ()	1* 0.1** mg/m ³ as Cu *dusts and mists **fume
TLV ()	1* 0.2** mg/m ³ *dusts and mists; **fume; as Cu
7440-74-6 indium	
REL ()	0.1 mg/m ³ and compounds, as In
TLV ()	0.1 mg/m ³
7440-28-0 thallium	
PEL ()	0.1 mg/m ³ & soluble compounds, as TI; Skin
REL ()	0.1 mg/m ³ & soluble compounds, as TI; Skin
TLV ()	0.02* mg/m ³ & soluble compounds, as Ti; *inh. fraction; Skin

· **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.

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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

Color: Yellow

- **Odor:** Odorless

- **Odour threshold:** Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/Melting range: 910 – 970 °C (1670 – 1778 °F)

Boiling point/Boiling range: Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Contact with combustible material may cause fire.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Not determined.

- **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

- **Vapor pressure:** Not applicable.

- **Density at 20 °C (68 °F):** 16.2 g/cm³ (135.189 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:**

Organic solvents: 0.0 %

Solids content: 100.0 %

- **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.

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- **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.
- **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

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Void

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

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· **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)

· *** Data compared to the previous version altered.**