

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 13.02.2013

Version number 5

Revision: 13.02.2013

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
- **Further information obtainable from:**
Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein
Regulatory Affairs
msds@ivoclarvivadent.com
- **Emergency telephone number:** *+423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)*

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Ox. Sol. 2 H272 May intensify fire; oxidiser.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
O; Oxidising
R8: 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 is according to the latest editions of the EU-lists, and extended by company and literature data.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS03

- **Signal word** *Danger*
- **Hazard statements**
H272 May intensify fire; oxidiser.
- **Precautionary statements**
 - P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.*
 - P221 Take any precaution to avoid mixing with combustibles.*
 - P280 Wear protective gloves/protective clothing/eye protection/face protection.*
 - P220 Keep/Store away from clothing/combustible materials.*
 - P370+P378 In case of fire: Use for extinction: CO₂, powder or water spray.*
 - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.*

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- **Additional information:** Void
- **Information concerning particular hazards for human 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.
- **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 substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 7440-22-4 EINECS: 231-131-3	silver substance with a Community workplace exposure limit	10-<25%
CAS: 7440-06-4 EINECS: 231-116-1	platinum O R8 Ox. Sol. 2, H272	3-<10%
CAS: 7440-50-8 EINECS: 231-159-6	copper substance with a Community workplace exposure limit	3-<10%
CAS: 7440-28-0 EINECS: 231-138-1	thallium T+ R26/28 R33-53 Acute Tox. 2, H300; Acute Tox. 2, H330; STOT RE 2, H373; Aquatic Chronic 4, H413	0.1-<0.3%

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

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.
- **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.

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- **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 fire - and explosion protection:** 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 facilities:** No further data; see item 7.
- **Control parameters**

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

7440-22-4 silver

WEL () Long-term value: 0.1 mg/m³

7440-06-4 platinum

WEL () Long-term value: 5 mg/m³

7440-50-8 copper

WEL () Short-term value: 2** mg/m³
Long-term value: 0.2* 1** mg/m³
*fume **dusts and mists (as Cu)

- **Additional information:** The lists valid during the making 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.
- **Respiratory protection:** Use respiratory protective device against the effects of fumes/dust/aerosol.

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- **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.
- **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:	Yellow
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/Melting range:	910 – 970 °C
Boiling point/Boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Contact with combustible material may cause fire.
- **Self-igniting:** Product is not selfigniting.
- **Danger of explosion:** Not determined.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure:** Not applicable.
- **Density at 20 °C:** 16.2 g/cm³
- **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.

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· 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.
- **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.

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:** 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 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.

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· **European waste catalogue**

20 01 40 metals

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**14 Transport information**· **UN-Number**· **ADR, ADN, IMDG, IATA** Void· **UN proper shipping name**· **ADR, ADN, IMDG, IATA** Void· **Transport hazard class(es)**· **ADR, ADN, IMDG, IATA**· **Class** Void· **Packing group**· **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**· **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.

· **Relevant phrases**

H272 May intensify fire; oxidiser.

H300 Fatal if swallowed.

H330 Fatal if inhaled.

H373 May cause damage to organs through prolonged or repeated exposure.

H413 May cause long lasting harmful effects to aquatic life.

R26/28 Very toxic by inhalation and if swallowed.

R33 Danger of cumulative effects.

R53 May cause long-term adverse effects in the aquatic environment.

R8 Contact with combustible material may cause fire.

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· 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

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

· * Data compared to the previous version altered.

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