

**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 PKF**
- **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: CO<sub>2</sub>, 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: 7440-28-0 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	0.3-<1%

- **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.
- **Advice for firefighters**
- **Protective equipment:** Do not inhale explosion gases or combustion gases.

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### 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:**

<b>7440-22-4 silver</b>	
WEL ()	Long-term value: 0.1 mg/m <sup>3</sup>
<b>7440-06-4 platinum</b>	
WEL ()	Long-term value: 5 mg/m <sup>3</sup>

- **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.
- **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:

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- 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:	945–1035 °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:	16.8 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:

Organic solvents: 0.0 %

Solids content: 100.0 %

· Other information: No further relevant information available.

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**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.

<b>European waste catalogue</b>	
20 01 40	metals

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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**14 Transport information**

· <b>UN-Number</b> · <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>UN proper shipping name</b> · <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>Packing group</b> · <b>ADR, 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>UN "Model Regulation":</b>	-

**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.

· **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.**