

## Safety Data Sheet in accordance with HSNO

Printing date 30.01.2020

Version number 5

Revision: 30.01.2020

### 1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** **Harmony PF**
- **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
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- **Importer:**  
Ivoclar Vivadent Ltd.  
12 Omega St, Rosedale, Auckland  
New Zealand  
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **Emergency telephone number:** 0800 764 766 (National Poison Centre - 24 hours / 7 days)

### 2 Hazards identification

- **Classification of the substance or mixture**  
The product is not classified, according to the Globally Harmonised System (GHS).

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- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **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/Information on ingredients

- **Chemical characterisation:** Mixtures
- **Description:** Dental alloy

· **Dangerous components:**

CAS: 7440-22-4 EINECS: 231-131-3	silver		10-25%
CAS: 7440-50-8 EINECS: 231-159-6	copper		2.5-10%

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CAS: 7440-06-4	platinum
EINECS: 231-116-1	

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Ox. Sol. 2, H272

2.5-10%

· **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.  
Use fire extinguishing methods suitable to surrounding conditions.
- **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.
- **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** Ensure good ventilation/exhaustion at the workplace.
- **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.

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- **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:**

CAS: 7440-22-4 silver

WES	Long-term value: 0.1* 0.01** mg/m <sup>3</sup> *metal; ** soluble compds., as Ag
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CAS: 7440-50-8 copper

WES	Long-term value: 0.2* 1** mg/m <sup>3</sup> *fume; **dusts and mists, as Cu
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CAS: 7440-06-4 platinum

WES	Long-term value: 1* 0.002** mg/m <sup>3</sup> *metal; **soluble salts, as Pt: sen
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- **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.
- **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:**

<b>Form:</b>	Solid
<b>Colour:</b>	Yellow
<b>Odour:</b>	Odourless
<b>Odour threshold:</b>	Not determined.

<b>pH-value:</b>	Not applicable.
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##### · **Change in condition**

<b>Melting point/freezing point:</b>	900 – 940 °C
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<b>Initial boiling point and boiling range:</b> Undetermined.	
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density at 20 °C:</b>	15.6 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>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<b>Solids content:</b>	100 %
· <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**
- **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.

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### 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

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

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### 15 Regulatory information

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

· New Zealand Inventory of Chemicals

CAS: 7440-22-4	silver
CAS: 7440-50-8	copper
CAS: 7440-06-4	platinum

· HSNO Approval numbers

CAS: 7440-22-4	silver	HSR003077
CAS: 7440-50-8	copper	HSR002948

· GHS label elements Void

· Hazard pictograms Void

· Signal word Void

· Hazard statements Void

· Directive 2012/18/EU

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

· 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.

· 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

EINECS: 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