

Safety Data Sheet
according to WHS Regulations

Printing date 30.01.2020

Version number 5

Revision: 30.01.2020

Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **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
- **Importer:**
Ivoclar Vivadent Pty. Ltd.
1- 5 Overseas Drive
Noble Park North VIC 3174
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

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

- **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 and Information on Ingredients

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

· **Dangerous components:**

| | | | |
|----------------|--------|--|---------|
| CAS: 7440-22-4 | silver | | 10-25% |
| CAS: 7440-50-8 | copper | | 2.5-10% |

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CAS: 7440-06-4 | platinum

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.
- **Further information about storage conditions:** None.

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· *Specific end use(s) No further relevant information available.*

8 Exposure controls and 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**NES Long-term value: 0.1 mg/m³WES Long-term value: 0.1 mg/m³**CAS: 7440-50-8 copper**NES Long-term value: 1* 0.2** mg/m³
*dust & mists (as Cu) **fumeWES Long-term value: 1* 0.2** mg/m³
*dust&mists **fume**CAS: 7440-06-4 platinum**NES Long-term value: 1 mg/m³WES Long-term value: 1 mg/m³· **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:**

Form: Solid

Colour: Yellow

· **Odour:** Odourless· **Odour threshold:** Not determined.· **pH-value:** Not applicable.

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| | |
|--|---|
| · Change in condition | |
| Melting point/freezing point: | 900 – 940 °C |
| Initial boiling point and boiling range: | Undetermined. |
| · Flash point: | Not applicable. |
| · Flammability (solid, gas): | Not determined. |
| · Auto-ignition temperature: | Product is not selfigniting. |
| · Explosive properties: | Product does not present an explosion hazard. |
| · Explosion limits: | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| · Vapour pressure: | Not applicable. |
| · Density at 20 °C: | 15.6 g/cm ³ |
| · 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: | |
| Solids content: | 100 % |
| · 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**
- **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

- | | |
|--|--|
| · UN-Number · ADG, ADN, IMDG, IATA | Void |
| · UN proper shipping name · ADG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class | Void |
| · Packing group · ADG, IMDG, IATA | Void |
| · Environmental hazards: · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | Void |

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15 Regulatory information

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

· **Australian Inventory of Chemical Substances**

| | |
|----------------|--------|
| CAS: 7440-22-4 | silver |
|----------------|--------|

| | |
|----------------|--------|
| CAS: 7440-50-8 | copper |
|----------------|--------|

| | |
|----------------|----------|
| CAS: 7440-06-4 | platinum |
|----------------|----------|

· **Standard for the Uniform Scheduling of Medicines and Poisons**

| | | |
|----------------|--------|----|
| CAS: 7440-22-4 | silver | S2 |
|----------------|--------|----|

· **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