

## Safety Data Sheet acc. to ISO/DIS 11014

Printing date 12/14/2012

Version number 4

Reviewed on 12/14/2012

### 1 Identification of the substance/mixture and of the company/undertaking

- **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 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**  
The product is not classified according to the Globally Harmonized System (GHS).

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- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **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.

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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.

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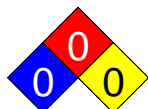
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- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



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:** Dental alloy

· **Dangerous components:**

7440-22-4	silver	10-<25%
7440-50-8	copper	1-<10%
7440-06-4	platinum	1-<10%

### 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 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** 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 protection against explosions and fires:** 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.
- **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 <sup>3</sup> metal and soluble compounds (as Ag)
REL ()	0.01 mg/m <sup>3</sup>
TLV ()	0.1 mg/m <sup>3</sup> metal: dust and fume

#### 7440-50-8 copper

PEL ()	1* 0.1** mg/m <sup>3</sup> as Cu *dusts and mists **fume
REL ()	1* 0.1** mg/m <sup>3</sup> as Cu *dusts and mists **fume
TLV ()	1* 0.2** mg/m <sup>3</sup> *dusts and mists; **fume; as Cu

#### 7440-06-4 platinum

PEL ()	0.002 mg/m <sup>3</sup> soluble salts, as Pt
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REL ()	1* 0.002** mg/m <sup>3</sup> *Metal **soluble salts, as Pt
TLV ()	1* 0.002** mg/m <sup>3</sup> *metal **soluble salts, as Pt

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** 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.
- **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.
- **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:** 900 – 940 °C (1652 – 1724 °F)
  - Boiling point/Boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not determined.
- **Auto igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
  - Lower:** Not determined.
  - Upper:** Not determined.
- **Vapor pressure:** Not applicable.
- **Density at 20 °C (68 °F):** 15.6 g/cm<sup>3</sup> (130.182 lbs/gal)
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.

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- |   |   |
|---|---|
| <b>· Solubility in / Miscibility with Water:</b>  | <i>Insoluble.</i>                                 |
| <b>· Partition coefficient (n-octanol/water):</b> | <i>Not determined.</i>                            |
| <b>· Viscosity:</b>                               |   |
| <b>Dynamic:</b>                                   | <i>Not applicable.</i>                            |
| <b>Kinematic:</b>                                 | <i>Not applicable.</i>                            |
| <b>· Solvent content:</b>                         |   |
| <b>Solids content:</b>                            | <i>100 %</i>                                      |
| <b>· Other information</b>                        | <i>No further relevant information available.</i> |

### 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.*
- **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.*

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· **Other adverse effects** No further relevant information available.

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### 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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

· <b>UN-Number</b>	
· <b>DOT</b>	NA3077
· <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>DOT</b>	
· <b>Class</b>	9 Miscellaneous dangerous substances and articles.
· <b>Label</b>	9
· <b>ADR, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>Packing group</b>	
· <b>DOT</b>	III
· <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**

· **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

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· **TSCA (Toxic Substances Control Act):**

7440-57-5	Gold
7440-22-4	silver
7440-50-8	copper
7440-06-4	platinum
7440-74-6	indium
7439-88-5	iridium

· **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.

· **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** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **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

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*IATA: International Air Transport Association*  
*ACGIH: American Conference of Governmental Industrial Hygienists*  
*NFPA: National Fire Protection Association (USA)*  
*HMIS: Hazardous Materials Identification System (USA)*

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USA