

Safety Data Sheet
acc. to OSHA HCS

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

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

- 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 SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized 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.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

Trade name: **Harmony PF**

(Contd. of page 1)

- **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	2.5-<10%
7440-06-4	platinum	2.5-<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 Fire-fighting 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.

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.

(Contd. on page 3)

US

Safety Data Sheet acc. to OSHA HCS

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

Trade name: **Harmony PF**

(Contd. of page 2)

- **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	Long-term value: 0.01 mg/m ³
REL	Long-term value: 0.01 mg/m ³
TLV	Long-term value: 0.1 mg/m ³ metal: dust and fume

7440-50-8 copper

PEL	Long-term value: 1* 0.1** mg/m ³ as Cu *dusts and mists **fume
REL	Long-term value: 1* 0.1** mg/m ³ as Cu *dusts and mists **fume
TLV	Long-term value: 1* 0.2** mg/m ³ *dusts and mists; **fume; as Cu

7440-06-4 platinum

PEL	Long-term value: 0.002 mg/m ³ soluble salts, as Pt
REL	Long-term value: 1* 0.002** mg/m ³ *Metal **soluble salts, as Pt
TLV	Long-term value: 1* 0.002** mg/m ³ *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:

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

Trade name: **Harmony PF**

(Contd. of page 3)

*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/cm³ (130.182 lbs/gal)*

- **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.*

US

(Contd. on page 5)

Safety Data Sheet acc. to OSHA HCS

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

Trade name: **Harmony PF**

(Contd. of page 4)

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.

- **OSHA-Ca (Occupational Safety & Health Administration)**

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.
- **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.

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

Trade name: **Harmony PF**

(Contd. of page 5)

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

14 Transport information

- **UN-Number**
- **DOT** NA3077
- **ADR, ADN, IMDG, IATA** Void
- **UN proper shipping name**
- **ADR, ADN, IMDG, IATA** Void
- **Transport hazard class(es)**
- **DOT**
- **Class** 9 Miscellaneous dangerous substances and articles
- **Label** 9
- **ADR, ADN, IMDG, IATA**
- **Class** Void
- **Packing group**
- **DOT** III
- **ADR, IMDG, IATA** Void
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 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":** -

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
-----------	--------

- **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
-----------	--------

(Contd. on page 7)

Safety Data Sheet acc. to OSHA HCS

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

Trade name: **Harmony PF**

(Contd. of page 6)

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.

- **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 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.

- **Date of preparation / last revision** 06/23/2015 / 4

- **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

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

- *** Data compared to the previous version altered.**