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 prothesis

2 Hazard(s) identification

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

2.1 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.

2.2 Classification system

- **NFPA ratings (scale 0 - 4)**
  - Health = 0
  - Fire = 0
  - Reactivity = 0

(Contd. on page 2)
Trade name: Harmony PF

- HMIS-ratings (scale 0 - 4)
  - Health = 0
  - Fire = 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.
  - 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.
Trade name: Harmony PF

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:

| Component     | PEL Long-term value: 0.01 mg/m³ | REL Long-term value: 0.01 mg/m³ | TLV Long-term value: 0.1 mg/m³ |
|---------------|---------------------------------|---------------------------------|---------------------------------
| 7440-22-4 silver | metal: dust and fume            |                                 |                                 |

<table>
<thead>
<tr>
<th>Component</th>
<th>PEL Long-term value: 1* 0.1** mg/m³ as Cu</th>
<th>REL Long-term value: 1* 0.1** mg/m³ as Cu</th>
<th>TLV Long-term value: 1* 0.2** mg/m³ *dusts and mists; **fume as Cu</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-50-8 copper</td>
<td>*dusts and mists **fume</td>
<td>*dusts and mists **fume</td>
<td>*dusts and mists; **fume; as Cu</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>PEL Long-term value: 0.002 mg/m³</th>
<th>REL Long-term value: 1* 0.002** mg/m³</th>
<th>TLV Long-term value: 1* 0.002** mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-06-4 platinum</td>
<td>soluble salts, as Pt</td>
<td>*Metal **soluble salts, as Pt</td>
<td>*metal **soluble salts, as Pt</td>
</tr>
</tbody>
</table>

- 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/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.
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.
Trade name: Harmony PF

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

14 Transport information

- UN-Number: NA3077
- DOT: Void
- ADR, ADN, IMDG, IATA: Void

- UN proper shipping name: Void
- ADR, ADN, IMDG, IATA: Void

- Transport hazard class(es)
  - DOT: Class 9 Miscellaneous dangerous substances and articles
  - Label: 9
  - ADR, ADN, IMDG, IATA: Void
  - 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
    - 7440-74-0 indium
Trade name: **Harmony PF**

---

| 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.