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 6925
    - Fax +1 716 691 2285

  - **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).

- **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

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th>CAS: 7440-22-4</th>
<th>EINECS: 231-131-3</th>
<th>silver</th>
<th>10-25%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CAS: 7440-50-8</td>
<td>EINECS: 231-159-6</td>
<td>copper</td>
<td>2.5-10%</td>
</tr>
</tbody>
</table>

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

CAS: 7440-06-4  EINECS: 231-116-1  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.
Trade name: **Harmony PF**

- **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/m³
        - *metal; **soluble compds., as Ag
    - **CAS: 7440-50-8 copper**
      - **WES Long-term value:** 0.2* 1** mg/m³
        - *fume; **dusts and mists, as Cu
    - **CAS: 7440-06-4 platinum**
      - **WES Long-term value:** 1* 0.002** mg/m³
        - *metal; **soluble salts, as Pt; sen
  - **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.
  - **Change in condition**
    - **Melting point/freezing point:** 900 – 940 °C
Trade name: Harmony PF

**Initial boiling point and boiling range:** Undetermined.

- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Auto-ignition temperature:** Product is not self-igniting.
- **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/cm³
- **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.
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
  - ADR/RID/ADN, ADN, IMDG, IATA: Void
- UN proper shipping name
  - ADR/RID/ADN, ADN, IMDG, IATA: Void
- Transport hazard class(es)
  - ADR/RID/ADN, ADN, IMDG, IATA
    - Class: Void
- Packing group
  - ADR/RID/ADN, 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
Safety Data Sheet
in accordance with HSNO

Printing date 30.01.2020
Revision: 30.01.2020
Version number 5

Trade name: Harmony PF

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: Oxidising solids – Category 2