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).

- **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.

- **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.
Trade name: Harmony PF

- Classification system:
  - NFPA ratings (scale 0 - 4)
    - Health = 0
    - Fire = 0
    - Reactivity = 0

- 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 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.
- 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.
35.0.51

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:

<table>
<thead>
<tr>
<th>Component ID</th>
<th>PEL (mg/m³)</th>
<th>REL (mg/m³)</th>
<th>TLV (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>0.01</td>
<td>0.01</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>metal and soluble compounds (as Ag)</td>
<td>metal and soluble compounds (as Ag)</td>
<td>metal and soluble compounds (as Ag)</td>
</tr>
<tr>
<td>7440-50-8 copper</td>
<td>1* 0.1**</td>
<td>1* 0.1**</td>
<td>1* 0.2**</td>
</tr>
<tr>
<td></td>
<td>mg/m³ as Cu as Cu *dusts and mists as Cu *fume</td>
<td>mg/m³ as Cu as Cu *dusts and mists as Cu *fume</td>
<td>mg/m³ as Cu as Cu *dusts and mists as Cu *fume</td>
</tr>
<tr>
<td>7440-06-4 platinum</td>
<td>0.002</td>
<td>0.002</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>mg/m³ soluble salts, as Pt</td>
<td>mg/m³ soluble salts, as Pt</td>
<td>mg/m³ soluble salts, as Pt</td>
</tr>
</tbody>
</table>

(Contd. on page 4)
Trade name: **Harmony PF**

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### 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 self-igniting.
  - **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.
Trade name: Harmony PF

- 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.

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.
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

- 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 Class 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.
- 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

(Contd. on page 7)
Trade name: Harmony PF

- **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
Trade name: Harmony PF

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