1 Identification

- **Product identifier**
  - Trade name: **Harmony X-Hard**

- **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

- **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)
    - Health = 0
    - Fire = 0
    - Reactivity = 0

(Contd. on page 2)
Trade name: *Harmony X-Hard*

- HMIS-ratings (scale 0 - 4)

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FIRE</th>
<th>REACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health = 0</td>
<td>Fire = 0</td>
<td>Reactivity = 0</td>
</tr>
</tbody>
</table>

- 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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-50-8 copper</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>7440-22-4 silver</td>
<td>≤10%</td>
</tr>
<tr>
<td>7440-05-3 palladium</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>7440-06-4 platinum</td>
<td>2.5-&lt;10%</td>
</tr>
</tbody>
</table>

### 4 First-aid measures

- Description of first aid measures
  - General information: No special measures required.
  - After inhalation: Grind dust. Supply fresh air; consult doctor in case of complaints.
  - 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.
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:

    | Material          | PEL Long-term value | REL Long-term value | TLV Long-term value |
    |-------------------|---------------------|---------------------|---------------------|
    | 7440-50-8 copper  | 1* 0.1** mg/m³      | 1* 0.1** mg/m³      | 1* 0.2** mg/m³      |
    |                   | as Cu *dusts and mists **fume | as Cu *dusts and mists **fume | as Cu *dusts and mists **fume |
    | 7440-22-4 silver  | 0.01 mg/m³          | 0.01 mg/m³          | 0.1 mg/m³           |
    | 7440-06-4 platinum| 0.002 mg/m³         | 1* 0.002** mg/m³    | 1* 0.002** mg/m³    |
    |                   | soluble salts, as Pt| *Metal **soluble salts, as Pt | *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.
Trade name: **Harmony X-Hard**

(Contd. of page 3)

- **Material of gloves**
  - Mechanical processing:
    - Leather gloves
    - Strong gloves
  - Thermal processing:
    - Heat protection gloves
- **Penetration time of glove material**
  The exact breakthrough 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 – 960 °C (1652 – 1760 °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):** 15.9 g/cm³ (132.686 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 %

(Contd. on page 5)
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.
**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**: 9 Miscellaneous dangerous substances and articles
  - **ADN, IMDG, IATA**: 9
- **Packing group**
  - **DOT**: III
  - **ADR, IMDG, IATA**: Void
- **Environmental hazards**: 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
**Trade name:** Harmony X-Hard

| 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.