1 Identification of the substance/mixture and of the company/undertaking

- **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 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 X-Hard

- **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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Chemical Formula</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-50-8</td>
<td>copper</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>7440-22-4</td>
<td>silver</td>
<td>10-10%</td>
</tr>
<tr>
<td>7440-05-3</td>
<td>palladium</td>
<td>1-&lt;10%</td>
</tr>
<tr>
<td>7440-06-4</td>
<td>platinum</td>
<td>1-&lt;10%</td>
</tr>
</tbody>
</table>

### 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 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
· 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 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:
    7440-50-8 copper
    PEL (†) 1 * 0.1 ‡ mg/m³ as Cu *dusts and mists **fume
    REL (†) 1 * 0.1 ‡ mg/m³ as Cu *dusts and mists **fume
    TLV (†) 1 * 0.2 ‡ mg/m³ *dusts and mists; **fume; as Cu
    7440-22-4 silver
    PEL (†) 0.01 mg/m³ metal and soluble compounds (as Ag)
    REL (†) 0.01 mg/m³
    TLV (†) 0.1 mg/m³ metal; dust and fume
    7440-06-4 platinum
    PEL (†) 0.002 mg/m³ soluble salts, as Pt
Trade name: Harmony X-Hard

- 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. After use of gloves apply skin-cleaning agents and skin cosmetics.
- 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 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): 15.9 g/cm³ (132.686 lbs/gal)
- Relative density Not determined.
Trade name: Harmony X-Hard

- 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.

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
Trade name: Harmony X-Hard

- 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 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 Void
    - Class III
    - ADR, IMDG, IATA 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.
Trade name: Harmony X-Hard

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
- 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.
Trade name: Harmony X-Hard

- **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
  
  NFPA: National Fire Protection Association (USA)
  
  HMIS: Hazardous Materials Identification System (USA)