1 Identification

- **Product identifier**
  - **Trade name:** Harmony Medium

- **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 Medium**

- **HMIS-ratings (scale 0 - 4)**
  - **HEALTH**
    - Health = 0
  - **FIRE**
    - Fire = 0
  - **REACTIVITY**
    - 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>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>7440-50-8 copper</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>7440-66-6 zinc powder -zinc dust (stabilized)</td>
<td>0.25-&lt;1%</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 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.
### Handling and storage

**Handling:**

- **Precautions for safe handling**
  Extractors are required on all machines used for thermal processing or splinter removal processes.

- **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.

### 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>Substance</th>
<th>PEL</th>
<th>REL</th>
<th>TLV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7440-22-4 silver</strong></td>
<td>Long-term value: 0.01 mg/m³</td>
<td>Long-term value: 0.01 mg/m³</td>
<td>Long-term value: 0.1 mg/m³ metal: dust and fume</td>
</tr>
<tr>
<td><strong>7440-50-8 copper</strong></td>
<td>Long-term value: 1* 0.1** mg/m³ as Cu</td>
<td>Long-term value: 1* 0.1** mg/m³ as Cu</td>
<td>Long-term value: 1* 0.2** mg/m³ as Cu</td>
</tr>
</tbody>
</table>

**Additional information:** The lists that were valid during the creation were used as basis.
## 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: 650 – 760 °C (1202 – 1400 °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):** 15.2 g/cm³ (126.844 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.
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.

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

14 Transport information

- UN-Number
- DOT
  NA3077
**Trade name:** Harmony Medium

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>Void</td>
</tr>
<tr>
<td>ADR, ADN, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td>9 Miscellaneous dangerous substances and articles</td>
</tr>
<tr>
<td>DOT</td>
<td>9</td>
</tr>
<tr>
<td>包装组</td>
<td>DOT III</td>
</tr>
<tr>
<td>ADR, ADN, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>包装组</td>
<td>III</td>
</tr>
<tr>
<td>ADR, ADN, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>Class</td>
<td>DOT III</td>
</tr>
<tr>
<td>Label</td>
<td>9</td>
</tr>
<tr>
<td>Class</td>
<td>DOT III</td>
</tr>
<tr>
<td>Label</td>
<td>9</td>
</tr>
<tr>
<td>Environmental hazards:</td>
<td>Marine pollutant:</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Special precautions for user</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Transport/Additional information:</td>
<td>Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).</td>
</tr>
<tr>
<td>UN &quot;Model Regulation&quot;:</td>
<td>-</td>
</tr>
</tbody>
</table>

**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
    - 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.

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Trade name: **Harmony Medium**

- **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
    - 7440-50-8 copper
  - **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.*