1 Identification

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

- 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:
  - 7440-22-4 silver 10-<25%
  - 7440-50-8 copper 2.5-<10%
  - 7440-05-3 palladium 2.5-<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.
    - Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
    - Mechanical effects only.
  - After eye contact:
  - 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.
Trade name: Harmony Hard

7 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.

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>Chemical</th>
<th>PEL Long-term value</th>
<th>REL Long-term value</th>
<th>TLV Long-term value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>0.01 mg/m³</td>
<td>0.01 mg/m³</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>7440-50-8 copper</td>
<td>0.1* mg/m³ as Cu</td>
<td>0.1** mg/m³ as Cu</td>
<td>0.2** mg/m³ as Cu</td>
</tr>
</tbody>
</table>

- 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
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: 895 – 970 °C (1643 – 1778 °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): 14.9 g/cm³ (124.341 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

(Contd. of page 6)
### Safety Data Sheet

**Trade name:** Harmony Hard

<table>
<thead>
<tr>
<th>ADR, ADN, IMDG, IATA</th>
<th>Void</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>
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<tr>
<td>Transport hazard class(es)</td>
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</tr>
<tr>
<td>DOT</td>
<td></td>
</tr>
<tr>
<td>Class</td>
<td></td>
</tr>
<tr>
<td>Label</td>
<td></td>
</tr>
<tr>
<td>9 Miscellaneous dangerous substances and articles</td>
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<tr>
<td>9</td>
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<tr>
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<td>Class</td>
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<tr>
<td>DOT</td>
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<tr>
<td>ADR, IMDG, IATA</td>
<td>Void</td>
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<tr>
<td>Packing group</td>
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<td>DOT</td>
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<tr>
<td>ADR, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>Environmental hazards:</td>
<td></td>
</tr>
<tr>
<td>Marine pollutant:</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 goods 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. |
Safety Data Sheet
acc. to OSHA HCS

Trade name: Harmony Hard

- 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.