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

- **Product identifier**
  - Trade name: **Harmony 2**

- **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 - Canute: 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**
  - Ox. Sol. 2  H272  May intensify fire; oxidizer.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
  - Oxidizing
  - Contact with combustible material may cause fire.
  - Dangerous for the environment
  - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- **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**
  - The product is classified and labelled according to the Globally Harmonized System (GHS).
Trade name: Harmony 2

3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: Dental alloy

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>25-50%</td>
<td></td>
</tr>
<tr>
<td>7440-05-3 palladium</td>
<td>25-50%</td>
<td></td>
</tr>
<tr>
<td>7440-74-6 indium</td>
<td>25-50%</td>
<td></td>
</tr>
<tr>
<td>Zink</td>
<td>2.5-&lt;10%</td>
<td></td>
</tr>
</tbody>
</table>

4 First aid measures

- Description of first aid measures
- General information: No special measures required.
35.0.51

· 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.
· 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:
  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.
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: 882–1140 °C (1620–2084 °F)
    - Boiling point/Boiling range: Undetermined.
  - Flash point: Not applicable.
  - Flammability (solid, gaseous): Not determined.

(Contd. on page 5)
Trade name: Harmony 2

- **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):** 9.8 g/cm³ (81.781 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.
- **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**
  - **IARC (International Agency for Research on Cancer)**
    - 7440-47-3 Chromium
Trade name: Harmony 2

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, ADR, ADN, IMDG, IATA: Void
- UN proper shipping name
- DOT, ADR, ADN, IMDG, IATA: Void
- Transport hazard class(es)
- DOT, ADR, ADN, IMDG, IATA: Void
- Class: Void
- Packing group
- DOT, 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
  - 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
      - 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.
    - OSHA-Ca (Occupational Safety & Health Administration)
      None of the ingredients is listed.
  - GHS label elements
    The product is classified and labelled according to the Globally Harmonized System (GHS).
  - Hazard pictograms
    - GHS03
  - Signal word Danger
Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 12/19/2012  Version number 1  Reviewed on 12/19/2012

Trade name: Harmony 2

- **Hazard statements**
  - May intensify fire; oxidizer.

- **Precautionary statements**
  - Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
  - Take any precaution to avoid mixing with combustibles.
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - Keep/Store away from clothing/combustible materials.
  - In case of fire: Use for extinction: CO2, powder or water spray.
  - Dispose of contents/container in accordance with local/regional/national/international regulations.

- **National regulations:**

- **Other regulations, limitations and prohibitive regulations**
  - This 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
  - IATA: International Air Transport Association
  - ACGIH: American Conference of Governmental Industrial Hygienists
  - NFPA: National Fire Protection Association (USA)
  - HMIS: Hazardous Materials Identification System (USA)