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

- **Product identifier**
  - **Trade name:** Harmony 3

- **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 prosthesis

- **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**
  - 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.
  - Harmful 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 3

- **Hazard pictograms**

![Hazard pictogram](image)

- **Signal word** Danger
- **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.
- **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)**
  ![NFPA ratings](image)
  Health = 0
  Fire = 0
  Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**
  ![HMIS-ratings](image)
  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>Substance</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>25-100%</td>
</tr>
<tr>
<td>7440-05-3 palladium</td>
<td>25-50%</td>
</tr>
<tr>
<td>7440-50-8 copper</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>7440-31-5 tin</td>
<td>1-&lt;10%</td>
</tr>
<tr>
<td>Zink</td>
<td>1-&lt;2.5%</td>
</tr>
</tbody>
</table>

(Contd. on page 3)
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.
  - 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.

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.

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.

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.
35.0.51

Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see item 7.

- Control parameters

<table>
<thead>
<tr>
<th>Component</th>
<th>PEL (mg/m³)</th>
<th>REL (mg/m³)</th>
<th>TLV (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>0.01 (metal and soluble compounds as Ag)</td>
<td>0.01</td>
<td>0.1 (metal: dust and fume)</td>
</tr>
<tr>
<td>7440-50-8 copper</td>
<td>1* 0.1** (as Cu *dusts and mists **fume)</td>
<td>1* 0.1** (as Cu *dusts and mists **fume)</td>
<td>1* 0.2** *dusts and mists; **fume; as Cu</td>
</tr>
<tr>
<td>7440-31-5 tin</td>
<td>2</td>
<td>2</td>
<td>2</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

- 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:** White
  - **Odor:** Odorless
  - **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**
  - **Melting point/Melting range:** 880–960 °C (1616–1760 °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):** 10.6 g/cm³ (88.457 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**
  - **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
  - **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**
  - NA3077
- **DOT**
  - Void
- **ADR, ADN, IMDG, IATA**
  - Void
- **UN proper shipping name**
  - Void
- **Transport hazard class(es)**
  - DOT
  - Class 9 Miscellaneous dangerous substances and articles.
Trade name: Harmony 3

- Label 9
- ADR, ADN, IMDG, IATA
- Class Void
- Packing group
- DOT 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.
  - 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 D
    7440-50-8 copper D
Trade name: Harmony 3

- **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

- **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**
  
  The product is classified as 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)