1 Identification of the substance or mixture and of the supplier

- **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 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 6925
    - Fax +1 716 691 2285

  - **Importer:**
    - Ivoclar Vivadent Ltd.
    - 12 Omega St, Rosedale, Auckland
    - New Zealand
    - Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990

- **Further information obtainable from:**
  - Regulatory Affairs
  - sds@ivoclargvivadent.com

- **Emergency telephone number:**
  - 0800 764 766 (National Poison Centre - 24 hours / 7 days)

2 Hazards identification

- **Classification of the substance or mixture**
  - Ox. Sol. 2 H272 May intensify fire; oxidiser.
  - Aquatic Acute 2 H401 Toxic to aquatic life.
  - Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

- **Label elements**
  - **GHS label elements**
    - The product is classified and labelled according to the Globally Harmonised System (GHS).

- **Hazard pictograms**
  - GHS03
  - GHS09

- **Signal word** Danger
- **Hazard statements**
  - May intensify fire; oxidiser.
  - Toxic to aquatic life with long lasting effects.

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

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

- 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.
- Other hazards
  - Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.

3 Composition/Information on ingredients

- Chemical characterisation: Mixtures
- Description: Dental alloy
- Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4</td>
<td>Silver</td>
<td>25-50%</td>
</tr>
<tr>
<td>231-131-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7440-74-6</td>
<td>Indium</td>
<td>25-50%</td>
</tr>
<tr>
<td>231-180-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7440-66-6</td>
<td>Zinc powder -zinc dust (stabilized)</td>
<td>2.5-10%</td>
</tr>
<tr>
<td>231-175-3</td>
<td>Aquatic Acute 1, H400; Aquatic Chronic 1, H410</td>
<td></td>
</tr>
</tbody>
</table>

- Additional information: For the wording of the listed hazard phrases refer to section 16.

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.
  - 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.

5 Fire fighting measures

- Extinguishing media
  - Suitable extinguishing agents: The product is not flammable.
  - Use fire extinguishing methods suitable to surrounding conditions.
- 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 fire - and explosion protection: 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 facilities: No further data; see item 7.
- Control parameters
- Ingredients with limit values that require monitoring at the workplace:
  CAS: 7440-22-4 silver
  WES Long-term value: 0.1* 0.01** mg/m³
  *metal; ** soluble compds., as Ag
  CAS: 7440-74-6 indium
  WES Long-term value: 0.1 mg/m³
  as In
- Additional information: The lists valid during the making were used as basis.
- Exposure controls
- Personal protective equipment:
- General protective and hygienic measures:
  Usual hygienic measures for dental practice and dental laboratories.
- Respiratory protection: 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 material gloves
  Thermal processing:
  Heat protection gloves

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49.0

- **Penetration time of glove material**
  The exact break through 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
    - Colour: Yellow
    - Odour: Odourless
    - Odour threshold: Not determined.
  
  - **pH-value:** Not applicable.

- **Change in condition**
  - Melting point/freezing point: 882–1140 °C
  - Initial boiling point and boiling range: Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Not determined.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**
  - Lower: Not determined.
  - Upper: Not determined.

- **Vapour pressure:** Not applicable.

- **Density at 20 °C:** 9.8 g/cm³
  - 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.
Trade name: Harmony 2

- **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**
  - **Skin corrosion/irritation**: No irritant effect.
  - **Serious eye damage/irritation**: No irritating effect.
  - **Respiratory or skin sensitisation**: No sensitising effects known.
  - **Additional toxicological information**: Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

### 12 Ecological information

- **Toxicity**
  - **Aquatic toxicity**: No further relevant information available.
- **Persistence and degradability**: No further relevant information available.
- **Behaviour in environmental systems**:
  - **Bioaccumulative potential**: No further relevant information available.
  - **Mobility in soil**: No further relevant information available.
- **Additional ecological information**:
  - **General notes**: 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 packaging**:
  - **Recommendation**: Disposal must be made according to official regulations.

### 14 Transport information

- **UN-Number**
  - **ADR/RID/ADN, ADN, IMDG, IATA**: Void
- **UN proper shipping name**
  - **ADR/RID/ADN, ADN, IMDG, IATA**: Void
- **Transport hazard class(es)**
  - **ADR/RID/ADN, ADN, IMDG, IATA**: Void

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Safety Data Sheet  
in accordance with HSNO

Printing date 30.01.2020  
Revision: 30.01.2020  
Version number 2

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- Packing group
  - ADR/RID/ADN, IMDG, IATA: Void
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user: Not applicable.
- Transport in bulk according to Annex II of Marpol and the IBC Code: Not applicable.
- Transport/Additional information: Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
- UN "Model Regulation": Void

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- New Zealand Inventory of Chemicals
  - CAS: 7440-22-4 silver
  - CAS: 7440-74-6 indium
- HSNO Approval numbers
  - CAS: 7440-22-4 silver HSR003077
  - CAS: 7440-74-6 indium HSR003007
- GHS label elements
  The product is classified and labelled according to the Globally Harmonised System (GHS).
- Hazard pictograms
  - GHS03
  - GHS09
- Signal word Danger
- Hazard statements
  May intensify fire; oxidiser.
  Toxic to aquatic life with long lasting effects.
- Precautionary statements
  Keep away from heat. - No smoking.
  Keep/Store away from clothing/combustible materials.
  Take any precaution to avoid mixing with combustibles.
  Wear protective gloves/protective clothing/eye protection/face protection.
  In case of fire: Use to extinguish: CO2, powder or water spray.
  Dispose of contents/container in accordance with local/regional/national/international regulations.

- Directive 2012/18/EU
  - Named dangerous substances - ANNEX I None of the ingredients is listed.
  - Seveso category
    P8 OXIDISING LIQUIDS AND SOLIDS
    E2 Hazardous to the Aquatic Environment
  - Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t
  - Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t

(Contd. page 7)
National regulations:
- Other regulations, limitations and prohibitive regulations
  The product is a medical device according to the Directive 93/42/EEC.
- 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.

Relevant phrases
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

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
- IATA: International Air Transport Association
- 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)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Ox. Sol. 2: Oxidizing solids – Category 2
- Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
- Aquatic Acute 2: Hazardous to the aquatic environment - acute aquatic hazard – Category 2
- Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
- Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2