1 Identification

- **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 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**
  Ox. Sol. 2 H272 May intensify fire; oxidizer.
- **Label elements**
  **GHS label elements**
  The product is classified and labeled 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.
  Take any precaution to avoid mixing with combustibles.
  Wear protective gloves / 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)**  
- Health = 0  
- Fire = 0  
- Reactivity = 0  
**HMIS-ratings (scale 0 - 4)**  
- 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:**  
- 7440-22-4 silver: 25-50%  
- 7440-05-3 palladium: 25-50%  
- 7440-74-6 indium: 25-50%  
- 7440-66-6 zinc powder -zinc dust (stabilized): 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.  
**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.
Trade name: Harmony 2

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.
- 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.
  - Control parameters
    - Components with limit values that require monitoring at the workplace:
      - 7440-22-4 silver
        - PEL: Long-term value: 0.01 mg/m³
        - REL: Long-term value: 0.01 mg/m³
        - TLV: Long-term value: 0.1 mg/m³
        - metal: dust and fume
      - 7440-74-6 indium
        - REL: Long-term value: 0.1 mg/m³, as In
        - TLV: Long-term value: 0.1 mg/m³, as In
  - 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 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).

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**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.

• **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.
Trade name: **Harmony 2**

- **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 3
  - **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.
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
- Packing group
  - DOT, ADR, IMDG, IATA: Void
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user
  - Transport in bulk according to Annex II of MARPOL 73/78 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": -

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
Trade name: Harmony 2

- 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
  - 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
  The product is classified and labeled 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.
  Take any precaution to avoid mixing with combustibles.
  Wear protective gloves / 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 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 / 1
- **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)
- Ox. Sol. 2: Oxidising Solids, Hazard Category 2
- * Data compared to the previous version altered.*