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

1.1 Product identifier
- Trade name: Harmony X-Hard

1.2 Relevant identified uses of the substance or mixture and uses advised against
- Application of the substance / the mixture: Manufacture of dental prothesis

1.3 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

- Further information obtainable from:
  Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein
  Regulatory Affairs
  sds@ivoclarvivadent.com

1.4 Emergency telephone number:
- +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008:
The product is not classified according to the CLP regulation.

2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008: 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.
    Safety data sheet available on request.

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

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures
- Description: Dental alloy

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 7440-50-8 EINECS: 231-159-6</td>
<td>copper</td>
</tr>
<tr>
<td>CAS: 7440-22-4 EINECS: 231-131-3</td>
<td>silver</td>
</tr>
</tbody>
</table>

(Contd. on page 2)
SECTION 4: First aid measures

4.1 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.

4.2 Most important symptoms and effects, both acute and delayed
No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed
No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing agents: The product is not flammable.

5.2 Special hazards arising from the substance or mixture
No further relevant information available.

5.3 Advice for firefighters
Protective equipment: Do not inhale explosion gases or combustion gases.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Not required.

6.2 Environmental precautions: No special measures required.

6.3 Methods and material for containment and cleaning up: Pick up mechanically.

6.4 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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Ensure good ventilation/exhaustion at the workplace.

Information about fire - and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage:
Requirements to be met by storerooms and receptacles: No special requirements.

7.3 Specific end use(s) No further relevant information available.
SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- 8.1 Control parameters

- Ingredients with limit values that require monitoring at the workplace:
  
<table>
<thead>
<tr>
<th>Substance</th>
<th>WEL</th>
<th>Short-term value</th>
<th>Long-term value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-50-8 copper</td>
<td>Short-term value: 2** mg/m³</td>
<td>Long-term value: 0.2* 1** mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*fume **dusts and mists (as Cu)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7440-22-4 silver</td>
<td>WEL Long-term value: 0.1 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7440-06-4 platinum</td>
<td>WEL Long-term value: 5 mg/m³</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Additional information: The lists valid during the making were used as basis.

- 8.2 Exposure controls
  
  - Personal protective equipment:
    
    - General protective and hygienic measures: Usual hygienic measures for dental practice.
    
    - 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
  
  - 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).

SECTION 9: Physical and chemical properties

- 9.1 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/Melting range: 900 – 960 °C
    
    Boiling point/Boiling range: Undetermined.
  
  - Flash point: Not applicable.
  
  - Flammability (solid, gaseous): Not determined.
Trade name: **Harmony X-Hard**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-igniting</td>
<td>Product is not self-igniting.</td>
</tr>
<tr>
<td>Danger of explosion</td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td>Explosion limits</td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Upper</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Density at 20 °C</td>
<td>15.9 g/cm³</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Solubility in / Miscibility with water</td>
<td>Insoluble.</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Dynamic</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Kinematic</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Solvent content</td>
<td></td>
</tr>
<tr>
<td>Solids content</td>
<td>100 %</td>
</tr>
<tr>
<td>9.2 Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided**: No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials**: No further relevant information available.
- **10.6 Hazardous decomposition products**: None under normal conditions of storage and use.

**SECTION 11: Toxicological information**

- **11.1 Information on toxicological effects**
- **Acute toxicity**: 
  - Primary irritant effect:
    - on the skin: No irritant effect.
    - on the eye: No irritating effect.
  - Sensitisation: No sensitising effects known.
- **Additional toxicological information**: Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

**SECTION 12: Ecological information**

- **12.1 Toxicity**
  - Aquatic toxicity: No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 23.06.2015
Version number 5
Revision: 08.05.2015

Trade name: Harmony X-Hard

12.4 Mobility in soil
No further relevant information available.

Additional ecological information:
- General notes: Generally not hazardous for water

12.5 Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.

12.6 Other adverse effects
No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Recommendation
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

European waste catalogue
20 01 40 metals

Uncleaned packaging:
Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN-Number
- ADR, ADN, IMDG, IATA Void

14.2 UN proper shipping name
- ADR, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)
- ADR, ADN, IMDG, IATA
  - Class Void

14.4 Packing group
- ADR, IMDG, IATA Void

14.5 Environmental hazards:
- Marine pollutant: No

14.6 Special precautions for user
Not applicable.

14.7 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": -

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- National regulations:
- Other regulations, limitations and prohibitive regulations
  The product is a medical device according to the Directive 93/42/EEC.
## SECTION 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**
  - H252 Self-heating in large quantities; may catch fire.
  - H272 May intensify fire; oxidiser.

- **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
  - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  - 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)
  - Self-heat. 2: Self-Heating Substances and Mixtures, Hazard Category 2
  - Ox. Sol. 2: Oxidising Solids, Hazard Category 2

* Data compared to the previous version altered.