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

- **Product identifier**
- **Trade name:** Harmony KF
- **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
  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.
- **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).
- **Hazard pictograms**
  - GHS03
- **Signal word** Danger
3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: Dental alloy

- Dangerous components:
  - 7440-22-4 silver 10-<25%
  - 7440-05-3 palladium 1-<10%
  - 7440-06-4 platinum 1-<10%
  - 7440-74-6 indium 1-<2.5%

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.
Trade name: Harmony KF

- 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.
- Control parameters

| Components with limit values that require monitoring at the workplace: |  |
|---------------------------------------------------------------|---|---|
| 7440-22-4 silver |  |
| PEL () | 0.01 mg/m³ | metal and soluble compounds (as Ag) |
| REL () | 0.01 mg/m³ |
| TLV () | 0.1 mg/m³ | metal: dust and fume |

(Contd. on page 4)
## 7440-06-4 platinum

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PEL (soluble salts, as Pt)</td>
<td>0.002 mg/m³</td>
</tr>
<tr>
<td>REL (soluble salts, as Pt)</td>
<td>1* 0.002** mg/m³</td>
</tr>
<tr>
<td>TLV (soluble salts, as Pt)</td>
<td>1* 0.002** mg/m³</td>
</tr>
</tbody>
</table>

## 7440-74-6 indium

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>REL (and compounds, as In)</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>TLV (soluble salts, as Pt)</td>
<td>0.1 mg/m³</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**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance:</td>
<td>Solid</td>
</tr>
<tr>
<td>Color:</td>
<td>Yellow</td>
</tr>
<tr>
<td>Odor:</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odour threshold:</td>
<td>Not determined.</td>
</tr>
</tbody>
</table>

**pH-value:**

Not applicable.

**Change in condition**

- Melting point/Melting range: 970–1080 °C (1778–1976 °F)
- Boiling point/Boiling range: Undetermined.

**Flammability (solid, gaseous):**

Not determined.

**Auto igniting:**

Product is not selfigniting.
### Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 12/19/2012  
Reviewed on 12/19/2012  
Version number 4  
Trade name: Harmony KF

<table>
<thead>
<tr>
<th><strong>Danger of explosion:</strong></th>
<th>Product does not present an explosion hazard.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Explosion limits:</strong></td>
<td></td>
</tr>
<tr>
<td>Lower:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Upper:</td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Vapor pressure:</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Density at 20 °C (68 °F):</strong></td>
<td>16.1 g/cm³ (134.355 lbs/gal)</td>
</tr>
<tr>
<td><strong>Relative density:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Vapour density:</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Evaporation rate:</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Solubility in / Miscibility with Water:</strong></td>
<td>Insoluble.</td>
</tr>
<tr>
<td><strong>Partition coefficient (n-octanol/water):</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Viscosity:</strong></td>
<td></td>
</tr>
<tr>
<td>Dynamic:</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Kinematic:</td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Solvent content:</strong></td>
<td></td>
</tr>
<tr>
<td>Solids content:</td>
<td>100 %</td>
</tr>
<tr>
<td>Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

#### 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**
  - 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
  - DOT: NA3077
  - ADR, ADN, IMDG, IATA: Void
- UN proper shipping name
  - ADR, ADN, IMDG, IATA: Void
- Transport hazard class(es)
  - DOT
    - Class: 9 Miscellaneous dangerous substances and articles.
    - 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.
Trade name: Harmony KF

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

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 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)