1 Identification

- 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 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.

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### Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Dental alloy

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

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### 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.
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:
    - 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
    - Platinum:
      - PEL Long-term value: 0.002 mg/m³
        - soluble salts, as Pt
      - REL Long-term value: 1* 0.002** mg/m³
        - Metal **soluble salts, as Pt
      - TLV Long-term value: 1* 0.002** mg/m³
        - metal **soluble salts, as Pt
40.1.5

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).

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: 970–1080 °C (1778–1976 °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): 16.1 g/cm³ (134.355 lbs/gal)
  - Relative density Not determined.
40.1.5

- 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.
- 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.
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
  ADR, IMDG, IATA: III 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.

- 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):

<table>
<thead>
<tr>
<th>Chemicals</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silver</td>
<td>7440-22-4</td>
</tr>
<tr>
<td>Copper</td>
<td>7440-50-8</td>
</tr>
</tbody>
</table>

### TSCA (Toxic Substances Control Act):

<table>
<thead>
<tr>
<th>Chemicals</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gold</td>
<td>7440-57-5</td>
</tr>
<tr>
<td>Silver</td>
<td>7440-22-4</td>
</tr>
<tr>
<td>Copper</td>
<td>7440-50-8</td>
</tr>
<tr>
<td>Platinum</td>
<td>7440-06-4</td>
</tr>
<tr>
<td>Indium</td>
<td>7440-74-6</td>
</tr>
<tr>
<td>Iridium</td>
<td>7439-88-5</td>
</tr>
</tbody>
</table>

### 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)**
  - Silver: D
  - 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**

![GHS pictogram]

### Hazard pictogram

- **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.**
Trade name: Harmony KF

- 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 / 4
- 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.