1 Identification

· Product identifier
  
  · Trade name: BioUniversal KFG+
  
  · 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
  
  The product is not classified according to the Globally Harmonized System (GHS).

· Label elements
  
  · GHS label elements 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.

· 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
  Avoid breathing of grinding dust and vapours. Melted material may cause burns.

(Contd. on page 2)
3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: Dental alloy

- Dangerous components:
  
<table>
<thead>
<tr>
<th>CAS</th>
<th>Component</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4</td>
<td>silver</td>
<td>25-50%</td>
</tr>
<tr>
<td>7440-05-3</td>
<td>palladium</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>7440-74-6</td>
<td>indium</td>
<td>10-&lt;25%</td>
</tr>
</tbody>
</table>

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.
  - 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

<table>
<thead>
<tr>
<th>CAS</th>
<th>Component</th>
<th>PEL Long-term value: 0.01 mg/m³</th>
<th>REL Long-term value: 0.01 mg/m³</th>
<th>TLV Long-term value: 0.1 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 7440-22-4 silver</td>
<td>silver metal: dust and fume</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REL Long-term value: 0.1 mg/m³</td>
<td>as In</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLV Long-term value: 0.1 mg/m³</td>
<td>as In</td>
<td></td>
<td></td>
<td></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 and dental laboratories.

- 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.
9 Physical and chemical properties

· Information on basic physical and chemical properties
  · General Information
    · Appearance: Solid
    · Color: Yellow
    · Odor: Odorless
    · Odor threshold: Not determined.
  · pH-value: Not applicable.

· Change in condition
  · Melting point/Melting range: 920-996 °C (1688-1825 °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.

· Vapor pressure: Not applicable.

· Density at 20 °C (68 °F): 12.1 g/cm³ (100.975 lbs/gal)

· Relative density: Not determined.

· Vapor 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:
    - on the skin: No irritant effect.
    - on the eye: No irritating effect.
  - Sensitization:
    Sensitization possible through inhalation.
    Sensitization possible through skin contact.
  - 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
  - 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
- ADR, RID, ADN, ADN, IMDG, IATA
  - NA3077
  - Void
- UN proper shipping name
  - ADR, RID, ADN, ADN, IMDG, IATA
  - Void

(Contd. on page 6)
Trade name: **BioUniversal KFG+**

### 43.0.9

- **Transport hazard class(es)**
  - DOT 9
  - Class Miscellaneous dangerous substances and articles
  - Label 9

- **ADR,RID,ADN, ADN, IMDG, IATA**
  - Class Void
  - Label Void

- **Packing group**
  - DOT III
  - 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 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":**
  - Void

### 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):**
      - CAS: 7440-22-4 silver
  - **TSCA (Toxic Substances Control Act):**
    - All ingredients are listed.

- **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)**
    - CAS: 7440-22-4 silver
  - **TLV (Threshold Limit Value established by ACGIH)**
    - None of the ingredients is listed.
Trade name: BioUniversal KFG+

<table>
<thead>
<tr>
<th>NIOSH-Ca (National Institute for Occupational Safety and Health)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None of the ingredients is listed.</td>
</tr>
</tbody>
</table>

- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

- **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** 12/05/2016 / -
- **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)
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - NIOSH: National Institute for Occupational Safety
  - OSHA: Occupational Safety & Health
  - TLV: Threshold Limit Value
  - PEL: Permissible Exposure Limit
  - REL: Recommended Exposure Limit