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

1.1 Product identifier

Trade name: BioUniversal KFG+

1.2 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

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

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

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

Dangerous components:

<table>
<thead>
<tr>
<th>CAS: 7440-22-4</th>
<th>7440-05-3</th>
<th>7440-74-6</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 231-131-3</td>
<td>EINECS: 231-115-6</td>
<td>EINECS: 231-180-0</td>
</tr>
<tr>
<td>silver</td>
<td>palladium</td>
<td>indium</td>
</tr>
</tbody>
</table>

substance with a Community workplace exposure limit

25-50%

10-<25%

10-<25%

(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

Extractors are required on all machines used for thermal processing or splinter removal processes.

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.

Information about storage in one common storage facility: Not required.
Further information about storage conditions: None.

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>CAS</th>
<th>WEL Long-term value: 0.1 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td></td>
</tr>
<tr>
<td>7440-74-6 indium</td>
<td>Long-term value: 0.1 mg/m³ as In</td>
</tr>
<tr>
<td></td>
<td>Short-term value: 0.3 mg/m³</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 and dental laboratories.
  - 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 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).

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: 920-996 °C
  Boiling point/Boiling range: Undetermined.

- Flash point: Not applicable.

- Flammability (solid, gaseous): Not determined.

- Self-igniting: Product is not selfigniting.
Danger of explosion: Product does not present an explosion hazard.

Vapour pressure: Not applicable.

Density at 20 °C: 12.1 g/cm³
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.

Viscosity:
Dynamic: Not applicable.
Kinematic: Not applicable.

Solvent content:
Solids content: 100%

9.2 Other information
No further relevant information available.

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
Based on available data, the classification criteria are not met.

Skin corrosion/irritation
Based on available data, the classification criteria are not met.

Serious eye damage/irritation
Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation
Based on available data, the classification criteria are not met.

Additional toxicological information:
Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.
Germ cell mutagenicity
Based on available data, the classification criteria are not met.
Carcinogenicity
Based on available data, the classification criteria are not met.
Reproductive toxicity
Based on available data, the classification criteria are not met.
STOT-single exposure
Based on available data, the classification criteria are not met.
STOT-repeated exposure
Based on available data, the classification criteria are not met.
Aspiration hazard
Based on available data, the classification criteria are not met.

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.
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,RID,ADN, ADN, IMDG, IATA Void

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

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

- 14.4 Packing group
  - ADR,RID,ADN, 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 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

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Directive 2012/18/EU
  - Named dangerous substances - ANNEX I None of the ingredients is listed.
National regulations:
- Other regulations, limitations and prohibitive regulations
  The product is a medical device according to the Directive 93/42/EEC.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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
- 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)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Ox. Sol. 2: Oxidizing solids – Category 2