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

- **1.1 Product identifier**
  - **Trade name:** Porta Aurium 2, Auropal KF, Aurium Hitex LC

- **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**
  - Dental alloy
  - Manufacture of dental prothesis

- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**
    - Wieland Dental + Technik GmbH & Co. KG
    - Lindenstraße 2
    - 75175 Pforzheim, Germany
    - Telefon +49(0) 7231-37050, Telefax +49(0) 7231-357959

  - **Further information obtainable from:**
    - Regulatory Affairs
    - msds@wieland-dental.de

- **1.4 Emergency telephone number:**
  - Tel. +49(0) 7231-37050 (MO-FR: 8:00 - 17:00, Wieland-Dental Germany)

**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.
  - **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterisation: Mixtures**
  - **Description:** Dental alloy

<table>
<thead>
<tr>
<th>CAS:</th>
<th>EINECS:</th>
<th>Substances</th>
<th>Community workplace exposure limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4</td>
<td>231-131-3</td>
<td>silver</td>
<td>25-50%</td>
</tr>
<tr>
<td>7440-05-3</td>
<td>231-115-6</td>
<td>palladium</td>
<td>Ox. Sol. 2, H272 2.5-&lt;10%</td>
</tr>
<tr>
<td>7440-74-6</td>
<td>231-180-0</td>
<td>indium</td>
<td>substance with a Community workplace exposure limit 2.5-&lt;10%</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.

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: No special measures required.

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
Only adequately trained personnel should handle this product.
For use in dentistry only.
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: Store only in the original receptacle.

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:
  - CAS: 7440-22-4 silver
    - WEL Long-term value: 0.1 mg/m³
  - CAS: 7440-74-6 indium
    - WEL Short-term value: 0.3 mg/m³
    - Long-term value: 0.1 mg/m³
      as In

- 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.
    - Keep away from foodstuffs, beverages and feed.
    - Wash hands before breaks and at the end of work.
  - 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.
  - Material of 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: 910 - 1110 °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.
 exploision limits: 
Lower: Not determined. 
Upper: Not determined. 

 Vapour pressure: Not applicable. 

 Density at 20 °C: 13.7 - 14.2 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. 
 10.3 Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications. 
 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. 

 (Contd. on page 5)
12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

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.

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: Not applicable.

14.6 Special precautions for user Not applicable.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

Transport/Additional information: Not applicable.

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.

(Contd. on page 6)
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