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

1.1 Product identifier
Trade name: **Auropal Lot M-1**

1.2 Relevant identified uses of the substance or mixture and uses advised against
- Application of the substance / the mixture
  - Dental alloy
  - Manufacture of dental prosthesis

1.3 Details of the supplier of the safety data sheet
- Manufacturer/Supplier:
  - Ivoclar Vivadent AG
  - Bendererstrasse 2
  - FL-9494 Schaan
  - PRINCIPALITY OF LIECHTENSTEIN
  - Tel: +423 235 35 35
  - Fax: +423 235 33 60
- Further information obtainable from:
  - Regulatory Affairs
  - sds@ivoclarvivadent.com
- 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.
  - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures
- Description: Dental alloy

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 7440-22-4</td>
<td>silver</td>
</tr>
<tr>
<td>EINECS: 231-131-3</td>
<td>substance with a Community workplace exposure limit 10-25%</td>
</tr>
<tr>
<td>CAS: 7440-50-8</td>
<td>copper</td>
</tr>
<tr>
<td>EINECS: 231-159-6</td>
<td>substance with a Community workplace exposure limit 2.5-&lt;10%</td>
</tr>
</tbody>
</table>

(Contd. on page 2)
**Trade name: Auropal Lot M-1**

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

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

**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.
  - Do not allow to enter sewers/surface or ground water.
- **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.
Trade name: Auropal Lot M-1

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

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: 7440-50-8 copper
  - WEL: Short-term value: 2** mg/m³
  - Long-term value: 0.2** 1** mg/m³
  - *fume **dusts and mists (as Cu)
- 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 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).

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.
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Auropal Lot M-1

- pH-value: Not applicable.
- Change in condition
  Melting point/freezing point: 770 - 770 °C
  Initial boiling point and boiling range: Undetermined.
- Flash point: Not applicable.
- Flammability (solid, gas): Not determined.
- Auto-ignition temperature: Product is not selfigniting.
- Explosive properties: Product does not present an explosion hazard.
- Explosion limits:
  Lower: Not determined.
  Upper: Not determined.
- Vapour pressure: Not applicable.
- Density: Not determined.
- 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.
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.
- 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 Not applicable.
- Transport/Additional information: Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

(Contd. on page 6)
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