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

1.1 Product identifier

Trade name: Simidur Reflex LC

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 prothesis

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

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.
vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Dental alloy

Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-05-3</td>
<td>231-115-6</td>
<td>palladium Ox. Sol. 2, H272</td>
<td>50-100%</td>
</tr>
<tr>
<td>7440-22-4</td>
<td>231-131-3</td>
<td>silver substance with a Community workplace exposure limit</td>
<td>25-50%</td>
</tr>
</tbody>
</table>

(Contd. on page 2)
Trade name: Simidur Reflex LC

CAS: 7440-74-6
EINECS: 231-180-0
indium substance with a Community workplace exposure limit 0.1-%<2.5%

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.
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.
Use fire extinguishing methods suitable to surrounding conditions.

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
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
Extractors are required on all machines used for thermal processing or splinter removal processes.
No special measures required.
Only adequately trained personnel should handle this product.
For use in dentistry only.
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.
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          | Long-term value | Short-term value |
    |--------------|-----------------|------------------|
    | 7440-22-4 silver | 0.1 mg/m³       | 0.3 mg/m³       |
    | 7440-74-6 indium | 0.1 mg/m³       |                  |

- Additional information: The lists valid during the making were used as basis.

- 8.2 Exposure controls

  - Personal protective equipment:

    - General protective and hygienic measures:
      Keep away from foodstuffs, beverages and feed.
      Wash hands before breaks and at the end of work.
      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.
      The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
      Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
      Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

    - Material of gloves
      Thermal processing:
      Heat protection gloves
      The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

    - 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: White
      Odour: Odourless
      Odour threshold: Not determined.
**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.
Trade name: Simidur Reflex LC

- 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.
- 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
    Smaller quantities can be disposed of with household waste.
    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).
SECTION 15: Regulatory information

- 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