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

1.1 Product identifier

Trade name: BioPorta G, Porta Reflex

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

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: 7440-06-4</th>
<th>platinum</th>
<th>Ox. Sol. 2, H272</th>
<th>10-&lt;25%</th>
</tr>
</thead>
</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.
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:
  
<table>
<thead>
<tr>
<th>CAS: 7440-06-4 platinum</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEL Long-term value: 5 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.
    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/freezing point: 1040 - 1130 °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 at 20 °C: 18.8 - 18.9 g/cm³
Trade name: BioPorta G, Porta Reflex

- **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.
- **12.4 Mobility in soil**: No further relevant information available.
- **Additional ecological information**:
  - **General notes**: Generally not hazardous for water.
Trade name: BioPorta G, Porta Reflex

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).

- 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