

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

Printing date 23.01.2018

Version number 1

Revision: 05.12.2017

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

- **1.1 Product identifier**
- **Trade name: Simidur S2**
- **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 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
- **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.
- **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:**

CAS: 7440-05-3 EINECS: 231-115-6	palladium	Ox. Sol. 2, H272	50-100%
CAS: 7440-50-8 EINECS: 231-159-6	copper	substance with a Community workplace exposure limit	2.5-<10%
CAS: 7440-55-3 EINECS: 231-163-8	gallium		2.5-<10%

(Contd. on page 2)

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(Contd. of page 1)

· **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.· **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.

GB

(Contd. on page 3)

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Trade name: **Simidur S2**

(Contd. of page 2)

### 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: 7440-50-8 copper

WEL	Short-term value: 2** mg/m <sup>3</sup> Long-term value: 0.2* 1** mg/m <sup>3</sup> *fume **dusts and mists (as Cu)
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· **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: White

· **Odour:** Odourless

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/freezing point: 1100-1190 °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.

(Contd. on page 4)

**Safety data sheet**  
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(Contd. of page 3)

· <b>Vapour pressure:</b>	<i>Not applicable.</i>
· <b>Density at 20 °C:</b>	<i>10.7 g/cm<sup>3</sup></i>
· <b>Relative density</b>	<i>Not determined.</i>
· <b>Vapour density</b>	<i>Not applicable.</i>
· <b>Evaporation rate</b>	<i>Not applicable.</i>
· <b>Solubility in / Miscibility with water:</b>	<i>Insoluble.</i>
· <b>Partition coefficient: n-octanol/water:</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
<b>Dynamic:</b>	<i>Not applicable.</i>
<b>Kinematic:</b>	<i>Not applicable.</i>
· <b>Solvent content:</b>	
<b>Solids content:</b>	<i>100 %</i>
· <b>9.2 Other information</b>	<i>No further relevant information available.</i>

### 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.*

(Contd. on page 5)

GB

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Trade name: **Simidur S2**

(Contd. of page 4)

- **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

- |  |  |                |
|--|--|----------------|
| · <b>14.1 UN-Number</b>  | · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>  | Void           |
| · <b>14.2 UN proper shipping name</b>  | · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>  | Void           |
| · <b>14.3 Transport hazard class(es)</b>   | · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>  | · <b>Class</b> |
| · <b>14.4 Packing group</b>  | · <b>ADR/RID/ADN, IMDG, IATA</b>   | Void           |
| · <b>14.5 Environmental hazards:</b>   | Not applicable.  |                |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable.  |                |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable.  |                |
| · <b>Transport/Additional information:</b>                                       | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |                |
| · <b>UN "Model Regulation":</b>  | 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.

GB

(Contd. on page 6)

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(Contd. of page 5)

**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*

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