

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

Printing date 23.01.2018



Version number 1

Revision: 16.01.2018

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

- **1.1 Product identifier**
- **Trade name: Stahlgoldlot Nr. 80 M-1**
- **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**  
Manufacture of dental prosthesis  
Dental alloy
- **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**  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
Carc. 2 H351 Suspected of causing cancer.  
STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**
- 


GHS07 GHS08
- **Signal word** Danger
- **Hazard-determining components of labelling:**  
nickel
- **Hazard statements**  
H317 May cause an allergic skin reaction.  
H351 Suspected of causing cancer.  
H372 Causes damage to organs through prolonged or repeated exposure.
- **Precautionary statements**  
P201 Obtain special instructions before use.  
P260 Do not breathe dust/fume/gas/mist/vapours/spray.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P321 Specific treatment (see on this label).  
P405 Store locked up.

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P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**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: 7440-02-0	nickel	Carc. 2, H351; STOT RE 1, H372; Skin Sens. 1, H317	10-<25%
EINECS: 231-111-4			

· **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.

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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: 7440-02-0 nickel**

WEL	Long-term value: 0.5 mg/m <sup>3</sup> as Ni; Sk; Carc
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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

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· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable.
· <b>Change in condition</b>	
<b>Melting point/freezing point:</b>	860 - 920 °C
<b>Initial boiling point and boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<b>Solids content:</b>	100 %
· <b>9.2 Other information</b>	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**  
May cause an allergic skin reaction.

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- **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**  
Suspected of causing cancer.
- **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**  
Causes damage to organs through prolonged or repeated exposure.
- **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**  
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>                             | Void            |
| · <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. |

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· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	<i>Not applicable.</i>
· <b>Transport/Additional information:</b>	<i>Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).</i>
· <b>UN "Model Regulation":</b>	<i>Void</i>

### **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.*
- **REGULATION (EC) No 1907/2006 ANNEX XVII** *Conditions of restriction: 27*
- **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**  
*H317 May cause an allergic skin reaction.*  
*H351 Suspected of causing cancer.*  
*H372 Causes damage to organs through prolonged or repeated exposure.*
- **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*  
*Skin Sens. 1: Skin sensitisation – Category 1*  
*Carc. 2: Carcinogenicity – Category 2*  
*STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1*

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