

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

Printing date 23.06.2015

Version number 7


Revision: 07.05.2015

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

- **1.1 Product identifier**
- **Trade name: d.SIGN 96**
- **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
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285
- **Further information obtainable from:**
Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein
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**
Ox. Sol. 2 H272 May intensify fire; oxidiser.

 - **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**
- 

GHS03
- **Signal word** Danger
 - **Hazard statements**
H272 May intensify fire; oxidiser.
 - **Precautionary statements**
 - P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 - P221 Take any precaution to avoid mixing with combustibles.
 - P280 Wear protective gloves/protective clothing/eye protection/face protection.
 - P220 Keep/Store away from clothing/combustible materials.
 - P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.
 - 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.
 - **Information concerning particular hazards for human and environment:**
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.

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- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

| | | | |
|-------------------------------------|-----------|---|--------|
| CAS: 7440-22-4 EINECS: 231-131-3 | silver | substance with a Community workplace exposure limit | 3-<10% |
| CAS: 7440-06-4 EINECS: 231-116-1 | platinum | Ox. Sol. 2, H272 | 3-<10% |
| CAS: 7440-05-3 EINECS: 231-115-6 | palladium | Self-heat. 2, H252; Ox. Sol. 2, H272 | 3-<10% |

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

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **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.
Mechanical effects only.
- **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:** Do not inhale explosion gases or combustion gases.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **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.

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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.
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about fire - and explosion protection:** Keep ignition sources away - Do not smoke.
- **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:**

| |
|-------------------------|
| 7440-22-4 silver |
|-------------------------|

| |
|--|
| WEL Long-term value: 0.1 mg/m ³ |
|--|

| |
|---------------------------|
| 7440-06-4 platinum |
|---------------------------|

| |
|--|
| WEL Long-term value: 5 mg/m ³ |
|--|

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

- **8.2 Exposure controls**

- **Personal protective equipment:**
- **General protective and hygienic measures:**
Wash hands before breaks and at the end of work.
Usual hygienic measures for dental practice.
- **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.
After use of gloves apply skin-cleaning agents and skin cosmetics.
- **Material of gloves**
Mechanical processing:
Leather gloves
Strong material 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).

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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/Melting range: | 1050–1170 °C |
| · Boiling point/Boiling range: | Undetermined. |

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Contact with combustible material may cause fire.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Not determined.

· **Explosion limits:**

| | |
|-----------------|-----------------|
| · Lower: | Not determined. |
| · Upper: | Not determined. |

· **Vapour pressure:** Not applicable.

| | |
|----------------------------|------------------------|
| · Density at 20 °C: | 16.7 g/cm ³ |
| · 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:**

· **Organic solvents:** 0.0 %

· **Solids content:** 100.0 %

· **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.

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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**

· **Acute toxicity:**

· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritating effect.

· **Sensitisation:** No sensitising effects known.

· **Additional toxicological information:**

Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

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**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

· **European waste catalogue**

| | |
|----------|--------|
| 20 01 40 | metals |
|----------|--------|

· **Uncleaned packaging:**

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, ADN, IMDG, IATA** Void

· **14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA** Void

· **14.3 Transport hazard class(es)**

· **ADR, ADN, IMDG, IATA**

· **Class** Void

· **14.4 Packing group**

· **ADR, IMDG, IATA** Void

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| | |
|---|--|
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 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": | - |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **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**
H252 Self-heating in large quantities; may catch fire.
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)
Self-heat. 2: Self-Heating Substances and Mixtures, Hazard Category 2
Ox. Sol. 2: Oxidising Solids, Hazard Category 2
- *** Data compared to the previous version altered.**

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