

Safety Data Sheet
according to WHS Regulations

Printing date 30.01.2020

Version number 7



Revision: 30.01.2020

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Product identifier**
- **Trade name: d.SIGN 84**
- **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*
- **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*
- **Importer:**
*Ivoclar Vivadent Pty. Ltd.
1- 5 Overseas Drive
Noble Park North VIC 3174
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645*
- **Further information obtainable from:**
*Regulatory Affairs
sds@ivoclarvivadent.com*
- **Emergency telephone number:** *131 126 (Poisons Information Centre - 24 hours / 7 days)*

2 Hazard(s) Identification

- **Classification of the substance or mixture**
*Ox. Sol. 2 H272 May intensify fire; oxidiser.
Skin Corr. 1B H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.*
- **Label elements**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**
 
GHS03 GHS05
- **Signal word** *Danger*
- **Hazard-determining components of labelling:**
gallium
- **Hazard statements**
*May intensify fire; oxidiser.
Causes severe skin burns and eye damage.*
- **Precautionary statements**
Take any precaution to avoid mixing with combustibles.

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Wear protective gloves/protective clothing/eye protection/face protection.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Immediately call a POISON CENTER/doctor.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

Store locked up.

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.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**

· **Description:** Dental alloy

· **Dangerous components:**

| | | | |
|----------------|-----------|---------------------|---------|
| CAS: 7440-05-3 | palladium | Ox. Sol. 2, H272 | 50-100% |
| CAS: 7440-22-4 | silver | | 10-25% |
| CAS: 7440-74-6 | indium | | 2.5-10% |
| CAS: 7440-55-3 | gallium | Skin Corr. 1B, H314 | 2.5-10% |

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

· **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.

Mechanical effects only.

· **After swallowing:** Seek medical treatment.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Fire Fighting Measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

The product is not flammable.

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- Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Do not inhale explosion gases or combustion gases.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**
Extractors are required on all machines used for thermal processing or splinter removal processes.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 7440-22-4 silver

NES Long-term value: 0.1 mg/m³WES Long-term value: 0.1 mg/m³

CAS: 7440-74-6 indium

NES Long-term value: 0.1 mg/m³
as InWES Long-term value: 0.1 mg/m³
as In

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

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
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.

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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).

9 Physical and Chemical Properties

· **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: | 1140–1335 °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: | 11.3 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:**

· **Solids content:** 100 %

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· **Other information** *No further relevant information available.*

10 Stability and Reactivity

- **Reactivity** *No further relevant information available.*
- **Chemical stability** *Stable under normal handling and storage conditions.*
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Possibility of hazardous reactions** *No dangerous reactions known.*
- **Conditions to avoid** *No further relevant information available.*
- **Incompatible materials:** *No further relevant information available.*
- **Hazardous decomposition products:** *None under normal conditions of storage and use.*

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**
- **Skin corrosion/irritation** *No irritant effect.*
- **Serious eye damage/irritation** *No irritating effect.*
- **Respiratory or skin sensitisation** *No sensitising effects known.*
- **Additional toxicological information:**
Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** *No further relevant information available.*
- **Mobility in soil** *No further relevant information available.*
- **Additional ecological information:**
- **General notes:** *Not hazardous for water.*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*
- **Other adverse effects** *No further relevant information available.*

13 Disposal considerations

- **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.*

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14 Transport information

| | |
|--|--|
| · UN-Number · ADG, ADN, IMDG, IATA | Void |
| · UN proper shipping name · ADG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class | Void |
| · Packing group · ADG, IMDG, IATA | Void |
| · Environmental hazards: · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · 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 |

15 Regulatory information

| | |
|--|--------|
| · Safety, health and environmental regulations/legislation specific for the substance or mixture | |
| · Australian Inventory of Chemical Substances | |
| CAS: 7440-22-4 | silver |
| CAS: 7440-74-6 | indium |
| · Standard for the Uniform Scheduling of Medicines and Poisons | |
| CAS: 7440-22-4 | silver |
| S2 | |
| · GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS). | |
| · Hazard pictograms | |
|  | |
| GHS03 GHS05 | |
| · Signal word Danger | |
| · Hazard-determining components of labelling: gallium | |
| · Hazard statements May intensify fire; oxidiser. Causes severe skin burns and eye damage. | |
| · Precautionary statements Take any precaution to avoid mixing with combustibles. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. IF INHALED: Remove person to fresh air and keep comfortable for breathing. | |

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Immediately call a POISON CENTER/doctor.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

Store locked up.

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

- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category P8 OXIDISING LIQUIDS AND SOLIDS**
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
- **Chemical safety assessment:** *A Chemical Safety Assessment has not been carried out.*

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.

H314 Causes severe skin burns and eye damage.

- **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

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

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Eye Dam. 1: Serious eye damage/eye irritation – Category 1