

**Safety Data Sheet**  
according to WHS Regulations

Printing date 30.01.2020

Version number 6

Revision: 30.01.2020

*Hazardous according to criteria of Australian Safety and Compensation Council.*

## 1 Identification

· **Product identifier**

· **Trade name:** **d.SIGN 91**

· **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 Irrit. 2 H315 Causes skin irritation.*

*Eye Irrit. 2A H319 Causes serious eye irritation.*

· **Label elements**

· **GHS label elements**

*The product is classified and labelled according to the Globally Harmonised System (GHS).*

· **Hazard pictograms**



GHS03 GHS07

· **Signal word** *Danger*

· **Hazard statements**

*May intensify fire; oxidiser.*

*Causes skin irritation.*

*Causes serious eye irritation.*

· **Precautionary statements**

*Keep away from heat. - No smoking.*

*Keep/Store away from clothing/combustible materials.*

*Take any precaution to avoid mixing with combustibles.*

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

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

*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	25-50%
CAS: 7440-74-6	indium		2.5-10%
CAS: 7440-55-3	gallium	Skin Corr. 1B, H314	<2.5%

· **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.*

*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.

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### 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: 7440-74-6 indium**

NES Long-term value: 0.1 mg/m<sup>3</sup>  
as In

WES Long-term value: 0.1 mg/m<sup>3</sup>  
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.  
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.

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- **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:**

· <b>Form:</b>	Solid
· <b>Colour:</b>	White
· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

· <b>Melting point/freezing point:</b>	1175–1305 °C
· <b>Initial boiling point and boiling range:</b>	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:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

- **Vapour pressure:** Not applicable.

· <b>Density at 20 °C:</b>	14.3 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.

- **Solubility in / Miscibility with water:** Insoluble.

- **Partition coefficient: n-octanol/water:** Not determined.

- **Viscosity:**

· <b>Dynamic:</b>	Not applicable.
· <b>Kinematic:</b>	Not applicable.

- **Solvent content:**

· <b>Solids content:</b>	100 %
· <b>Other information</b>	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.

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- **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.

### 14 Transport information

- |  |      |
|--|------|
| · <b>UN-Number</b><br>· <b>ADG, ADN, IMDG, IATA</b>                                    | Void |
| · <b>UN proper shipping name</b><br>· <b>ADG, ADN, IMDG, IATA</b>                      | Void |
| · <b>Transport hazard class(es)</b><br>· <b>ADG, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void |
| · <b>Packing group</b><br>· <b>ADG, IMDG, IATA</b>                                     | Void |

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· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>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

### 15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Chemical Substances**

CAS: 7440-74-6 indium

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS03 GHS07

· **Signal word** *Danger*

· **Hazard statements**

May intensify fire; oxidiser.

Causes skin irritation.

Causes serious eye irritation.

· **Precautionary statements**

Keep away from heat. - No smoking.

Keep/Store away from clothing/combustible materials.

Take any precaution to avoid mixing with combustibles.

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

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

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.

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### 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*

*Skin Irrit. 2: Skin corrosion/irritation – Category 2*

*Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A*

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