

Printing date 30.01.2020 Version number 7 Revision: 30.01.2020

#### 1 Identification of the substance or mixture and of the supplier

- · Product identifier
- · Trade name: d.SIGN 84
- Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- $\cdot \textbf{\textit{Application of the substance / the mixture}} \ \textit{Manufacture of dental prothesis}$
- · 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 Ltd.

12 Omega St, Rosedale, Auckland

New Zealand

Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990

· Further information obtainable from:

Regulatory Affairs

sds@ivoclarvivadent.com

· Emergency telephone number: 0800 764 766 (National Poison Centre - 24 hours / 7 days)

#### 2 Hazards 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.

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.

· 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/Information on ingredients

- · Chemical characterisation: Mixtures
- · Description: Dental alloy

Dangerous components:				
CAS: 7440-22-4 EINECS: 231-131-3	silver		10-25%	
CAS: 7440-74-6 EINECS: 231-180-0	indium		2.5-10%	
CAS: 7440-55-3 EINECS: 231-163-8		Skin Corr. 1B, H314	2.5-10%	

<sup>·</sup> 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.

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- · 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/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

WES Long-term value: 0.1\* 0.01\*\* mg/m³ \*metal; \*\* soluble compds., as Ag

CAS: 7440-74-6 indium

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

- · 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

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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

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· General Information			

General Information

· Appearance:

Form: Solid Colour: White · Odour: **Odourless** · Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

1140–1335°C Melting point/freezing point: **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. Not determined. Upper: Not applicable. · Vapour pressure: · Density at 20 °C: 11.3 g/cm<sup>3</sup>

Not determined. · Relative density · Vapour density Not applicable. · Evaporation rate Not applicable.

· Solubility in / Miscibility with

Insoluble. water:

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

Viscosity:

Dynamic: Not applicable. Kinematic: Not applicable.

· Solvent content:

100 % Solids content:

No further relevant information available. · Other information

#### 10 Stability and reactivity

· Reactivity No further relevant information available.

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- · 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.

#### 14 Transport information

- · UN-Number
- · ADR/RID/ADN, ADN, IMDG, IATA Void
- · UN proper shipping name
- · ADR/RID/ADN, ADN, IMDG, IATA Void

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· Transport hazard class(es)	
· ADR/RID/ADN, ADN, IMDG, IATA · Class	Void
· Packing group · ADR/RID/ADN, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpo and the IBC Code	<b>l</b> 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
- · New Zealand Inventory of Chemicals

All ingredients are listed.

#### · HSNO Approval numbers

CAS: 7440-22-4	silver	HSR003077
CAS: 7440-74-6	indium	HSR003007

GHS label elements

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· Hazard pictograms





GHS03

03 GHS05

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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

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

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