

Printing date 29.08.2022 Version number 7 Revision: 29.08.2022

1 Identification of the substance or mixture and of the supplier

· Product identifier

· Trade name: d.SIGN 96

 $\cdot \textit{Relevant identified uses of the substance or \textit{mixture and uses advised against}}$

No further relevant information available.

· Application of the substance / the mixture 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 Pty. 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.

- · Label elements
- · GHS label elements

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

· Hazard pictograms



- · Signal word Danger
- · Hazard statements

May intensify fire; oxidiser.

· 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.

In case of fire: Use CO2, powder or water spray to extinguish.

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.

(Contd. on page 2)

Printing date 29.08.2022 Version number 7 Revision: 29.08.2022

Trade name: d.SIGN 96

(Contd. of page 1)

· 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.

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

3 Composition/Information on ingredients

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

· Dangerous compone	ents:		
CAS: 7440-22-4 EINECS: 231-131-3	silver		2.5-10%
CAS: 7440-06-4 EINECS: 231-116-1	platinum	Ox. Sol. 2, H272	2.5-10%
CAS: 7440-74-6 EINECS: 231-180-0	indium		<2.5%
CAS: 7439-89-6 EINECS: 231-096-4	iron	Acute Tox. 2, H300	<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
- · 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.
- · 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.
- · 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 Wear protective equipment. Keep unprotected persons away.

(Contd. on page 3)

Printing date 29.08.2022 Version number 7 Revision: 29.08.2022

Trade name: d.SIGN 96

(Contd. of page 2)

- 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.

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.
- · 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.
- · 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 tha	t reauire	monitoring	at the	worknlace.

CAS: 7440-22-4 silver

WES Long-term value: 0.1 mg/m³

CAS: 7440-06-4 platinum

WES Long-term value: 1* 0.002** mg/m³ *metal; **soluble salts, as Pt: dsen

CAS: 7440-74-6 indium

WES Long-term value: 0.1 mg/m³

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

(Contd. on page 4)

Printing date 29.08.2022 Version number 7 Revision: 29.08.2022

Trade name: d.SIGN 96

(Contd. of page 3)

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 chem	ical properties
· General Information	• •
· Appearance:	
Form:	Solid
Colour:	Yellow
· Odour:	Odourless
· Odour threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition	
Melting point/freezing point:	1050−1170 °C
Initial boiling point and boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gas):	Contact with combustible material may cause fire.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	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 %
· Other information	No further relevant information available.

Printing date 29.08.2022 Version number 7 Revision: 29.08.2022

Trade name: d.SIGN 96

(Contd. of page 4)

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
- · Specific symptoms in biological assay:
- · 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

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.

Void

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

14 Transport information

- · UN-Number
- · ADR/RID/ADN, ADN, IMDG, IATA

(Contd. on page 6)

Printing date 29.08.2022 Version number 7 Revision: 29.08.2022

Trade name: d.SIGN 96

	(Contd. of
UN proper shipping name ADR/RID/ADN, ADN, IMDG, IATA	Void
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 I and the IBC Code	Marpol 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

• •		- C			
· New Zealand Inventory of Chemicals					
All ingredients ar	e listed.				
· HSNO Approval	numbers				
CAS: 7440-22-4	silver				HSR003077
CAS: 7440-74-6	indium				HSR003007

· GHS label elements

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

· Hazard pictograms



- · Signal word Danger
- · Hazard statements

May intensify fire; oxidiser.

· 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.

In case of fire: Use CO2, powder or water spray to extinguish.

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

(Contd. on page 7)

Printing date 29.08.2022 Version number 7 Revision: 29.08.2022

Trade name: d.SIGN 96

(Contd. of page 6)

- · 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.

H300 Fatal if swallowed.

· Abbreviations and acronyms:

ADR: Accord relatif au transport international 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

Acute Tox. 2: Acute toxicity - Category 2