

Safety Data Sheet according to WHS Regulations

Printing date 29.08.2022

Version number 5

Revision: 29.01.2020

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Product identifier**
- **Trade name: d.SIGN 30**
- **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**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Dam. 1 H318 Causes serious eye damage.
Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sens. 1 H317 May cause an allergic skin reaction.

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

- **Hazard pictograms**



GHS05 GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**
cobalt
gallium
iron
- **Hazard statements**
Causes skin irritation.

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*Causes serious eye damage.**May cause allergy or asthma symptoms or breathing difficulties if inhaled.**May cause an allergic skin reaction.***· Precautionary statements***Avoid breathing dust/fume/gas/mist/vapours/spray.**Wear protective gloves / eye protection / face protection.**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).**Take off contaminated clothing and wash it before reuse.**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: 7440-48-4	cobalt Resp. Sens. 1, H334; Muta. 2, H341; Carc. 1B, H350; Repr. 1B, H360; Skin Sens. 1, H317	50-100%
CAS: 7440-47-3	chromium	25-50%
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.

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- **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** 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: 7440-48-4 cobalt	
NES	Long-term value: 0.05 mg/m ³
	Sen
WES	Long-term value: 0.05 mg/m ³
	Sen
CAS: 7440-47-3 chromium	
NES	Long-term value: 0.5 mg/m ³
WES	Long-term value: 0.5 mg/m ³

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

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- **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.
- **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: | 1145–1165 °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: | 7.8 g/cm ³ |
| Relative density | Not determined. |
| Vapour density | Not applicable. |
| Evaporation rate | Not applicable. |
| · Solubility in / Miscibility with water: | |
| Insoluble. | |

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· Partition coefficient: n-octanol/water:	<i>Not determined.</i>
· Viscosity:	
Dynamic:	<i>Not applicable.</i>
Kinematic:	<i>Not applicable.</i>
· Solvent content:	
Solids content:	<i>100 %</i>
· Other information	<i>No further relevant information available.</i>

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**
- Sensitisation possible through inhalation.*
- Sensitisation possible through skin contact.*
- **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.*

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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 | |
| · 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 Industrial Chemicals

CAS: 7440-57-5	Gold
CAS: 7440-22-4	silver
CAS: 7440-50-8	copper
CAS: 7440-06-4	platinum
CAS: 7440-74-6	indium
CAS: 7439-88-5	iridium

· Standard for the Uniform Scheduling of Medicines and Poisons

CAS: 7440-22-4	silver	S2
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· **GHS label elements**

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

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· **Hazard pictograms**

GHS05 GHS08

· **Signal word** *Danger*· **Hazard-determining components of labelling:**cobalt
gallium
iron· **Hazard statements**

Causes skin irritation.
 Causes serious eye damage.
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.
 Wear protective gloves / eye protection / face protection.
 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).
 Take off contaminated clothing and wash it before reuse.
 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.· **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.
 H317 May cause an allergic skin reaction.
 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 H341 Suspected of causing genetic defects.
 H350 May cause cancer.
 H360 May damage fertility or the unborn child.

· **Contact:**· **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

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vPvB: very Persistent and very Bioaccumulative
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Resp. Sens. 1: Respiratory sensitisation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Muta. 2: Germ cell mutagenicity – Category 2
Carc. 1B: Carcinogenicity – Category 1B
Repr. 1B: Reproductive toxicity – Category 1B

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