

## Safety Data Sheet in accordance with HSNO

Printing date 29.08.2022

Version number 5

Revision: 29.01.2020

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

- **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 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**
- Acute Tox. 5      H333 May be harmful if inhaled.
- 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.
- Aquatic Chronic 4      H413 May cause long lasting harmful effects to aquatic life.

- **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**

May be harmful if inhaled.  
Causes skin irritation.  
Causes serious eye damage.

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*May cause allergy or asthma symptoms or breathing difficulties if inhaled.**May cause an allergic skin reaction.**May cause long lasting harmful effects to aquatic life.***· 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.**IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**Immediately call a POISON CENTER/doctor.**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/Information on ingredients

**· Chemical characterisation: Mixtures****· Description:** Dental alloy**· Dangerous components:**

CAS: 7440-48-4 EINECS: 231-158-0	cobalt Resp. Sens. 1, H334; Muta. 2, H341; Carc. 1B, H350; Repr. 1B, H360; Skin Sens. 1, H317; Aquatic Chronic 4, H413	50-100%
CAS: 7440-47-3 EINECS: 231-157-5	chromium	25-50%
CAS: 7440-55-3 EINECS: 231-163-8	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/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

WES Long-term value: 0.02 mg/m<sup>3</sup>  
dust, fume: bio, sen, suspected carcinogen

CAS: 7440-47-3 chromium

WES Long-term value: 0.5 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.

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- **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

- |  |   |
|--|---|
| · <b>Information on basic physical and chemical properties</b> |   |
| · <b>General Information</b>                                   |   |
| · <b>Appearance:</b>   |   |
| Form:  | Solid   |
| Colour:  | White   |
| · <b>Odour:</b>  | Odourless                                     |
| · <b>Odour threshold:</b>                                      | Not determined.                               |
| · <b>pH-value:</b>   | Not applicable.                               |
| · <b>Change in condition</b>                                   |   |
| Melting point/freezing point:                                  | 1145–1165 °C                                  |
| Initial boiling point and boiling range:                       | Undetermined.                                 |
| · <b>Flash point:</b>  | Not applicable.                               |
| · <b>Flammability (solid, gas):</b>                            | Not determined.                               |
| · <b>Auto-ignition temperature:</b>                            | Product is not selfigniting.                  |
| · <b>Explosive properties:</b>                                 | Product does not present an explosion hazard. |
| · <b>Explosion limits:</b>                                     |   |
| Lower:   | Not determined.                               |
| Upper:   | Not determined.                               |
| · <b>Vapour pressure:</b>                                      | Not applicable.                               |
| · <b>Density at 20 °C:</b>                                     | 7.8 g/cm <sup>3</sup>                         |
| · <b>Relative density</b>                                      | Not determined.                               |
| · <b>Vapour density</b>  | Not applicable.                               |
| · <b>Evaporation rate</b>                                      | Not applicable.                               |
| · <b>Solubility in / Miscibility with water:</b>               |   |
| Insoluble.   |   |
| · <b>Partition coefficient: n-octanol/water:</b>               |   |
| Not determined.  |   |
| · <b>Viscosity:</b>  |   |
| Dynamic:   | Not applicable.                               |
| Kinematic:   | Not applicable.                               |

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· **Solvent content:****Solids content:**

100 %

· **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**
- **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.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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

### 14 Transport information

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

- **New Zealand Inventory of Chemicals**

All ingredients are listed.

- **HSNO Approval numbers**

CAS: 7440-48-4	cobalt	HSR003639
CAS: 7440-47-3	chromium	HSR002943

- **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

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- **Hazard statements**

- May be harmful if inhaled.

- Causes skin irritation.

- Causes serious eye damage.

- May cause allergy or asthma symptoms or breathing difficulties if inhaled.

- May cause an allergic skin reaction.

- May cause long lasting harmful effects to aquatic life.

- **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.

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

- Immediately call a POISON CENTER/doctor.

- 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.

- H413 May cause long lasting harmful effects to aquatic life.

- **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

- vPvB: very Persistent and very Bioaccumulative

- Acute Tox. 5: Acute toxicity – Category 5

- 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

- Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4