

**Safety Data Sheet**  
according to HPR, Schedule 1

Printing date 04/27/2018


Version number 5.1

Reviewed on 04/27/2018


**1 Identification**

- **Product identifier**
- **Trade name: d.SIGN 30**
- **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
  
- Ivoclar Vivadent Inc.  
1-6600 Dixie Road  
Mississauga, Ontario  
L5T 2Y2  
Canada  
Phone: +1 905 670 8499  
Fax: +1 905 670 3102
- **Information department:** *Quality Assurance / Regulatory Affairs*
- **Emergency telephone number:**  
24 Hour Emergency Assistance:  
Emergency-Call USA - Infotrac: 1-800-535-5053  
Emergency-Call Canada - Canutec: 1-613-996-6666
  
- General SDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

**2 Hazard identification**

- **Classification of the substance or mixture**
  - Skin Irritation - Category 2                    H315 Causes skin irritation.*
  - Serious Eye Damage - Category 1        H318 Causes serious eye damage.*
  - Respiratory Sensitizer - Category 1    H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.*
  
  - Skin Sensitizer - Category 1                H317 May cause an allergic skin reaction.*
  - Carcinogenicity – Category 2            H351 Suspected of causing cancer.*
  
  - **Label elements**
  - **GHS label elements**  
*The product is classified and labeled according to the Globally Harmonized System (GHS).*
  - **Hazard pictograms**
- 

GHS05



GHS08
- **Signal word** *Danger*
  - **Hazard-determining components of labeling:**  
*cobalt*  
*gallium*

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- **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.

Suspected of causing cancer.

- **Precautionary statements**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wash thoroughly after handling.

Contaminated work clothing should not be allowed out of the workplace.

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

[In case of inadequate ventilation] wear respiratory protection.

IF ON SKIN: Wash with plenty of water.

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.

IF exposed or concerned: Get medical advice/attention.

Immediately call a POISON CENTER/doctor.

Specific treatment (see on this label).

If skin irritation or rash occurs: Get medical advice/attention.

If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

Take off contaminated clothing and wash it before reuse.

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.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 1

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



HEALTH 0 Health = 0

FIRE 0 Fire = 0

REACTIVITY 0 Reactivity = 0

### 3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**

- **Description: Dental alloy**

- **Dangerous components:**

CAS: 7440-48-4	cobalt	40-70% w/w
CAS: 7440-47-3	chromium	25-40% w/w
CAS: 7440-55-3	gallium	3-5% w/w

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### 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 Firefighting 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 protection against explosions and fires:** 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.

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### 8 Exposure controls/ Personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

**CAS: 7440-48-4 cobalt**

EL Long-term value: 0.02 mg/m<sup>3</sup>  
as Co; ACGIH 2B

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

**CAS: 7440-47-3 chromium**

EL Long-term value: 0.5 mg/m<sup>3</sup>  
as metal

EV Long-term value: 0.05 mg/m<sup>3</sup>

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Usual hygienic measures for dental practice and dental laboratories.

· **Breathing equipment:** 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 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

Color: White

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range: 1145–1165 °C

Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable.

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· <b>Flammability (solid, gaseous):</b>	Not determined.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not applicable.
· <b>Density at 20 °C:</b>	7.8 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapor 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>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<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.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:**
- Sensitization possible through inhalation.
- Sensitization possible through skin contact.
- **Additional toxicological information:**
- Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.
- **Carcinogenic categories**

· <b>IARC (International Agency for Research on Cancer)</b>		
CAS: 7440-48-4	cobalt	2B
CAS: 7440-47-3	chromium	3

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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally 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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                       |   |
|---------------------------------------|---|
| · <b>UN-Number</b>                    |   |
| · <b>DOT</b>                          | NA3077  |
| · <b>TDG, ADN, IMDG, IATA</b>         | Void  |
| · <b>UN proper shipping name</b>      |   |
| · <b>TDG, ADN, IMDG, IATA</b>         | Void  |
| · <b>Transport hazard class(es)</b>   |   |
| · <b>DOT</b>                          |   |
| · <b>Class</b>                        | 9 Miscellaneous dangerous substances and articles |
| · <b>Label</b>                        | 9   |
| · <b>TDG, ADN, IMDG, IATA</b>         |   |
| · <b>Class</b>                        | Void  |
| · <b>Packing group</b>                |   |
| · <b>DOT</b>                          | III   |
| · <b>TDG, IMDG, IATA</b>              | Void  |
| · <b>Environmental hazards:</b>       |   |
| · <b>Marine pollutant:</b>            | No  |
| · <b>Special precautions for user</b> | Not applicable.                                   |

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- |  |  |
|--|--|
| <b>· Transport in bulk according to Annex II of MARPOL73/78 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

- Sara

- Section 355 (extremely hazardous substances):

None of the ingredients is listed.

- Section 313 (Specific toxic chemical listings):

CAS: 7440-22-4	silver
CAS: 7440-50-8	copper

- TSCA (Toxic Substances Control Act):

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

- GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- Hazard pictograms



GHS05    GHS08

- Signal word Danger

- Hazard-determining components of labeling:

cobalt

gallium

- 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.

Suspected of causing cancer.

- Precautionary statements

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wash thoroughly after handling.

Contaminated work clothing should not be allowed out of the workplace.

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

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*[In case of inadequate ventilation] wear respiratory protection.*

*IF ON SKIN: Wash with plenty of water.*

*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.*

*IF exposed or concerned: Get medical advice/attention.*

*Immediately call a POISON CENTER/doctor.*

*Specific treatment (see on this label).*

*If skin irritation or rash occurs: Get medical advice/attention.*

*If experiencing respiratory symptoms: Call a POISON CENTER/doctor.*

*Take off contaminated clothing and wash it before reuse.*

*Store locked up.*

*Dispose of contents/container in accordance with local/regional/national/international regulations.*

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

*The product is a medical device according to the Directive 93/42/EEC.*

*This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.*

· **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.*

· **Date of preparation / last revision** 04/27/2018 / 5

· **Abbreviations and acronyms:**

*IMDG: International Maritime Code for Dangerous Goods*

*DOT: US Department of Transportation*

*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)*

*NFPA: National Fire Protection Association (USA)*

*HMIS: Hazardous Materials Identification System (USA)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

· **\* Data compared to the previous version altered.**