

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 23.06.2015

Version number 5

Revision: 07.05.2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name: d.SIGN 30**
- **1.2 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
- **1.3 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
- **Further information obtainable from:**
Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein
Regulatory Affairs
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
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.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms**



GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**
cobalt
- **Hazard statements**
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 May cause an allergic skin reaction.
H413 May cause long lasting harmful effects to aquatic life.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P284 [In case of inadequate ventilation] wear respiratory protection.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P321 Specific treatment (see on this label).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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· **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.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Dental alloy

· **Dangerous components:**

| | | |
|-------------------|--|---------|
| CAS: 7440-48-4 | cobalt | 50-100% |
| EINECS: 231-158-0 | Resp. Sens. 1, H334; Skin Sens. 1, H317; Aquatic Chronic 4, H413 | |
| CAS: 7440-47-3 | chromium | 25-50% |
| EINECS: 231-157-5 | substance with a Community workplace exposure limit | |

· **Additional information:** For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 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.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:** The product is not flammable.

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

· **5.3 Advice for firefighters**

· **Protective equipment:** Do not inhale explosion gases or combustion gases.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures** Not required.

· **6.2 Environmental precautions:** No special measures required.

· **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.

· **6.4 Reference to other sections**

See Section 7 for information on safe handling.

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See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 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.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

| |
|---------------------------|
| 7440-47-3 chromium |
|---------------------------|

| |
|--|
| WEL Long-term value: 0.5 mg/m ³ |
|--|

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

- **8.2 Exposure controls**

- **Personal protective equipment:**
- **General protective and hygienic measures:** Usual hygienic measures for dental practice.
- **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).

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

| | |
|----------------|-------|
| Form: | Solid |
| Colour: | White |

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| | |
|---|---|
| · Odour: | Odourless |
| · Odour 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. |
| · Flammability (solid, gaseous): | Not determined. |
| · Self-igniting: | Product is not selfigniting. |
| · Danger of explosion: | 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. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| Dynamic: | Not applicable. |
| Kinematic: | Not applicable. |
| · Solvent content: | |
| Solids content: | 100 % |
| · 9.2 Other information | No further relevant information available. |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.

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- **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.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
 - **European waste catalogue**
- | | |
|----------|--------|
| 20 01 40 | metals |
|----------|--------|
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** Void
- **14.2 UN proper shipping name**
- **ADR, ADN, IMDG, IATA** Void
- **14.3 Transport hazard class(es)**
- **ADR, ADN, IMDG, IATA**
- **Class** Void
- **14.4 Packing group**
- **ADR, IMDG, IATA** Void
- **14.5 Environmental hazards:**
- **Marine pollutant:** No
- **14.6 Special precautions for user** Not applicable.
- **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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| | |
|--|--|
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | - |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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**
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H413 May cause long lasting harmful effects to aquatic life.
- **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
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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)
Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
Aquatic Chronic 4: Hazardous to the aquatic environment - Chronic Hazard, Category 4
- *** Data compared to the previous version altered.**

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