

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/19/2012

Version number 4

Reviewed on 12/19/2012

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

- **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 preparation** 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

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 MSDS Assistance:

US: 1-800-533-6825

Canada: 1-800-263-8182

2 Hazards identification

- **Classification of the substance or mixture**

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.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**

Irritant

May cause sensitisation by inhalation and skin contact.

May cause long-term adverse effects in the aquatic environment.

- **Information concerning particular hazards for human and environment:**

Avoid breathing of grinding dust and vapours. Melted material may cause burns.

- **Classification system:**

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- **Label elements**

- **GHS label elements**

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

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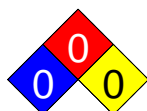
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· **Hazard pictograms**

GHS08

· **Signal word** *Danger*· **Hazard-determining components of labelling:***cobalt*· **Hazard statements***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/protective clothing/eye protection/face protection.**In case of inadequate ventilation wear respiratory protection.**Specific treatment (see on this label).**If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.**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 = 0**Fire = 0**Reactivity = 0*· **HMIS-ratings (scale 0 - 4)***Health = 0**Fire = 0**Reactivity = 0*· **Other hazards**· **Results of PBT and vPvB assessment**· **PBT:** *Not applicable.*· **vPvB:** *Not applicable.*

3 Composition/information on ingredients

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

7440-48-4	cobalt	25-100%
7440-47-3	chromium	25-50%
7440-55-3	gallium	1-<10%

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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:**

7440-48-4 cobalt

PEL ()	0.1* mg/m ³ as Co; *for metal dust & fume, as Co
REL ()	0.05* mg/m ³ inorg. compds.: *metal dust & fume, as Co
TLV ()	0.02 mg/m ³ as Co; BEI

7440-47-3 chromium

PEL ()	1* 0.5** mg/m ³ *metal; **inorganic compds., as Cr
REL ()	0.5* ** mg/m ³ *metal, **inorg.compds.; See Pocket Guide App. C
TLV ()	0.5 mg/m ³

· **Ingredients with biological limit values:**

7440-48-4 cobalt

BEI ()	15 µg/L Medium: urine Time: end of shift at end of workweek Parameter: Cobalt (background)
	1 µg/L Medium: blood Time: end of shift at end of workweek Parameter: Cobalt (background, semi-quantitative)

· **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.

· **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.

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- **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
Odour threshold:	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/Melting range:	1145–1165 °C (2093–2129 °F)
Boiling point/Boiling range:	Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapor pressure:** Not applicable.

- **Density at 20 °C (68 °F):** 7.8 g/cm³ (65.091 lbs/gal)

- **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 %

- **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.

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- **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:**
- **Primary irritant effect:**
- **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**

- **IARC (International Agency for Research on Cancer)**

7440-48-4	cobalt	2B
7440-47-3	chromium	3

- **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.

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14 Transport information

· UN-Number	
· DOT	NA3077
· ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT	
· Class	9 Miscellaneous dangerous substances and articles.
· Label	9
· ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT	III
· ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	-

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):

7440-22-4 silver

7440-50-8 copper

· TSCA (Toxic Substances Control Act):

7440-57-5 Gold

7440-22-4 silver

7440-50-8 copper

7440-06-4 platinum

7440-74-6 indium

7439-88-5 iridium

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

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· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

7440-22-4	silver	D
7440-50-8	copper	D

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **GHS label elements**

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

· **Hazard pictograms**



GHS08

· **Signal word Danger**

· **Hazard-determining components of labelling:**

cobalt

· **Hazard statements**

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/protective clothing/eye protection/face protection.

In case of inadequate ventilation wear respiratory protection.

Specific treatment (see on this label).

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

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 EC-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.

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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.

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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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