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Material Safety Data Sheet acc. to ISO 11014

Printing date 06/23/2015

Version number 5

Reviewed on 05/07/2015

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 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 SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

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.

Carc. 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



· Signal word Danger

• Hazard-determining components of labeling: cobalt

(Contd. on page 2)

CA

Printing date 06/23/2015

Version number 5

Reviewed on 05/07/2015

Trade name: d.SIGN 30

(Contd. of page 1) 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. Avoid breathing dust/fume/gas/mist/vapors/spray Wear protective gloves. *Wear eye protection / face protection.* [In case of inadequate ventilation] wear respiratory protection. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Do not handle until all safety precautions have been read and understood. 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). If experiencing respiratory symptoms: Call a poison center/doctor. Wash contaminated clothing before reuse. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. IF exposed or concerned: Get medical advice/attention. If skin irritation or rash occurs: Get medical advice/attention. If on skin: Wash with plenty of water. 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. · Hazard description: · WHMIS-symbols: D2A - Very toxic material causing other toxic effects · Classification system: · NFPA ratings (scale 0 - 4) Health = 1Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



• Other hazards

· Results of PBT and vPvB assessment

• **PBT:** Not applicable.

(Contd. on page 3)

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Version number 5

Reviewed on 05/07/2015

Trade name: d.SIGN 30

Printing date 06/23/2015

(Contd. of page 2)

40-70%

25-40%

3-5%

· vPvB: Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- **Description:** Dental alloy
- · Dangerous components:
- 7440-48-4 cobalt 7440-47-3 chromium
- 7440-47-3 chromun 7440-55-3 gallium

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 *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.

(Contd. on page 4)

Printing date 06/23/2015

Version number 5

Reviewed on 05/07/2015

Trade name: d.SIGN 30

(Contd. of page 3)

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.

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
- EL Long-term value: 0.02 mg/m³

as Co; ACGIH 2B

EV Long-term value: 0.1 mg/m³

7440-47-3 chromium

EL Long-term value: 0.5 mg/m³

as metal

EV Long-term value: 0.05 mg/m³

• 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.

• Eye protection:

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

(Contd. on page 5)

Printing date 06/23/2015

Version number 5

Reviewed on 05/07/2015

Trade name: d.SIGN 30

(Contd. of page 4)

Information on basic physical and	chemical properties
General Information Appearance:	
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
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:	$7.8 \ g/cm^3$
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water:	Insoluble.
Partition coefficient (n-octanol/wat	er): 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.
- Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: None under normal conditions of storage and use.

(Contd. on page 6)

CA

Printing date 06/23/2015

Version number 5

Reviewed on 05/07/2015

Trade name: d.SIGN 30

(Contd. of page 5)

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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

7440-47-3 chromium

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

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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· UN-Number

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CA

Material Safety Data Sheet acc. to ISO 11014

Printing date 06/23/2015

Version number 5

Reviewed on 05/07/2015

Trade name: d.SIGN 30

	(Contd. of pag	
TDG, ADN, IMDG, IATA	Void	
UN proper shipping name TDG, ADN, IMDG, IATA	Void	
Transport hazard class(es)		
DOT		
Class	9 Miscellaneous dangerous substances and articles	
Label	9	
TDG, ADN, IMDG, IATA		
Class	Void	
Packing group		
DOT	III	
TDG, 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.	
Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).	
UN ''Model Regulation'':	-	

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture · Sara

<u> </u>				
\cdot Section 35.	• Section 355 (extremely hazardous substances):			
None of the	e ingredients is listed.			
· Section 31.	3 (Specific toxic chemical listings):			
7440-22-4	silver			
7440-50-8	copper			
· TSCA (Tox	xic 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	· Proposition 65			
· Chemicals	known to cause cancer:			
None of the	None of the ingredients is listed.			
· Chemicals	known to cause reproductive toxicity for females:			
	e ingredients is listed.			
	(Contd. on page 8)			

Printing date 06/23/2015

Version number 5

Reviewed on 05/07/2015

(Contd. of page 7)

D

D

Trade name: d.SIGN 30

• 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

7440-50-8 copper

· 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.

· GHS label elements

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



· 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. Avoid breathing dust/fume/gas/mist/vapors/spray Wear protective gloves. Wear eye protection / face protection. [In case of inadequate ventilation] wear respiratory protection. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Do not handle until all safety precautions have been read and understood. 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). If experiencing respiratory symptoms: Call a poison center/doctor. Wash contaminated clothing before reuse. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. IF exposed or concerned: Get medical advice/attention. If skin irritation or rash occurs: Get medical advice/attention. If on skin: Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

(Contd. on page 9)

-C

Printing date 06/23/2015

Version number 5

Reviewed on 05/07/2015

Trade name: d.SIGN 30

(Contd. of page 8)

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 06/23/2015 / 4

· Abbreviations and acronyms: IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation IATA: International Air Transport Association ACGIH: American Conference of Governmental Industrial Hygienists 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) WHMIS: Workplace Hazardous Materials Information System (Canada) Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2 Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1 Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1 Skin Sens. 1: Sensitisation - Skin, Hazard Category 1 Carc. 2: Carcinogenicity, Hazard Category 2 • * Data compared to the previous version altered.