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

Printing date 23.06.2015

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Version number 7

Revision: 07.05.2015

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

- · 1.1 Product identifier
- · Trade name: d.SIGN 67

• 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 prothesis
- 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
- \cdot Classification according to Regulation (EC) No 1272/2008

Ox. Sol. 2 H272 May intensify fire; oxidiser.

· 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



· Signal word Danger

· Hazard statements

H272 May intensify fire; oxidiser.

· Precautionary statements

- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P221 Take any precaution to avoid mixing with combustibles.
- *P280 Wear protective gloves/protective clothing/eye protection/face protection.*
- P220 Keep/Store away from clothing/combustible materials.
- P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.

P501 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.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.

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· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

• **Description:** Dental alloy

· Dangerous components:				
CAS: 7440-05-3 EINECS: 231-115-6		Self-heat. 2, H252; Ox. Sol. 2, H272	50-100%	
CAS: 7440-22-4 EINECS: 231-131-3		substance with a Community workplace exposure limit	10-<25%	

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

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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:

7440-22-4 silver

WEL Long-term value: 0.1 mg/m³

• 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.*

· Eve protection:

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

9.1 Information on basic physical and chemical properties General Information			
Appearance:			
Form:	Solid		
Colour:	White		
Odour:	Odourless		
Odour threshold:	Not determined.		
pH-value:	Not applicable.		

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· Change in condition		
Melting point/Melting range:	1150–1270 °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:	10.8 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	t er): 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.

 \cdot 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.

• Sensitisation: No sensitising effects known.

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· Additional toxicological information:

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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:
- \cdot 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 Anne MARPOL73/78 and the IBC Code	e x II of Not applicable.	
• Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).	
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· UN "Model Regulation":

SECTION 15: Regulatory information

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

· 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

H252 Self-heating in large quantities; may catch fire.
H272 May intensify fire; oxidiser.
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) Self-heat. 2: Self-Heating Substances and Mixtures, Hazard Category 2 Ox. Sol. 2: Oxidising Solids, Hazard Category 2

 \cdot * Data compared to the previous version altered.

[·] National regulations: