

Printing date 06/23/2015 Version number 5 Reviewed on 05/07/2015

### 1 Identification

- · Product identifier
- · Trade name: d.SIGN 53
- · 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-

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

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

- · Label elements
- · GHS label elements

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

· Hazard pictograms



GHS03

- · Signal word Danger
- · Hazard statements

May intensify fire; oxidizer.

· Precautionary statements

Keep away from heat.

Take any precaution to avoid mixing with combustibles.

Wear protective gloves / eye protection / face protection.

 ${\it Keep/Store\ away\ from\ clothing/combustible\ materials}.$ 

(Contd. on page 2)

Printing date 06/23/2015 Version number 5 Reviewed on 05/07/2015

Trade name: d.SIGN 53

(Contd. of page 1)

*In case of fire: Use for extinction: CO2, powder or water spray.* 

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 = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



- · 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:			
7440-05-3	palladium	30-60%	
7440-22-4	silver	25-40%	
7440-31-5	tin	5-<10%	
7440-74-6	indium	1-<3%	

## 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.
- $\cdot$  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.

CA

Printing date 06/23/2015 Version number 5 Reviewed on 05/07/2015

Trade name: d.SIGN 53

(Contd. of page 2)

### 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.

### 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.
- $\cdot$  *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:

### 7440-22-4 silver

EL Short-term value: 0.03 mg/m³ Long-term value: 0.01 mg/m³

as Ag

EV Long-term value: 0.1\* 0.01\*\* mg/m³

\*metal; \*\*water-soluble compdounds (as silver)

### 7440-31-5 tin

EL Long-term value: 2 mg/m³

metal

EV Long-term value:  $2*0.1**mg/m^3$ 

\*metal, oxide, inorg. compds.; \*\*org. compds.: Skin

(Contd. on page 4)

Printing date 06/23/2015 Version number 5 Reviewed on 05/07/2015

Trade name: d.SIGN 53

(Contd. of page 3)

### 7440-74-6 indium

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

as In; ACGIH 2B

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

as indium

- · 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).

# 9 Physical and chemical properties

· I	nformation	on basic p	hysical	l and c	hemical	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: 1180-1280 °C Boiling point/Boiling range: Undetermined. · Flash point: Not applicable.

· Flammability (solid, gaseous): Not determined.

Product is not selfigniting. · Auto igniting:

· Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

Lower: Not determined. Not determined. Upper:

· Vapor pressure: Not applicable.

· Density at 20 °C: 10.7 g/cm<sup>3</sup> · Relative density Not determined.

(Contd. on page 5)

Printing date 06/23/2015 Version number 5 Reviewed on 05/07/2015

Trade name: d.SIGN 53

		(Contd. of page 4
· Vapour density	Not applicable.	
· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
Water:	Insoluble.	
· Partition coefficient (n-octano	ol/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.
- · 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: No sensitizing effects known.
- · Additional toxicological information:

Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

- · Carcinogenic categories
- · 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

(Contd. on page 6)

Printing date 06/23/2015 Version number 5 Reviewed on 05/07/2015

Trade name: d.SIGN 53

(Contd. of page 5)

- · 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.

UN-Number	
DOT	NA3077
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).

## 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.

(Contd. on page 7)

Printing date 06/23/2015 Version number 5 Reviewed on 05/07/2015

Trade name: d.SIGN 53

	(Contd. of page
· Section 313	(Specific toxic chemical listings):
7440-22-4 s	silver
7440-50-8 c	copper
· TSCA (Toxio	c Substances Control Act):
7440-57-5 C	Gold
7440-22-4 s	silver
7440-50-8 c	copper
7440-06-4 p	platinum
7440-74-6 ii	indium
7439-88-5 ii	ridium

#### · Proposition 65

### · Chemicals known to cause cancer:

None of the ingredients is listed.

· 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.

· GHS label elements

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

· Hazard pictograms



011303

- · Signal word Danger
- · Hazard statements

May intensify fire; oxidizer.

· Precautionary statements

Keep away from heat.

Take any precaution to avoid mixing with combustibles.

Wear protective gloves / eye protection / face protection.

Keep/Store away from clothing/combustible materials.

In case of fire: Use for extinction: CO2, powder or water spray.

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

(Contd. on page 8)

Printing date 06/23/2015 Version number 5 Reviewed on 05/07/2015

Trade name: d.SIGN 53

(Contd. of page 7)

- · 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)

Ox. Sol. 2: Oxidising Solids, Hazard Category 2

\* Data compared to the previous version altered.

CA