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 59
- 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

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

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

Oxidizing

Contact with combustible material may cause fire.

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).

· Hazard pictograms



· Signal word Danger

(Contd. on page 2)

Printing date 12/19/2012 Version number 4 Reviewed on 12/19/2012

Trade name: d.SIGN 59

(Contd. of page 1)

#### · Hazard statements

May intensify fire; oxidizer.

#### · Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Take any precaution to avoid mixing with combustibles.

Wear protective gloves/protective clothing/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.

· 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	25-100%
7440-22-4	silver	25-50%
7440-31-5	tin	1-<10%
7440-74-6	indium	1-<10%

### 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.

(Contd. on page 3)

Printing date 12/19/2012 Version number 4 Reviewed on 12/19/2012

Trade name: d.SIGN 59

(Contd. of page 2)

- · 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.

#### 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

 $PEL() 0.01 \text{ mg/m}^3$ 

metal and soluble compounds (as Ag)

 $REL() 0.01 \text{ mg/m}^3$ 

TLV() 0.1 mg/m<sup>3</sup>

metal: dust and fume

(Contd. on page 4)

Version number 4 Printing date 12/19/2012 Reviewed on 12/19/2012

Trade name: d.SIGN 59

	(Contd. of page 3)
7440-3	1-5 tin
PEL ()	$2 mg/m^3$
	metal
REL ()	$2 mg/m^3$
TLV ()	$2 mg/m^3$
	metal
7440-7	4-6 indium
REL ()	$0.1 \text{ mg/m}^3$
	and compounds, as In
	$0.1 \text{ mg/m}^3$

- · 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).

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:	1230–1280 °C (2246–2336 °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.	

Printing date 12/19/2012 Version number 4 Reviewed on 12/19/2012

Trade name: d.SIGN 59

		(Contd. of pag
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not applicable.	
· Density at 20 °C (68 °F):	10.7 g/cm³ (89.292 lbs/gal)	
· Relative density		
· Vapour density	Not applicable.	
· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
Water:	Insoluble.	
· Partition coefficient (n-octanol/wa	ter); 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.

### 12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.

(Contd. on page 6)

Printing date 12/19/2012 Version number 4 Reviewed on 12/19/2012

Trade name: d.SIGN 59

(Contd. of page 5)

- · 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.

UN-Number	NA 2077
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.

IIS A

Printing date 12/19/2012 Version number 4 Reviewed on 12/19/2012

Trade name: d.SIGN 59

(Contd. of page 6)

## 15 Regulatory information

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

Sur u		
· 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	
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.

· 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 l	isted.	

· 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



· Signal word Danger

Printing date 12/19/2012 Version number 4 Reviewed on 12/19/2012

Trade name: d.SIGN 59

(Contd. of page 7)

### · Hazard statements

May intensify fire; oxidizer.

#### · Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Take any precaution to avoid mixing with combustibles.

Wear protective gloves/protective clothing/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.

#### · 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.

### 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)

- USA