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

· Product identifier

· Trade name: Elektra

- 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

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· 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:			
7440-22-4	silver	25-100%	
7440-05-3	palladium	25-25%	
7440-50-8	copper	10-<25%	
7440-74-6	indium	1-≤2.5%	

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.

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- · 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/m³

metal: dust and fume

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	(Contd. of page
7440-5	0-8 copper
PEL ()	$1*0.1**mg/m^3$
	as Cu *dusts and mists **fume
$REL\left(\right)$	$1*0.1**mg/m^3$
	as Cu *dusts and mists **fume
TLV()	1* 0.2** mg/m³ *dusts and mists; **fume; as Cu
	*dusts and mists; **fume; as Cu
7440-7	4-6 indium
	0.1 mg/m^3
	and compounds, as In
TLV()	0.1 mg/m^3
.,	0.1 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 o · General Information · Appearance:	chemical properties	
Form:	Solid	
Color:	White	
· Odor:	Odorless	
Odour threshold:	Not determined.	
· pH-value:	Not applicable.	
Change in condition Melting point/Melting range: Boiling point/Boiling range:	865 – 990 °C (1589 – 1814 °F) Undetermined.	
· Flash point:	Not applicable.	
· Flammability (solid, gaseous):	Not determined.	
· Auto igniting:	Product is not selfigniting.	

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		(Contd. of page
· 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):	10.4 g/cm³ (86.788 lbs/gal)	
· Relative density	Not determined.	
· Vapour density	Not applicable.	
· Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water:	Insoluble.	
· Partition coefficient (n-octanol/w	vater): 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.

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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.
- $\cdot \textit{Other adverse effects} \ \textit{No further relevant information available}.$

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
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.

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Trade	name:	El	el	ttr	a
1 / uuc	nume.		•	•••	••

	(Contd. of page 6)
· 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 (Tox	· 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			

· Proposition 65

7439-88-5 iridium

· 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.

· 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).

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· Hazard pictograms



- · Signal word Danger
- · 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)

 ${\it HMIS: Hazardous\ Materials\ Identification\ System\ (USA)}$

USA