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

- · Product identifier
- · Trade name: XL-X
- 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.

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USA

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Fax +1 716 691 2285

Ivoclar Vivadent Inc.

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L5T 2Y2

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*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

The product is not classified according to the Globally Harmonized System (GHS).

- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.
- · 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 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 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.

Void

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- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



 $0 \quad Health = 0$ Fire = 0

- · 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	10-<25%	
7440-50-8	copper	10-<25%	
7440-05-3	palladium	3-<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.

- · 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.

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- · 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  $0.1*0.01**mg/m^3$ 

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

#### 7440-50-8 copper

EL 1\* 0.2\*\* mg/m³
\*dusts and mists; \*\*fume

 $EV \mid 0.2*1**mg/m^3$ 

as copper, \*fume;\*\*dust and mists

- · 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.

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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	chemical properties
General Information	• •
Appearance:	
Form:	Solid
Color:	Yellow
Odor:	Odorless
Odour threshold:	Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	870 − 910 °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:	$13.9 \text{ g/cm}^3$
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 %

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· 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.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- $\cdot \textit{\textbf{Mobility in soil}} \ \textit{No further relevant information available}.$
- · 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.

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- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

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	
TDG 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	Tof
MARPOL73/78 and the IBC Code	Not applicable.
UN "Model Regulation":	_

### 15 Regulatory information

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

7440-50-8	copper	
· TSCA (Toxic Substances Control Act):		
7440-57-5		
7440-22-4		
7440-50-8		
7440-06-4		
7440-74-6		
7439-88-5	iridium	

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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	
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.	
OSHA-Ca (Occupational Safety & Health Administration)	
None of the ingredients is listed.	
Canadian substance listings:	
Canadian Domestic Substances List (DSL)	
7440-57-5 Gold	
7440-22-4 silver	
7440-50-8 copper	
7440-06-4 platinum	
7440-74-6 indium	
7439-88-5 iridium	
Canadian Ingredient Disclosure list (limit 0.1%)	
None of the ingredients is listed.	
Canadian Ingredient Disclosure list (limit 1%)	
7440-22-4 silver	
7440-50-8 copper	

- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the EC-directive 93/42/EEC.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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## 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:

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)

CA