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.
      - 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**
  - 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.
Trade name: XL-X

Classification system:
- NFPA ratings (scale 0 - 4)
  - Health = 0
  - Fire = 0
  - Reactivity = 0

- HMIS-ratings (scale 0 - 4)
  - Health = 0
  - Fire = 0
  - Reactivity = 0

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

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 1-<10%

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.
- 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.

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.
Trade name: XL-X

- 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 (g) | 0.01 mg/m³ |
  | REL (g) | 0.01 mg/m³ |
  | TLV (g) | 0.1 mg/m³ |
  metal: dust and fume
  7440-50-8 copper
  | PEL (g) | 1* 0.1** mg/m³ |
  | REL (g) | 1* 0.1** mg/m³ |
  | TLV (g) | 1* 0.2** mg/m³ |
  *dusts and mists; **fume; as Cu
- 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.
Trade name: XL-X

- **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 breakthrough 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

- **Information on basic physical and 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 (1598 – 1670 °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.
- **Explosion limits:**
  - Lower: Not determined.
  - Upper: Not determined.
- **Vapor pressure:** Not applicable.
- **Density at 20 °C (68 °F):** 13.9 g/cm³ (115.996 lbs/gal)
- **Relative density**
  Not applicable.
- **Vapour density**
  Not applicable.
- **Evaporation rate**
  Not applicable.
- **Solubility in / Miscibility with**
  Water: Insoluble.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  Dynamic: Not applicable.
Trade name: **XL-X**

| 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**: No irritant effect.
  - **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.
  - **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.

14 Transport information

- 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.

- Transport in bulk according to Annex II of 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

- 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 silver
Trade name: XL-X

- **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.

  - **OSHA-Ca (Occupational Safety & Health Administration)**
    
    None of the ingredients is listed.

  - **GHS label elements** Void
    
    - **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.
      
      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)