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

- **Product identifier**
  - Trade name: Protocol

- **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**
    - GHS03

- **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 = 0
    Reactivity = 0
  - HMIS-ratings (scale 0 - 4)
    HEALTH
    Health = 0
    FIRE
    Fire = 0
    REACTIVITY
    Reactivity = 0

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

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### Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Dental alloy

- **Dangerous components:**
  - 7440-05-3 palladium 25-100%
  - 7440-22-4 silver 1-<10%
  - 7440-55-3 gallium 1-<10%
  - 7440-74-6 indium 1-<10%

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### 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.
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:
    
    | Component | Limit Value | Description |
    |-----------|-------------|-------------|
    | 7440-22-4 silver | 0.01 mg/m³ | PEL (metal and soluble compounds (as Ag)) |
    | 7440-22-4 silver | 0.01 mg/m³ | REL (metal: dust and fume) |
Trade name: Protocol

7440-74-6 indium

REL ( ) 0.1 mg/m³
and compounds, as In
TLV ( ) 0.1 mg/m³

- 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 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: White
      Odor: Odorless
      Odour threshold: Not determined.
    - pH-value: Not applicable.

  - Change in condition
    Melting point/Melting range: 1270–1310 °C (2318–2390 °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): 11 g/cm³ (91.795 lbs/gal)
  - Relative density Not determined.
Trade name: Protocol

- 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.
  - 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.
  - 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

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- **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 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.
### Trade name: Protocol

#### 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
- 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 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).**
- **Hazard pictograms**
  - GHS03

#### 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.
Trade name: **Protocol**

(Contd. of page 7)

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)