1 Identification

- **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 mixture**
  - Manufacture of dental prosthesis
- **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
  - 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 SDS Assistance:
    - US: 1-800-533-6825
    - Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
  - Ox. Sol. 2 H272 May intensify fire; oxidizer.
  - Skin Corr. 1C H314 Causes severe skin burns and eye damage.
  - Eye Dam. 1 H318 Causes serious eye damage.
Trade name: **Protocol**

- **Label elements**
  - **GHS label elements**
    The product is classified and labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms**
    ![GHS03](image) ![GHS05](image)
- **Signal word** Danger
- **Hazard-determining components of labeling:**
  - **gallium**
- **Hazard statements**
  - May intensify fire; oxidizer.
  - Causes severe skin burns and eye damage.
- **Precautionary statements**
  - Keep away from heat.
  - Take any precaution to avoid mixing with combustibles.
  - Wear protective gloves / eye protection / face protection.
  - Do not breathe dusts or mists.
  - Keep/Store away from clothing/combustible materials.
  - Wash thoroughly after handling.
  - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
  - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
  - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
  - Continue rinsing.
  - Immediately call a poison center/doctor.
  - Specific treatment (see on this label).
  - If swallowed: Rinse mouth. Do NOT induce vomiting.
  - Wash contaminated clothing before reuse.
  - In case of fire: Use for extinction: CO2, powder or water spray.
  - Store locked up.
  - 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](image) ![Fire](image) ![Reactivity](image)
    - Health = 1
    - Fire = 0
    - Reactivity = 0
  - **HMIS-ratings (scale 0 - 4)**
    ![Health](image) ![Fire](image) ![Reactivity](image)
    - Health = 1
    - Fire = 0
    - Reactivity = 0
- **Other hazards**
  - **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
Trade name: Protocol

° vPoB: Not applicable.

3 Composition/information on ingredients

° Chemical characterization: Mixtures
° Description: Dental alloy

° Dangerous components:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-05-3 palladium</td>
<td>50-100%</td>
</tr>
<tr>
<td>7440-22-4 silver</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>7440-55-3 gallium</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>7440-74-6 indium</td>
<td>2.5-&lt;10%</td>
</tr>
</tbody>
</table>

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 Fire-fighting 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

<table>
<thead>
<tr>
<th>Component</th>
<th>PEL Long-term value:</th>
<th>REL Long-term value:</th>
<th>TLV Long-term value:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td>0.01 mg/m³</td>
<td>0.01 mg/m³</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>as metal dust and fume</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7440-74-6 indium</td>
<td>0.1 mg/m³</td>
<td>as In</td>
<td>0.1 mg/m³ as In</td>
</tr>
</tbody>
</table>

- 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).
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.
- 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.
  - OSHA-Ca (Occupational Safety & Health Administration)
    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: NA3077
- DOT: Void
- ADR, ADN, IMDG, IATA: Void
- UN proper shipping name
  - ADR, ADN, IMDG, IATA: Void
### Transport hazard class(es)
- **DOT**
- **Class** 9
- **Label** Miscellaneous dangerous substances and articles

#### 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.

#### Transport/Additional information:
Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

### 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
- 7440-50-8 copper
- 7440-06-4 platinum
- 7440-74-6 indium
- 7459-88-5 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
  - 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.

### GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

### Hazard pictograms

- GHS03
- GHS05

### Signal word

Danger

### Hazard-determining components of labeling:

- Gallium

### Hazard statements

- May intensify fire; oxidizer.
- Causes severe skin burns and eye damage.

### Precautionary statements

- Keep away from heat.
- Take any precaution to avoid mixing with combustibles.
- Wear protective gloves / eye protection / face protection.
- Wear eye protection / face protection.
- Do not breathe dusts or mists.
- Keep/Store away from clothing/combustible materials.
- Wash thoroughly after handling.
- If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- If INHALED: Remove person to fresh air and keep comfortable for breathing.
- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- Immediately call a poison center/doctor.
- Specific treatment (see on this label).
- If swallowed: Rinse mouth. Do NOT induce vomiting.
- Wash contaminated clothing before reuse.
- In case of fire: Use for extinction: CO2, powder or water spray.
- Store locked up.
- 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 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.

(Contd. on page 9)
40.1.5  *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.

- **Date of preparation / last revision** 06/23/2015 / 4
- **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
  EINECS: European Inventory of Existing Commercial Chemical Substances
  ELINCS: European List of Notified Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  NFPA: National Fire Protection Association (USA)
  HMIS: Hazardous Materials Identification System (USA)
  Ox. Sol. 2: Oxidising Solids, Hazard Category 2
  Skin Corr. 1C: Skin corrosion/irritation, Hazard Category 1C
  Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
- *Data compared to the previous version altered.*