

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 06/23/2015

Version number 5

Reviewed on 05/18/2015

**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*  
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- Ivoclar Vivadent Inc.*  
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*Canada*  
*Phone: +1 905 670 8499*  
*Fax: +1 905 670 3102*
- **Information department:**  
*Quality Assurance / Regulatory Affairs*  
*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.*

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· **Label elements**

· **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: CO<sub>2</sub>, 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 = 1

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1

Fire = 0

Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

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· **vPvB:** Not applicable.

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### 3 Composition/information on ingredients

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

· **Dangerous components:**

7440-05-3	palladium	50-100%
7440-22-4	silver	2.5-<10%
7440-55-3	gallium	2.5-<10%
7440-74-6	indium	2.5-<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 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.

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### 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 Long-term value: 0.01 mg/m<sup>3</sup>

REL Long-term value: 0.01 mg/m<sup>3</sup>

TLV Long-term value: 0.1 mg/m<sup>3</sup>  
metal: dust and fume

#### 7440-74-6 indium

REL Long-term value: 0.1 mg/m<sup>3</sup>  
as In

TLV Long-term value: 0.1 mg/m<sup>3</sup>  
as In

- **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).

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### 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· <b>Form:</b>	Solid
· <b>Color:</b>	White
· <b>Odor:</b>	Odorless
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· <b>Melting point/Melting range:</b>	1270–1310 °C (2318–2390 °F)
· <b>Boiling point/Boiling range:</b>	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:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapor pressure:** Not applicable.

· <b>Density at 20 °C (68 °F):</b>	11 g/cm <sup>3</sup> (91.795 lbs/gal)
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.

· **Solubility in / Miscibility with**

· **Water:** Insoluble.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

· <b>Dynamic:</b>	Not applicable.
· <b>Kinematic:</b>	Not applicable.

· **Solvent content:**

· <b>Solids content:</b>	100 %
· <b>Other information</b>	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.

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### 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**

· <b>NTP (National Toxicology Program)</b>
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None of the ingredients is listed.
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· <b>OSHA-Ca (Occupational Safety &amp; Health Administration)</b>
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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.
- **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

- |                                  |        |
|----------------------------------|--------|
| · <b>UN-Number</b>               |        |
| · <b>DOT</b>                     | NA3077 |
| · <b>ADR, ADN, IMDG, IATA</b>    | Void   |
| · <b>UN proper shipping name</b> |        |
| · <b>ADR, ADN, IMDG, IATA</b>    | Void   |

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· <b>Transport hazard class(es)</b>	
· <b>DOT</b>	
· <b>Class</b>	9 Miscellaneous dangerous substances and articles
· <b>Label</b>	9
· <b>ADR, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>Packing group</b>	
· <b>DOT</b>	III
· <b>ADR, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	
	Not applicable.
· <b>Transport/Additional information:</b>	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· <b>UN "Model Regulation":</b>	-

### 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

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.

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· **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.

· **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: CO<sub>2</sub>, 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.

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· **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.*

· **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.**

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