

## Safety Data Sheet in accordance with HSNO

Printing date 30.01.2020


Version number 2

Revision: 30.01.2020


### 1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** ***Harmony 2***
- **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
- 
- **Importer:**  
Ivoclar Vivadent Ltd.  
12 Omega St, Rosedale, Auckland  
New Zealand  
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **Emergency telephone number:** 0800 764 766 (National Poison Centre - 24 hours / 7 days)

### 2 Hazards identification

- **Classification of the substance or mixture**  
Ox. Sol. 2      H272 May intensify fire; oxidiser.  
Aquatic Acute 2      H401 Toxic to aquatic life.  
Aquatic Chronic 2      H411 Toxic to aquatic life with long lasting effects.
  - **Label elements**
  - **GHS label elements**  
The product is classified and labelled according to the Globally Harmonised System (GHS).
  - **Hazard pictograms**
- 

GHS03



GHS09
- **Signal word** *Danger*
  - **Hazard statements**  
May intensify fire; oxidiser.  
Toxic to aquatic life with long lasting effects.
  - **Precautionary statements**  
Keep away from heat. - No smoking.  
Keep/Store away from clothing/combustible materials.  
Take any precaution to avoid mixing with combustibles.  
Wear protective gloves/protective clothing/eye protection/face protection.  
In case of fire: Use to extinguish: CO<sub>2</sub>, powder or water spray.  
Dispose of contents/container in accordance with local/regional/national/international regulations.

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

### 3 Composition/Information on ingredients

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

- **Dangerous components:**

CAS: 7440-22-4 EINECS: 231-131-3	silver	25-50%
CAS: 7440-74-6 EINECS: 231-180-0	indium	25-50%
CAS: 7440-66-6 EINECS: 231-175-3	zinc powder -zinc dust (stabilized) Aquatic Acute 1, H400; Aquatic Chronic 1, H410	2.5-10%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 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.  
Use fire extinguishing methods suitable to surrounding conditions.
- **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.

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### 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 fire - and explosion protection:** 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 facilities:** No further data; see item 7.
- **Control parameters**

#### Ingredients with limit values that require monitoring at the workplace:

CAS: 7440-22-4 silver

WES	Long-term value: 0.1* 0.01** mg/m <sup>3</sup> *metal; ** soluble compds., as Ag
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CAS: 7440-74-6 indium

WES	Long-term value: 0.1 mg/m <sup>3</sup> as In
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- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.
- **Respiratory protection:** 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 material gloves  
Thermal processing:  
Heat protection gloves

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- **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:**

· <b>Form:</b>	Solid
· <b>Colour:</b>	Yellow
· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

· <b>Melting point/freezing point:</b>	882–1140 °C
· <b>Initial boiling point and boiling range:</b>	Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Not determined.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

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

- **Vapour pressure:** Not applicable.

· <b>Density at 20 °C:</b>	9.8 g/cm <sup>3</sup>
· <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.

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- **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**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:**  
Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** 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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                       |      |
|---------------------------------------|------|
| · <b>UN-Number</b>                    |      |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b> | Void |
| · <b>UN proper shipping name</b>      |      |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b> | Void |
| · <b>Transport hazard class(es)</b>   |      |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b> |      |
| · <b>Class</b>                        | Void |

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· <b>Packing group</b>	Void
· <b>ADR/RID/ADN, 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 Marpol 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>	Void

### 15 Regulatory information

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

· **New Zealand Inventory of Chemicals**

CAS: 7440-22-4	silver
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CAS: 7440-74-6	indium
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· **HSNO Approval numbers**

CAS: 7440-22-4	silver	HSR003077
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CAS: 7440-74-6	indium	HSR003007
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· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS03    GHS09

· **Signal word** Danger

· **Hazard statements**

May intensify fire; oxidiser.

Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

Keep away from heat. - No smoking.

Keep/Store away from clothing/combustible materials.

Take any precaution to avoid mixing with combustibles.

Wear protective gloves/protective clothing/eye protection/face protection.

In case of fire: Use to extinguish: CO<sub>2</sub>, powder or water spray.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category**

P8 OXIDISING LIQUIDS AND SOLIDS

E2 Hazardous to the Aquatic Environment

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t

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- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to the Directive 93/42/EEC.
- **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.*

- **Relevant phrases**

*H400 Very toxic to aquatic life.*

*H410 Very toxic to aquatic life with long lasting effects.*

- **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*

*IATA: International Air Transport Association*

*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)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Ox. Sol. 2: Oxidizing solids – Category 2*

*Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1*

*Aquatic Acute 2: Hazardous to the aquatic environment - acute aquatic hazard – Category 2*

*Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1*

*Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2*