

**Material Safety Data Sheet**  
acc. to ISO 11014

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

**1 Identification**

- **Product identifier**
- **Trade name:** ***Harmony Medium***
- **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
- **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**  
The product is not classified according to the Globally Harmonized System (GHS).

---

- **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.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



(Contd. on page 2)

# Material Safety Data Sheet

acc. to ISO 11014

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

Trade name: **Harmony Medium**

(Contd. of page 1)

- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

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

### 3 Composition/information on ingredients

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

- **Dangerous components:**

7440-22-4	silver	10-13%
7440-50-8	copper	5-<10%
7440-66-6	zinc powder -zinc dust (stabilized)	0.3-<1%

### 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.

(Contd. on page 3)

CA

# Material Safety Data Sheet

## acc. to ISO 11014

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

Trade name: **Harmony Medium**

(Contd. of page 2)

- **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

EL Short-term value: 0.03 mg/m<sup>3</sup>  
Long-term value: 0.01 mg/m<sup>3</sup>  
as Ag

EV Long-term value: 0.1 \* 0.01 \*\* mg/m<sup>3</sup>  
\*metal; \*\*water-soluble compounds (as silver)

#### 7440-50-8 copper

EL Long-term value: 1 \* 0.2 \*\* mg/m<sup>3</sup>  
\*dusts and mists; \*\*fume, as Cu

EV Long-term value: 0.2 \* 1 \*\* mg/m<sup>3</sup>  
as copper, \*fume; \*\*dust and mists

- **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

(Contd. on page 4)

CA

## Material Safety Data Sheet

acc. to ISO 11014

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

Trade name: **Harmony Medium**

(Contd. of page 3)

· **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>Color:</b>	Yellow
· <b>Odor:</b>	Odorless
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· <b>Melting point/Melting range:</b>	650 – 760 °C
· <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:</b>	15.2 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:**

· **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.

(Contd. on page 5)

# Material Safety Data Sheet

## acc. to ISO 11014

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

Trade name: **Harmony Medium**

(Contd. of page 4)

- **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**
- **DOT** NA3077

(Contd. on page 6)

CA

## Material Safety Data Sheet

acc. to ISO 11014

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

Trade name: **Harmony Medium**

(Contd. of page 5)

· TDG, ADN, IMDG, IATA	Void
· UN proper shipping name · TDG, ADN, IMDG, IATA	Void
· Transport hazard class(es) · DOT · Class · Label · TDG, ADN, IMDG, IATA · Class	9 Miscellaneous dangerous substances and articles 9 Void
· Packing group · DOT · TDG, IMDG, IATA	III 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).
· 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

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.

(Contd. on page 7)

CA

## Material Safety Data Sheet

acc. to ISO 11014

Printing date 06/23/2015

Version number 5

Reviewed on 05/08/2015

**Trade name: *Harmony Medium***

(Contd. of page 6)

· **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.

· **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 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.

· **Date of preparation / last revision** 06/23/2015 / 4

· **Abbreviations and acronyms:**

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)

· **\* Data compared to the previous version altered.**

CA