

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/19/2012

Version number 4

Reviewed on 12/19/2012

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

- **Product identifier**
- **Trade name:** ***Harmony Hard***
- **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**
The product is not classified according to the Globally Harmonized System (GHS).
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** *Not applicable.*
- **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** *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.

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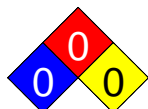
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- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

- **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-<25%
7440-50-8	copper	1-<10%
7440-05-3	palladium	1-<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 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.

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- **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:**

7440-22-4 silver

PEL ()	0.01 mg/m ³ metal and soluble compounds (as Ag)
REL ()	0.01 mg/m ³
TLV ()	0.1 mg/m ³ metal: dust and fume

7440-50-8 copper

PEL ()	1* 0.1** mg/m ³ as Cu *dusts and mists **fume
REL ()	1* 0.1** mg/m ³ as Cu *dusts and mists **fume
TLV ()	1* 0.2** mg/m ³ *dusts and mists; **fume; as Cu

- **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.

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- **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: | Yellow |
| · Odor: | Odorless |
| · Odour threshold: | Not determined. |
| · pH-value: | Not applicable. |
| · Change in condition | |
| Melting point/Melting range: | 895 – 970 °C (1643 – 1778 °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): | 14.9 g/cm ³ (124.341 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. |

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Kinematic:	<i>Not applicable.</i>
· Solvent content:	
Solids content:	<i>100 %</i>
· Other information	<i>No further relevant information available.</i>

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*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*
- **Other adverse effects** *No further relevant information available.*

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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 | |
| · 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. |
| · 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

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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** 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 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)