

Safety Data Sheet acc. to ISO/DIS 11014

Printing date 12/17/2012

Version number 2

Reviewed on 12/17/2012

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

- **Product identifier**
- **Trade name:** **Harmony 3**
- **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**
Ox. Sol. 2 H272 May intensify fire; oxidizer.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Oxidizing
Contact with combustible material may cause fire.
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- **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**
The product is classified and labelled according to the Globally Harmonized System (GHS).

(Contd. on page 2)

USA

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/17/2012

Version number 2

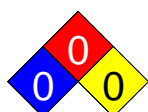
Reviewed on 12/17/2012

Trade name: **Harmony 3**

(Contd. of page 1)

· **Hazard pictograms**

GHS03

· **Signal word** *Danger*· **Hazard statements***May intensify fire; oxidizer.*· **Precautionary statements***Keep away from heat/sparks/open flames/hot surfaces. - No smoking.**Take any precaution to avoid mixing with combustibles.**Wear protective gloves/protective clothing/eye protection/face protection.**Keep/Store away from clothing/combustible materials.**In case of fire: Use for extinction: CO₂, powder or water spray.**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 = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 0

Fire = 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	25-100%
7440-05-3	palladium	25-50%
7440-50-8	copper	10-<25%
7440-31-5	tin	1-<10%
	Zink	1-<2.5%

USA

(Contd. on page 3)

Safety Data Sheet acc. to ISO/DIS 11014

Printing date 12/17/2012

Version number 2

Reviewed on 12/17/2012

Trade name: **Harmony 3**

(Contd. of page 2)

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.
- **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.

USA

(Contd. on page 4)

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/17/2012

Version number 2

Reviewed on 12/17/2012

Trade name: **Harmony 3**

(Contd. of page 3)

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

7440-31-5 tin

PEL ()	2 mg/m ³ metal
REL ()	2 mg/m ³
TLV ()	2 mg/m ³ metal

- **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).

USA

(Contd. on page 5)

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/17/2012

Version number 2

Reviewed on 12/17/2012

Trade name: **Harmony 3**

(Contd. of page 4)

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: 880–960 °C (1616–1760 °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):** 10.6 g/cm³ (88.457 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.

USA

(Contd. on page 6)

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/17/2012

Version number 2

Reviewed on 12/17/2012

Trade name: **Harmony 3**

(Contd. of page 5)

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.

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. |

(Contd. on page 7)

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/17/2012

Version number 2

Reviewed on 12/17/2012

Trade name: *Harmony 3*

(Contd. of page 6)

· 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

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

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7440-50-8 copper

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(Contd. on page 8)

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/17/2012

Version number 2

Reviewed on 12/17/2012

Trade name: Harmony 3

(Contd. of page 7)

· **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**

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

· **Hazard pictograms**



GHS03

· **Signal word Danger**

· **Hazard statements**

May intensify fire; oxidizer.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Take any precaution to avoid mixing with combustibles.

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

Keep/Store away from clothing/combustible materials.

In case of fire: Use for extinction: CO₂, powder or water spray.

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 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)