Printing date 06/23/2015

vivadent:

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Version number 3

Reviewed on 05/08/2015

1 Identification

- · 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 mixture 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 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.

- · Label elements
- · GHS label elements

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

· Hazard pictograms



· Signal word Danger

- · Hazard statements
- May intensify fire; oxidizer.
- · Precautionary statements

Keep away from heat. Take any precaution to avoid mixing with combustibles. Wear protective gloves / eye protection / face protection. Keep/Store away from clothing/combustible materials.

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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)



· HMIS-ratings (scale 0 - 4)



· 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	50-100%
7440-05-3	palladium	25-50%
7440-50-8	copper	10-<25%
7440-31-5	tin	2.5-<10%
7440-66-6	zinc powder -zinc dust (stabilized)	1-<2.5%

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.

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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.

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/m³ REL Long-term value: 0.01 mg/m³

- REL Long-term value: 0.01 mg/m³
- TLV Long-term value: 0.1 mg/m³

metal: dust and fume

- 7440-50-8 copper
- PEL Long-term value: 1* 0.1** mg/m³ as Cu *dusts and mists **fume
- REL Long-term value: 1* 0.1** mg/m³ as Cu *dusts and mists **fume
- TLV Long-term value: 1* 0.2** mg/m³ *dusts and mists; **fume; as Cu

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7440	0-31-5 tin
PEL	Long-term value: 2 mg/m ³
	metal
REL	Long-term value: 2 mg/m ³
TLV	Long-term value: 2 mg/m ³
	metal
·Add	itional information: The lists that were valid during the creation were used as basis.
· Exn	osure controls
-	onal protective equipment:
	eral protective and hygienic measures: Usual hygienic measures for dental practice.
	thing equipment: Use respiratory protective device against the effects of fumes/dust/aerosol.
	ection of hands:
Prot	ective gloves should always be worn during mechanical and thermal processing.
	r use of gloves apply skin-cleaning agents and skin cosmetics.
· Mate	erial of gloves
	hanical processing:
	her gloves
	ng gloves
	mal processing:
	t protection gloves
	etration time of glove material
	exact break through time has to be found out by the manufacturer of the protective gloves and has to be rved.
0050	
	protection:

9 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: Boiling point/Boiling range:	880–960 °C (1616–1760 °F) 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: Upper:	Not determined. Not determined.	
Vapor pressure:	Not applicable.	
Density at 20 °C (68 °F):	10.6 g/cm ³ (88.457 lbs/gal)	

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· Relative density	Not determined.	
· Vapour density	Not applicable.	
· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
Water:	Insoluble.	
· Partition coefficient (n-octanol/w	ater): 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.

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.

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Trade name: Harmony 3

· 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:

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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.
Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
UN "Model Regulation":	-

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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
 D

 7440-50-8
 copper
 D

 TLV (Threshold Limit Value established by ACGIH)
 D

 None of the ingredients is listed.
 D
 - · 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*



· Signal word Danger

· Hazard statements

May intensify fire; oxidizer.

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· Precautionary statements

Keep away from heat.

Take any precaution to avoid mixing with combustibles. Wear protective gloves / 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 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 / 2