

Printing date 06/23/2015 Version number 5 Reviewed on 05/06/2015

1 Identification

- · Product identifier
- · Trade name: BioUniversal
- · 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.

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USA

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Ivoclar Vivadent Inc.

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- · 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



GHS03

- · 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)



Health = 0Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



 $0 \quad Health = 0$ Fire = 0REACTIVITY 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:

7440-05-3 palladium

25-50%

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.

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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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · 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.

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· Eye protection:

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

Physical and chemical proper	
Information on basic physical and	chemical properties
General Information	
Appearance:	
Form: Color:	Solid Yellow
Odor:	Odorless
Odour threshold:	Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	1020–1100 °C (1868–2012 °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):	14.5 g/cm³ (121.003 lbs/gal)
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water:	Insoluble.
Partition coefficient (n-octanol/wat	ter): 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.

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· 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.
- $\cdot \textit{\textbf{Mobility in soil}} \ \textit{No further relevant information available}.$
- · 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.

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· UN-Number	
$\cdot DOT$	NA3077
· ADR ADN IMDG IATA	Void

· UN proper shipping name

· ADR, ADN, IMDG, IATA Void

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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 I	I 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

- $\cdot \textit{Safety, health and environmental regulations/legislation specific for the substance or \textit{mixture}}$
- $\cdot \textit{Sara}$

· 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	

· Proposition 65

7440-74-6 indium 7439-88-5 iridium

· 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.

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· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Envi	ronmental 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

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.

 ${\it Keep/Store\ away\ from\ clothing/combustible\ materials}.$

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 / 4

· 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

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)

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Ox. Sol. 2: Oxidising Solids, Hazard Category 2

* Data compared to the previous version altered.