ivoclar vivadeni:

Safety Data Sheet according to WHS Regulations

Printing date 29.08.2022

Version number 5

Revision: 29.08.2022

Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· Product identifier

• Trade name: Midigold 50

- **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

Importer: Ivoclar Vivadent Pty. Ltd. I- 5 Overseas Drive Noble Park North VIC 3174 Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

Further information obtainable from: Regulatory Affairs sds@ivoclarvivadent.com

• Emergency telephone number: 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

• *Classification of the substance or mixture The product is not classified, according to the Globally Harmonised 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.

• Other hazards

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

• **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- Description: Dental alloy

· Dangerous components:			
CAS: 7440-22-4	silver		25-50%
CAS: 7440-50-8	copper		2.5-10%
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CAS: 7440-05-3 palladium	Ox. Sol. 2, H272	2.5-10%
CAS: 7440-74-6 indium		<2.5%
	16	

• Additional information: For the wording of the listed hazard phrases refer to section 16.

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.
- · 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 fire - and explosion protection:* 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.

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• Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

• Additional information about design of technical facilities: No further data; see item 7.

· Control parameters

· Ingredients with	limit values that r	equire monitoring	at the workplace:
		1	real real real real real real real real

CAS: 7440-22-4 silver WES Long-term value: 0.1 mg/m³

CAS: 7440-50-8 copper

WES Long-term value: 1* 0.2** mg/m³ *dust & mists (as Cu) **fume

CAS: 7440-74-6 indium

WES Long-term value: 0.1 mg/m³

as In

• Additional information: The lists valid during the making were used as basis.

· Exposure controls

- · Personal protective equipment:
- General protective and hygienic measures:
- Usual hygienic measures for dental practice and dental laboratories.
- Respiratory protection: 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 material 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 c • General Information	hemical properties	
· Appearance:		
Form:	Solid	
Colour:	Yellow	
Odour:	Odourless	
Odour threshold:	Not determined.	
pH-value:	Not applicable.	
Change in condition		
Melting point/freezing point:	825 – 915 °C	
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Initial boiling point and boiling range	: Undetermined.	
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Not determined.	
Auto-ignition temperature:	Product is not selfigniting.	
· Explosive properties:	Product does not present an explosion hazard.	
Explosion limits: Lower: Upper:	Not determined. Not determined.	
Vapour pressure:	Not applicable.	
· Density at 20 °C: · Relative density · Vapour density · Evaporation rate	13.2 g/cm ³ Not determined. Not applicable. Not applicable.	
Solubility in / Miscibility with water:	Insoluble.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity: Dynamic: Kinematic:	Not applicable. 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.
- \cdot 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
- · Specific symptoms in biological assay:
- · Skin corrosion/irritation No irritant effect.
- · Serious eye damage/irritation No irritating effect.
- Respiratory or skin sensitisation No sensitising effects known.
- · Additional toxicological information:

Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

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12 Ecological Information

· Toxicity

· Aquatic toxicity: No further relevant information available.

· Persistence and degradability No further relevant information available.

· Behaviour in environmental systems:

· Bioaccumulative potential No further relevant information available.

· Mobility in soil No further relevant information available.

- Additional ecological information:
- · General notes: 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 packaging:
- · Recommendation: Disposal must be made according to official regulations.

UN-Number	
ADG, ADN, IMDG, IATA	Void
UN proper shipping name ADG, ADN, IMDG, IATA	Void
Transport hazard class(es)	
ADG, ADN, IMDG, IATA	
Class	Void
Packing group	
ADG, IMDG, IATA	Void
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex II	of Marpol
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":	Void

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15 Regulatory information

 \cdot Safety, health and environmental regulations/legislation specific for the substance or mixture

· Australian Inventory	of Industrial	Chemicals
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CAS: 7440-57-5 Gold

CAS: 7440-22-4 silver

CAS: 7440-50-8 copper

CAS: 7440-06-4 platinum

CAS: 7440-74-6 indium

CAS: 7439-88-5 iridium

· Standard for the Uniform Scheduling of Medicines and Poisons

CAS: 7440-22-4 silver

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

• GHS label elements Void

• Hazard pictograms Void

• Signal word Void

• Hazard statements Void

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· National regulations:

• Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

· 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.

· Relevant phrases

H272 May intensify fire; oxidiser.

· Contact:

• Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Ox. Sol. 2: Oxidizing solids – Category 2

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