

Printing date 11.01.2021 Version number 1 Revision: 11.01.2021

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
- · Trade name: Colado CAD Ti5
- · 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

Titanium disc for the CAD/CAM technology (Type 4)

- Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

Ivoclar Vivadent AG Bendererstrasse 2

9494 Schaan

PRINCIPALITY OF LIECHTENSTEIN
Tel: +423 235 35 35 / Fax: +423 235 33 60

Importer:

Ivoclar Vivadent Pty. Ltd. 1-5 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-determining components of labelling:

iron

- · 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.

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3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · **Description:** Dental alloy

| · Dangerous components: | | | | |
|-------------------------|-----------|--|---------|--|
| CAS: 7440-32-6 | titanium | Self-heat. 1, H251; Water-react. 1, H260 | 50-100% | |
| CAS: 7429-90-5 | aluminium | Pyr. Sol. 1, H250; Water-react. 2, H261 | 2.5-10% | |
| CAS: 7439-89-6 | iron | Acute Tox. 2, H300; Acute Tox. 3, H311; Acute Tox. 3, H331 | <2.5% | |

[·] 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: Generally the product does not irritate the skin.
- · 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.

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7 Handling and Storage

- · Handling.
- Precautions for safe handling

Extractors are required on all machines used for thermal processing or splinter removal processes. For use in dentistry only.

- · 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.
- · 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 require monitoring at the workplace:

CAS: 7429-90-5 aluminium

WES Long-term value: 10* 5** mg/m³

*metal dust; **welding, pyro powders

- · 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.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

- 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.

Eve protection:

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

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| Information on basic physical and chemi | ical proporties |
|--|---|
| General Information | icui properues |
| Appearance: | |
| Form: | Solid |
| Colour: | White |
| Odour: | Odourless |
| Odour threshold: | Not determined. |
| pH-value: | Not applicable. |
| Change in condition | |
| Melting point/freezing point: | 1610 - 1650 °C |
| 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. |
| Vapour pressure: | Not applicable. |
| Density at 20 °C: | 4.43 g/cm^3 |
| 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

- $\cdot \textit{Reactivity} \ \textit{No further relevant information available}.$
- · 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

Mechanical processing:

Flammable.

- · 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.

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11 Toxicological Information

- Information on toxicological effects
- · Additional toxicological information:

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

· Sensitisation May cause sensitisation by inhalation and skin contact.

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.

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|----------------------------|---|
| | Product is not classified as a dangerous good for ransport (ADR, IMDG, IATA). |
| · UN ''Model Regulation'': | ['] oid |

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Industrial Chemicals

All ingredients are listed.

Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard-determining components of labelling:

iron

- · 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

H250 Catches fire spontaneously if exposed to air.

H251 Self-heating: may catch fire.

H260 In contact with water releases flammable gases which may ignite spontaneously.

H261 In contact with water releases flammable gases.

H300 Fatal if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

· 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

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

Pyr. Sol. 1: Pyrophoric solids - Category 1

Self-heat. 1: Self-heating substances and mixtures - Category 1

Water-react. 1: Substances and mixtures which in contact with water emit flammable gases – Category 1

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Water-react. 2: Substances and mixtures which in contact with water emit flammable gases – Category 2 Acute Tox. 2: Acute toxicity - oral – Category 2 Acute Tox. 3: Acute toxicity - dermal – Category 3