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

1.1 Product identifier

Trade name: Colado CAD Ti5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Application of the substance / the mixture

Manufacture of dental prothesis
Titanium disc for the CAD/CAM technology (Type 4)

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60

Further information obtainable from:

Regulatory Affairs
sds@ivoclarvivadent.com

1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is not classified according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 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.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Dental alloy

Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS</th>
<th>Ingredient</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-32-6</td>
<td>231-142-3</td>
<td>titanium</td>
<td>50-100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flam. Sol. 1, H228; Pyr. Sol. 1, H250; Self-heat. 1, H251; Water-react. 1, 2, H260</td>
<td></td>
</tr>
<tr>
<td>7429-90-5</td>
<td>231-072-3</td>
<td>aluminium powder (pyrophoric)</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pyr. Sol. 1, H250; Water-react. 2, H261</td>
<td></td>
</tr>
</tbody>
</table>

(Contd. on page 2)
Trade name: Colado CAD Ti5

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

SECTION 4: First aid measures

· 4.1 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.

· 4.2 Most important symptoms and effects, both acute and delayed: No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed: No further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media
  · Suitable extinguishing agents: The product is not flammable.

· 5.2 Special hazards arising from the substance or mixture: No further relevant information available.

· 5.3 Advice for firefighters
  · Protective equipment: Do not inhale explosion gases or combustion gases.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures: Not required.

· 6.2 Environmental precautions: No special measures required.

· 6.3 Methods and material for containment and cleaning up: Pick up mechanically.

· 6.4 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.

SECTION 7: Handling and storage

· 7.1 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.

· 7.2 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.

· 7.3 Specific end use(s) No further relevant information available.
SECTION 8: Exposure controls/personal protection

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

- 8.1 Control parameters

- Ingredients with limit values that require monitoring at the workplace:
  
<table>
<thead>
<tr>
<th>CAS: 7429-90-5 aluminium powder (pyrophoric)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEL: Long-term value: 10* 4** mg/m³ *inhalable dust **respirable dust</td>
</tr>
</tbody>
</table>

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

- 8.2 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.

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

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties

- General Information

- Appearance:
  
<table>
<thead>
<tr>
<th>Form:</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour:</td>
<td>White</td>
</tr>
<tr>
<td>Odour:</td>
<td>Odourless</td>
</tr>
<tr>
<td>Odour threshold:</td>
<td>Not determined.</td>
</tr>
</tbody>
</table>

- pH-value:
  Not applicable.

- Change in condition
  
  | Melting point/Melting range: | 1610 - 1650 °C |
  | Boiling point/Boiling range: | Undetermined. |

- Flash point:
  Not applicable.

- Flammability (solid, gaseous):
  Not determined.

- Self-igniting:
  Product is not selfigniting.

- Danger of explosion:
  Product does not present an explosion hazard.
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 13.03.2017 Version number 1 Revision: 13.03.2017

Trade name: Colado CAD Ti5

- Vapour pressure: Not applicable.
- Density at 20 °C: 4.43 g/cm³
- 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 %
- 9.2 Other information
  - No further relevant information available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity
  - No further relevant information available.
- 10.2 Chemical stability
  - Stable under normal handling and storage conditions.
- 10.3 Possibility of hazardous reactions
  - Mechanical processing:
    - Flammable.
- 10.4 Conditions to avoid
  - No further relevant information available.
- 10.5 Incompatible materials
  - No further relevant information available.
- 10.6 Hazardous decomposition products
  - None under normal conditions of storage and use.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity
    - Based on available data, the classification criteria are not met.
  - Skin corrosion/irritation
    - Based on available data, the classification criteria are not met.
  - Serious eye damage/irritation
    - Based on available data, the classification criteria are not met.
  - Respiratory or skin sensitisation
    - Based on available data, the classification criteria are not met.
  - Additional toxicological information:
    - Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.
  - Germ cell mutagenicity
    - Based on available data, the classification criteria are not met.
  - Carcinogenicity
    - Based on available data, the classification criteria are not met.
  - Reproductive toxicity
    - Based on available data, the classification criteria are not met.
  - STOT—single exposure
    - Based on available data, the classification criteria are not met.
  - STOT—repeated exposure
    - Based on available data, the classification criteria are not met.
  - Aspiration hazard
    - Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity
    - No further relevant information available.
  - 12.2 Persistence and degradability
    - No further relevant information available.

(Contd. on page 5)
SECTION 13: Disposal considerations

13.1 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.

SECTION 14: Transport information

14.1 UN-Number
ADR, RID, ADN, ADN, IMDG, IATA Void

14.2 UN proper shipping name
ADR, RID, ADN, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)
ADR, RID, ADN, ADN, IMDG, IATA Void
Class Void

14.4 Packing group
ADR, RID, ADN, IMDG, IATA Void

14.5 Environmental hazards:
Marine pollutant: No

14.6 Special precautions for user
Not applicable.

14.7 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

SECTION 15: Regulatory information

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

Directive 2012/18/EU
Named dangerous substances - ANNEX I oxygen

National regulations:
Other regulations, limitations and prohibitive regulations
The product is a medical device according to the Directive 93/42/EEC.
· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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
  H228 Flammable solid.
  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.

· 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
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  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
  Flam. Sol. 1: Flammable solids – Category 1
  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
  Water-react. 2: Substances and mixtures which in contact with water emit flammable gases – Category 2