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

· 1.1 Product identifier
  · Trade name: Colado CAD CoCr4

· 1.2 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 prosthesis
    CoCr 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
    Resp. Sens. 1  H334  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
    Skin Sens. 1  H317  May cause an allergic skin reaction.
    Aquatic Chronic 4  H413  May cause long lasting harmful effects to aquatic life.

· 2.2 Label elements
  · Labelling according to Regulation (EC) No 1272/2008
    The product is classified and labelled according to the CLP regulation.

  · Hazard pictograms
    GHS08

  · Signal word Danger

  · Hazard-determining components of labelling:
    cobalt

  · Hazard statements
    H334  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
    H317  May cause an allergic skin reaction.
    H413  May cause long lasting harmful effects to aquatic life.

  · Precautionary statements
    P280  Wear protective gloves/protective clothing/eye protection/face protection.
    P260  Do not breathe dust/fume/gas/mist/vapours/spray.
    P285  In case of inadequate ventilation wear respiratory protection.
    P273  Avoid release to the environment.
    P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
Trade name: **Colado CAD CoCr4**

*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.

### SECTION 3: Composition/information on ingredients

#### 3.2 Chemical characterisation: Mixtures

**Description:** Dental alloy

**Dangerous components:**

<table>
<thead>
<tr>
<th>CAS: 7440-48-4</th>
<th>cobalt</th>
<th>Resp. Sens. 1, H334; Skin Sens. 1, H317; Aquatic Chronic 4, H413</th>
<th>50-100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 231-158-0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 7440-47-3</th>
<th>chromium</th>
<th>substance with a Community workplace exposure limit</th>
<th>25-50%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 231-157-5</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 7439-89-6</th>
<th>iron</th>
<th>Acute Tox. 2, H300</th>
<th>0.1-&lt;2.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 231-096-4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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.

(Contd. on page 3)
**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**:
    
    | CAS   | Description          | Limit Value  |
    |-------|----------------------|--------------|
    | CAS: 7440-48-4 cobalt | Co | Long-term value: 0.1 mg/m³ |
    | CAS: 7440-47-3 chromium | Co | Long-term value: 0.5 mg/m³ |
    | WEL   | Long-term value: 0.1 mg/m³ as Co; Carc; Sen |
    | WEL   | Long-term value: 0.5 mg/m³ |

- **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.
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:
- Form: Solid
- Colour: White

Odour:
- Odour: Odourless
- Odour threshold: Not determined.

pH-value:
- Not applicable.

Change in condition
- Melting point/Melting range: Undetermined.
- Boiling point/Boiling range: Undetermined.

Flash point:
- Not applicable.

Flammability (solid, gaseous):
- Not determined.

Self-igniting:
- Product is not self-igniting.

Danger of explosion:
- Product does not present an explosion hazard.

Vapour pressure:
- Not applicable.

Density at 20 °C:
- 8.4 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.

Thermal decomposition / conditions to be avoided:
- No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions
- No dangerous reactions known.

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
  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  May cause an allergic skin reaction.
- 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.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
  General notes: Generally not hazardous for water
  12.5 Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.
  - 12.6 Other adverse effects No further relevant information available.

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
- Class Void
Trade name: Colado CAD CoCr⁴

- 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 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.

- 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
  H300 Fatal if swallowed.
  H317 May cause an allergic skin reaction.
  H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  H413 May cause long lasting harmful effects to aquatic life.

- 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
  Acute Tox. 2: Acute toxicity – Category 2
  Resp. Sens. 1: Respiratory sensitisation – Category 1
  Skin Sens. 1: Skin sensitisation – Category 1
  Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4