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

- **Product identifier**
  - **Trade name:** d.SIGN 30

- **Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **Application of the substance / the preparation**
  - Manufacture of dental prosthesis

- **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
    - Ivoclar Vivadent Inc.
      - 1-6600 Dixie Road
      - Mississauga, Ontario
      - L5T 2Y2
      - Canada
      - Phone: +1 905 670 8499
      - Fax: +1 905 670 3102

  - **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 MSDS Assistance:
        - US: 1-800-533-6825
        - Canada: 1-800-263-8182

2 Hazards identification

- **Classification of the substance or mixture**
  - 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.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
  - Irritant
    - May cause sensitisation by inhalation and skin contact.
    - May cause long-term adverse effects in the aquatic environment.

- **Information concerning particular hazards for human and environment:**
  - Avoid breathing of grinding dust and vapours. Melted material may cause burns.

- **Classification system:**
  - The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- **Label elements**
  - **GHS label elements**
    - The product is classified and labelled according to the Globally Harmonized System (GHS). 

(Contd. on page 2)
Trade name: d.SIGN 30

- **Hazard pictograms**

  ![GHS08]

- **Signal word** Danger

- **Hazard-determining components of labelling:**
  - cobalt

- **Hazard statements**
  - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  - May cause an allergic skin reaction.

- **Precautionary statements**
  - Avoid breathing dust/fume/gas/mist/vapours/spray.
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - In case of inadequate ventilation wear respiratory protection.
  - Specific treatment (see on this label).
  - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
  - 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 = 0
    - Fire = 0
    - Reactivity = 0
  - **HMIS-ratings (scale 0 - 4)**
    - HEALTH: Health = 0
    - FIRE: Fire = 0
    - REACTIVITY: 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:**
  - 7440-48-4 cobalt 25-100%
  - 7440-47-3 chromium 25-50%
  - 7440-55-3 gallium 1-<10%
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 Firefighting 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 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

<table>
<thead>
<tr>
<th>Substance</th>
<th>PEL (mg/m³)</th>
<th>REL (mg/m³)</th>
<th>TLV (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>cobalt (7440-48-4)</td>
<td>0.1 as Co</td>
<td>0.05 inorg. compds.: metal dust &amp; fume, as Co</td>
<td>0.02 as Co; BEI</td>
</tr>
<tr>
<td>chromium (7440-47-3)</td>
<td>1* 0.5 metal; 0.5* inorganic compds., as Cr</td>
<td>1 metal, **inorganic compds.; See Pocket Guide App. C</td>
<td>0.5 mg/m³</td>
</tr>
</tbody>
</table>

- Ingredients with biological limit values:

<table>
<thead>
<tr>
<th>Substance</th>
<th>BEI (µg/L)</th>
<th>Medium</th>
<th>Time</th>
<th>Parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>cobalt (7440-48-4)</td>
<td>15</td>
<td>urine</td>
<td>end of shift at end of workweek</td>
<td>Cobalt (background)</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>blood</td>
<td>end of shift at end of workweek</td>
<td>Cobalt (background, semi-quantitative)</td>
</tr>
</tbody>
</table>

- 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.
Trade name: d.SIGN 30

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

9 Physical and chemical properties

- Information on basic physical and chemical properties
- General Information
  - Form: Solid
  - Color: White
  - Odor: Odorless
  - Odour threshold: Not determined.
  - pH-value: Not applicable.
  - Melting point/Melting range: 1145–1165 °C (2093–2129 °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: Not determined.
  - Density at 20 °C (68 °F): 7.8 g/cm³ (65.091 lbs/gal)
  - 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

- 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.
Trade name: d SIGN 30

- 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:
  - Primary irritant effect:
    - on the skin: No irritant effect.
    - on the eye: No irritating effect.
  - Sensitization:
    Sensitization possible through inhalation.
    Sensitization possible through skin contact.
  - Additional toxicological information:
    Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

- Carcinogenic categories

  - IARC (International Agency for Research on Cancer)
    7440-48-4 cobalt 2B
    7440-47-3 chromium 3

  - NTP (National Toxicology Program)
    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.
    - Mobility in soil: 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.
14 Transport information

- **UN-Number**
  - DOT NA3077

- **UN proper shipping name**
  - ADR, ADN, IMDG, IATA Void

- **Transport hazard class(es)**
  - **DOT**
    - Class Void
    - Label Void
  - ADR, ADN, IMDG, IATA 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 II of MARPOL73/78 and the IBC Code**: Not applicable.

- **UN "Model Regulation":** -

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **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
    - 7440-74-6 indium
    - 7439-88-3 iridium

  - **Proposition 65**

    - **Chemicals known to cause cancer:** None of the ingredients is listed.
**Trade name: d.SIGN 30**

- **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.

- **Chemicals known to cause developmental toxicity:**
  None of the ingredients is listed.

- **Carcinogenic categories**
  - **EPA (Environmental 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.
  - **OSHA-Ca (Occupational Safety & Health Administration)**
    None of the ingredients is listed.

- **GHS label elements**
  The product is classified and labelled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**
  ![GHS08]

- **Signal word** Danger

- **Hazard-determining components of labelling:**
  cobalt

- **Hazard statements**
  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  May cause an allergic skin reaction.

- **Precautionary statements**
  Avoid breathing dust/fume/gas/mist/vapours/spray.
  Wear protective gloves/protective clothing/eye protection/face protection.
  In case of inadequate ventilation wear respiratory protection.
  Specific treatment (see on this label).
  If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
  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 EC-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.

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
- **NFPA**: National Fire Protection Association (USA)
- **HMIS**: Hazardous Materials Identification System (USA)