1 Identification

· Product identifier

· Trade name: Colado NC

· 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

  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 SDS Assistance:
  US: 1-800-533-6825
  Canada: 1-800-263-8182

2 Hazard(s) identification

· Classification of the substance or mixture
  Skin Sens. 1 H317 May cause an allergic skin reaction.
  Carc. 2 H351 Suspected of causing cancer.
  STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.

· Label elements

· GHS label elements
  The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms

  GHS07  GHS08

· Signal word
  Danger

· Hazard-determining components of labeling:
  nickel

· Hazard statements
  May cause an allergic skin reaction.

(Contd. on page 2)
Suspected of causing cancer.
Causes damage to organs through prolonged or repeated exposure.

· **Precautionary statements**
  Obtain special instructions before use.
  Wear protective gloves.
  Do not breathe dust/fume/gas/mist/vapors/spray.
  Wash thoroughly after handling.
  Do not eat, drink or smoke when using this product.
  Contaminated work clothing must not be allowed out of the workplace.
  Do not handle until all safety precautions have been read and understood.
  Specific treatment (see on this label).
  Wash contaminated clothing before reuse.
  IF exposed or concerned: Get medical advice/attention.
  If skin irritation or rash occurs: Get medical advice/attention.
  Get medical advice/attention if you feel unwell.
  If on skin: Wash with plenty of water.
  Store locked up.
  Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Information pertaining to particular dangers for man and environment:**
  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
  FIRE
  REACTIVITY
  Health = 0
  Fire = 0
  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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-02-0 nickel</td>
<td>50-100%</td>
</tr>
<tr>
<td>7440-47-3 chromium</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>7440-33-7 tungsten</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>7440-21-3 silicon</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>7429-90-5 aluminium powder (pyrophoric)</td>
<td>1-&lt;2.5%</td>
</tr>
<tr>
<td>7439-98-7 molybdenum</td>
<td>1-&lt;2.5%</td>
</tr>
</tbody>
</table>
4 First-aid measures

- **Description of first aid measures**
  - **After inhalation:** Grinding dust: Supply fresh air; consult doctor in case of complaints.
  - **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.
    Only adequately trained personnel should handle this product.
    For use in dentistry only.
  - **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: Store only in the original receptacle.
    - 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>Component</th>
<th>PEL Long-term value</th>
<th>REL Long-term value</th>
<th>TLV Long-term value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-02-0 nickel</td>
<td>1 mg/m³</td>
<td>0.015 mg/m³</td>
<td>1.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>as Ni; See Pocket Guide App. A</td>
<td></td>
<td>elemental, *inhale fraction</td>
</tr>
<tr>
<td>7440-47-3 chromium</td>
<td>0.5 mg/m³</td>
<td>0.015 mg/m³</td>
<td>1.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>metal, **inorganic compds., as Cr</td>
<td></td>
<td>elemental, *inhale fraction</td>
</tr>
<tr>
<td>7440-33-7 tungsten</td>
<td>10 mg/m³</td>
<td>5 mg/m³</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>as W</td>
<td></td>
<td>as W</td>
</tr>
<tr>
<td>7440-21-3 silicon</td>
<td>15 mg/m³</td>
<td>10 mg/m³</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td></td>
<td>total dust, **respirable fraction</td>
<td></td>
<td>as Al, *as respirable fraction</td>
</tr>
<tr>
<td>7429-90-5 aluminium powder (pyrophoric)</td>
<td>15 mg/m³</td>
<td>10 mg/m³</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Total dust, **Respirable fraction</td>
<td></td>
<td>as Al, *as respirable fraction</td>
</tr>
<tr>
<td>7439-98-7 molybdenum</td>
<td>15 mg/m³</td>
<td>10 mg/m³</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Total dust</td>
<td></td>
<td>as Mo, *inhale fraction, **respirable fraction</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.
Trade name: Colado NC

- **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.
- **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**
  - **Appearance:** Solid
  - **Color:** White
  - **Odor:** Odorless
  - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.
  - **Change in condition**
    - Melting point/Melting range: 1230-1325 °C (2246-2417 °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:**
    - Lower: Not determined.
    - Upper: Not determined.
  - **Vapor pressure:** Not applicable.
  - **Density at 20 °C (68 °F):** 8.4 g/cm³ (70.098 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.
Trade name: Colado NC

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.
- 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 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)
    - 7440-02-0 nickel 2B
    - 7440-47-3 chromium 3
  - NTP (National Toxicology Program)
    - 7440-02-0 nickel R
  - OSHA-Ca (Occupational Safety & Health Administration)
    - 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.
Trade name: Colado NC

- 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, ADR, ADN, IMDG, IATA: Void
- UN proper shipping name
  - DOT, ADR, ADN, IMDG, IATA: Void
- Transport hazard class(es)
  - DOT, ADR, ADN, IMDG, IATA: Void
- Packing group
  - DOT, ADR, IMDG, IATA: Void
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user: Not applicable.
- Transport in bulk according to Annex II of MARPOL 73/78 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": -

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):
      - 7440-02-0 nickel
      - 7440-47-3 chromium
      - 7429-90-5 aluminium powder (pyrophoric)
  - TSCA (Toxic Substances Control Act):
    - All ingredients are listed.
Trade name: Colado NC

- **Proposition 65**
  - **Chemicals known to cause cancer:**
    - 7440-02-0 nickel
  - **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)**
    - 7440-47-3 chromium D
  - **TLV (Threshold Limit Value established by ACGIH)**
    - 7440-02-0 nickel A5
    - 7440-47-3 chromium A4
    - 7429-90-5 aluminium powder (pyrophoric) A4
    - 7439-98-7 molybdenum A3
  - **NIOSH-Ca (National Institute for Occupational Safety and Health)**
    - 7440-02-0 nickel

- **GHS label elements**
  - The product is classified and labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms**
    - GHS07
    - GHS08

- **Signal word** Danger

- **Hazard-determining components of labeling:**
  - nickel

- **Hazard statements**
  - May cause an allergic skin reaction.
  - Suspected of causing cancer.
  - Causes damage to organs through prolonged or repeated exposure.

- **Precautionary statements**
  - Obtain special instructions before use.
  - Wear protective gloves.
  - Do not breathe dust/fume/gas/mist/vapors/spray.
  - Wash thoroughly after handling.
  - Do not eat, drink or smoke when using this product.
  - Contaminated work clothing must not be allowed out of the workplace.
  - Do not handle until all safety precautions have been read and understood.
  - Specific treatment (see on this label).
  - Wash contaminated clothing before reuse.
  - IF exposed or concerned: Get medical advice/attention.
  - If skin irritation or rash occurs: Get medical advice/attention.
  - Get medical advice/attention if you feel unwell.
  - If on skin: Wash with plenty of water.
Trade name: Colado NC

(Contd. of page 8)

40.1.5
Store locked up.
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 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.

- Date of preparation / last revision 06/23/2015 / 2
- 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
  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)
  NFPA: National Fire Protection Association (USA)
  HMIS: Hazardous Materials Identification System (USA)
  Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
  Carc. 2: Carcinogenicity, Hazard Category 2
  STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1
  * Data compared to the previous version altered.