1 Identification

- **Product identifier**
  - Trade name: d.SIGN 15

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

- **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 6925
    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:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

2 Hazard(s) identification

- **Classification of the substance or mixture**
  - Acute Tox. 4 H302 Harmful if swallowed.
  - 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.
  - 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
  - iron
  - cobalt

- **Hazard statements**
  - Harmful if swallowed.
  - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  - May cause an allergic skin reaction.
  - Suspected of causing cancer.
  - Causes damage to organs through prolonged or repeated exposure.
Trade name: d.SIGN 15

- Precautionary statements
  Obtain special instructions before use.
  Wear protective gloves.
  Do not breathe dust/fume/gas/mist/vapors/spray.
  [In case of inadequate ventilation] wear respiratory protection.
  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).
  If experiencing respiratory symptoms: Call a poison center/doctor.
  If swallowed: Call a poison center/doctor if you feel unwell.
  Wash contaminated clothing before reuse.
  If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
  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.
  Rinse mouth.
  If on skin: Wash with plenty of water.
  Store locked up.
  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 = 3
    Fire = 0
    Reactivity = 0
  - HMIS-ratings (scale 0 - 4)
    
    HEALTH 3
    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: Mixture of the substances listed below with nonhazardous additions.
- Dangerous components:
<table>
<thead>
<tr>
<th>Substance</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>≤25%</td>
</tr>
<tr>
<td>7439-98-7 molybdenum</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>7439-89-6 iron</td>
<td>1-&lt;2.5%</td>
</tr>
<tr>
<td>7440-21-3 silicon</td>
<td>1-&lt;2.5%</td>
</tr>
</tbody>
</table>

(Contd. on page 3)
4 First-aid measures

- Description of first aid measures
  - After inhalation:
    Supply fresh air and to be sure call for a doctor.
    In case of unconsciousness place patient stably in side position for transportation.
  - After skin contact: Immediately wash with water and soap and rinse thoroughly.
  - After eye contact: Rinse opened eye for several minutes under running water.
  - After swallowing: If symptoms persist consult doctor.
- 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:
    CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- Special hazards arising from the substance or mixture: No further relevant information available.
- Advice for firefighters
  - Protective equipment: No special measures required.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures: Not required.
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up:
  Dispose contaminated material as waste according to item 13.
- 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
    Prevent formation of dust.
    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.
Trade name: d.SIGN 15

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 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 (as Ni)</td>
<td>1.5 mg/m³ (elemental, *inhalelable fraction)</td>
</tr>
<tr>
<td>7440-47-3 chromium</td>
<td>1* 0.5** mg/m³ (*metal; **inorganic compds., as Cr)</td>
<td>0.5 mg/m³ (*metal+inorg.compd.as Cr; See Pocket Guide App. C)</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>7439-98-7 molybdenum</td>
<td>15* 5** mg/m³ (*total dust; **respirable fraction)</td>
<td>10* 3** mg/m³ (as Mo; *inhalelable fraction ** respirable fraction)</td>
<td></td>
</tr>
<tr>
<td>7440-21-3 silicon</td>
<td>15* 5** mg/m³ (*total dust; **respirable fraction)</td>
<td>10* 5** mg/m³ (*total dust; **respirable fraction)</td>
<td></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:**
    - Keep away from foodstuffs, beverages and feed.
    - Immediately remove all soiled and contaminated clothing.
    - Wash hands before breaks and at the end of work.
    - Usual hygienic measures for dental practice.
  - **Breathing equipment:**
    - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
  - **Protection of hands:**

    The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **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:** Not required.

### 9 Physical and chemical properties

<table>
<thead>
<tr>
<th>Information on basic physical and chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Information</strong></td>
</tr>
<tr>
<td><strong>Appearance:</strong></td>
</tr>
<tr>
<td>Form: Solid</td>
</tr>
<tr>
<td>Color: According to product specification</td>
</tr>
<tr>
<td>Odor: Odorless</td>
</tr>
<tr>
<td>Odour threshold: Not determined.</td>
</tr>
<tr>
<td>pH-value: Not applicable.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Change in condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting point/Melting range: Undetermined.</td>
</tr>
<tr>
<td>Boiling point/Boiling range: Undetermined.</td>
</tr>
</tbody>
</table>

| 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. |

<table>
<thead>
<tr>
<th>Explosion limits:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower: Not determined.</td>
</tr>
<tr>
<td>Upper: Not determined.</td>
</tr>
</tbody>
</table>

| Vapor pressure: Not applicable.                      |

| Density: Not determined.                              |
| 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:                                     |
| Organic solvents: 0.0 %                              |
Trade name: d.SIGN 15

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: No further relevant information available.
- Carcinogenic categories
  - IARC (International Agency for Research on Cancer)
    - 7440-02-0 nickel 2B
    - 7440-47-3 chromium 3
    - 7440-48-4 cobalt 2B, 2A
  - 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:
  - Water hazard class 2 (Self-assessment): hazardous for water
  - Do not allow product to reach ground water, water course or sewage system.
  - Danger to drinking water if even small quantities leak into the ground.
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.
13 Disposal considerations

- Waste treatment methods
  - Recommendation:
    Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
    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
  - Class: 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):
      | Code   | Substance  |
      |--------|------------|
      | 7440-02-0 | nickel |
      | 7440-47-3 | chromium |
      | 7440-48-4 | cobalt |

    - TSCA (Toxic Substances Control Act):
      | Code   | Substance  |
      |--------|------------|
      | 7440-02-0 | nickel |
      | 7440-47-3 | chromium |

(Contd. of page 6)
Trade name: d.SIGN 15

<table>
<thead>
<tr>
<th>Chemicals known to cause cancer:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-02-0 nickel</td>
</tr>
<tr>
<td>7440-48-4 cobalt</td>
</tr>
</tbody>
</table>

- 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
  7439-98-7 molybdenum A3
  7440-48-4 cobalt 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](image) ![GHS08](image)

Signal word Danger

Hazard-determining components of labeling:
  nickel
  iron
  cobalt

Hazard statements
  Harmful if swallowed.
  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  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.
40.1.5 [In case of inadequate ventilation] wear respiratory protection. 
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).
If experiencing respiratory symptoms: Call a poison center/doctor.
If swallowed: Call a poison center/doctor if you feel unwell.
Wash contaminated clothing before reuse.
If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
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.
Rinse mouth.
If on skin: Wash with plenty of water.
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 / 1
· 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)
  Acute Tox. 4: Acute toxicity, Hazard Category 4
  Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1
  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.