1 Identification

· **Product identifier**

· **Trade name:** d.SIGN 91

· **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**

  Ox. Sol. 2  H272  May intensify fire; oxidizer.
  Skin Irrit. 2  H315  Causes skin irritation.
  Eye Irrit. 2A  H319  Causes serious eye irritation.

· **Label elements**

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

· **Hazard pictograms**

  GHS03  GHS07

· **Signal word**

  Danger

· **Hazard statements**

  May intensify fire; oxidizer.
  Causes skin irritation.
  Causes serious eye irritation.
Precautionary statements

Keep away from heat.
Take any precaution to avoid mixing with combustibles.
Wear protective gloves / eye protection / face protection.
Wear protective gloves.
Wear eye protection / face protection.
Keep/Store away from clothing/combustible materials.
Wash thoroughly after handling.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Specific treatment (see on this label).
If skin irritation occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
In case of fire: Use for extinction: CO2, powder or water spray.
If on skin: Wash with plenty of water.
Take off contaminated clothing and wash it before reuse.
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)

<table>
<thead>
<tr>
<th>Health</th>
<th>Fire</th>
<th>Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS-ratings (scale 0 - 4)

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FIRE</th>
<th>REACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health = 1</td>
<td>Fire = 0</td>
<td>Reactivity = 0</td>
</tr>
</tbody>
</table>

Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

Composition/information on ingredients

Chemical characterization: Mixtures

Description: Dental alloy

Dangerous components:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>palladium</td>
<td>25-50%</td>
</tr>
<tr>
<td>indium</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>gallium</td>
<td>1-&lt;2.5%</td>
</tr>
</tbody>
</table>

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.
40.1.5 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.
  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.

(Contd. on page 4)
40.1.5 · Control parameters

- Components with limit values that require monitoring at the workplace:
  7440-74-6 indium

  REL Long-term value: 0.1 mg/m³ as In
  TLV Long-term value: 0.1 mg/m³ as In

- 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.
  - 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:
      Form: Solid
      Color: White
    - Odor: Odorless
    - Odour threshold: Not determined.
    - pH-value: Not applicable.

- Change in condition
  Melting point/Melting range: 1175–1305 °C (2147–2381 °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.
Trade name: d.SIGN 91

- **Vapor pressure:** Not applicable.
- **Density at 20 °C (68 °F):** 14.3 g/cm³ (119.334 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.
- **Incompatible materials:** 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:** No sensitizing effects known.
  - **Additional toxicological information:** Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.
- **Carcinogenic categories**
  - **NTP (National Toxicology Program)** None of the ingredients is listed.
  - **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.
Trade name: d.SIGN 91

40.1.5 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
  - ADR, ADN, IMDG, IATA: Void
- UN proper shipping name
  - ADR, ADN, IMDG, IATA: Void
- Transport hazard class(es)
  - DOT
    - Class: 9 Miscellaneous dangerous substances and articles
    - Label: 9
  - ADR, ADN, IMDG, IATA
    - Class: 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.
- Transport/Additional information:
  - Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

**UN "Model Regulation":**
Safety Data Sheet
acc. to OSHA HCS

Trade name: d.SIGN 91

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
    7439-88-5 iridium
- Proposition 65
  - Chemicals known to cause cancer:
    None of the ingredients is listed.
  - 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.
- GHS label elements
  The product is classified and labeled according to the Globally Harmonized System (GHS).
- Hazard pictograms
  - GHS03
  - GHS07
- Signal word Danger
- Hazard statements
  May intensify fire; oxidizer.
  Causes skin irritation.
Causes serious eye irritation.

- **Precautionary statements**

  - Keep away from heat.
  - Take any precaution to avoid mixing with combustibles.
  - Wear protective gloves / eye protection / face protection.
  - Wear protective gloves.
  - Wear eye protection / face protection.
  - Keep/Store away from clothing/combustible materials.
  - Wash thoroughly after handling.
  - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - Specific treatment (see on this label).
  - If skin irritation occurs: Get medical advice/attention.
  - If eye irritation persists: Get medical advice/attention.
  - In case of fire: Use for extinction: CO2, powder or water spray.
  - If on skin: Wash with plenty of water.
  - Take off contaminated clothing and wash it before reuse.
  - 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 / 5

- **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)
  - Ox. Sol. 2: Oxidising Solids, Hazard Category 2
  - Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
  - Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

- * Data compared to the previous version altered.