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

- **Product identifier**
  - Trade name: d.SIGN 59
- **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**
  - Ox. Sol. 2 H272 May intensify fire; oxidizer.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
  - Oxidizing
  - Contact with combustible material may cause fire.
- **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).
  - **Hazard pictograms**
    - GHS03
- **Signal word** Danger

(Contd. on page 2)
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· Hazard statements
  May intensify fire; oxidizer.

· Precautionary statements
  Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
  Take any precaution to avoid mixing with combustibles.
  Wear protective gloves/protective clothing/eye protection/face protection.
  Keep/Store away from clothing/combustible materials.
  In case of fire: Use for extinction: CO2, powder or water spray.
  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
  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>Chemical</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palladium</td>
<td>25-100%</td>
</tr>
<tr>
<td>Silver</td>
<td>25-50%</td>
</tr>
<tr>
<td>Tin</td>
<td>1-&lt;10%</td>
</tr>
<tr>
<td>Indium</td>
<td>1-&lt;10%</td>
</tr>
</tbody>
</table>

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.

(Contd. on page 3)
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
- Components with limit values that require monitoring at the workplace:

<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>7440-22-4 silver</td>
<td>0.01</td>
<td>0.01</td>
<td>0.1</td>
</tr>
<tr>
<td>metal and soluble compounds (as Ag)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Contd. of page 2)
Trade name: d.SIGN 59

<table>
<thead>
<tr>
<th>7440-31-5 tin</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEL (metal)</td>
</tr>
<tr>
<td>REL (metal)</td>
</tr>
<tr>
<td>TLV (metal)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7440-74-6 indium</th>
</tr>
</thead>
<tbody>
<tr>
<td>REL (metal)</td>
</tr>
<tr>
<td>TLV (metal)</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.
- **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:** 1230–1280 °C (2246–2336 °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.
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- **Explosion limits:**
  - Lower: Not determined.
  - Upper: Not determined.

- **Vapor pressure:** Not applicable.

- **Density at 20 °C (68 °F):** 10.7 g/cm³ (89.292 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:** 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:** 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.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
### 35.0.51 Persistence and degradability
- No further relevant information available.
### 35.0.52 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: NA3077
- DOT: Void
- ADR, ADN, IMDG, IATA: Void
- UN proper shipping name: Void
- ADR, ADN, IMDG, IATA: Void
- Transport hazard class(es)
  - DOT: 9 Miscellaneous dangerous substances and articles.
  - Class: 9
- ADR, ADN, IMDG, IATA: Void
- 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 MARPOL 73/78 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
      - 7439-88-5 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.
    - 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
      - GHS03
    - Signal word Danger

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Hazard statements
May intensify fire; oxidizer.

Precautionary statements
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Take any precaution to avoid mixing with combustibles.
Wear protective gloves/protective clothing/eye protection/face protection.
Keep/Store away from clothing/combustible materials.
In case of fire: Use for extinction: CO2, powder or water spray.
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)