1 Identification

- 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 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.
- Label elements
  GHS label elements
  The product is classified and labeled according to the Globally Harmonized System (GHS).
- Hazard pictograms
  GHS03
  - Signal word Danger
  - Hazard statements
  May intensify fire; oxidizer.
  - Precautionary statements
  Keep away from heat.
  Take any precaution to avoid mixing with combustibles.
  Wear protective gloves / eye protection / face protection.
  Keep/Store away from clothing/combustible materials.
Trade name: d SIGN 59

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 = 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

<table>
<thead>
<tr>
<th>Dangerous components</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-05-3</td>
<td>palladium</td>
</tr>
<tr>
<td>7440-22-4</td>
<td>silver</td>
</tr>
<tr>
<td>7440-31-5</td>
<td>tin</td>
</tr>
<tr>
<td>7440-74-6</td>
<td>indium</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.
- **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.
- Control parameters
  - Components with limit values that require monitoring at the workplace:
    7440-22-4 silver
    - PEL: Long-term value: 0.01 mg/m³
    - REL: Long-term value: 0.01 mg/m³
    - TLV: Long-term value: 0.1 mg/m³
      metal: dust and fume
    7440-31-5 tin
    - PEL: Long-term value: 2 mg/m³
      metal
    - REL: Long-term value: 2 mg/m³
    - TLV: Long-term value: 2 mg/m³
      metal
40.1.5

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: 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.

· 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.
Trade name: d.SIGN 59

- 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.
  - 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

(Contd. on page 6)
Trade name: d.SIGN 59

- 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 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": -

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.
<table>
<thead>
<tr>
<th>Section 313 (Specific toxic chemical listings):</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
</tr>
<tr>
<td>7440-50-8 copper</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TSCA (Toxic Substances Control Act):</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-57-5 Gold</td>
</tr>
<tr>
<td>7440-22-4 silver</td>
</tr>
<tr>
<td>7440-50-8 copper</td>
</tr>
<tr>
<td>7440-06-4 platinum</td>
</tr>
<tr>
<td>7440-74-6 indium</td>
</tr>
<tr>
<td>7439-88-5 iridium</td>
</tr>
</tbody>
</table>

- 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)
    | Ingredient | Carcinogenic Category |
    |------------|-----------------------|
    | 7440-22-4  | silver                |
    | 7440-50-8  | copper                |

  - 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

- Signal word: Danger

- Hazard statements
  May intensify fire; oxidizer.

- Precautionary statements
  Keep away from heat.
  Take any precaution to avoid mixing with combustibles.
  Wear protective gloves / 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.
Trade name: **d.SIGN 59**

- **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** 06/25/2015 / 4
- **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
- **Data compared to the previous version altered.**