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

- **Product identifier**
  - Trade name: *d.SIGN 53*

- **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 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 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](image)

- **Signal word** Danger

(Contd. on page 2)
Trade name: d.SIGN 53

- **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 = 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:**
  - 7440-05-3 palladium 25-100%
  - 7440-22-4 silver 25-50%
  - 7440-31-5 tin 1-<10%
  - 7440-74-6 indium 1-%

### 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.
Trade name: d.SIGN 53

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 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>Component</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>
</tbody>
</table>

metal and soluble compounds (as Ag)
metal: dust and fume
7440-31-5 tin

<table>
<thead>
<tr>
<th></th>
<th>PEL (m⁴)</th>
<th>REL (m⁴)</th>
<th>TLV (m⁴)</th>
</tr>
</thead>
<tbody>
<tr>
<td>metal</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

7440-74-6 indium

<table>
<thead>
<tr>
<th></th>
<th>REL (m⁴)</th>
<th>TLV (m⁴)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.1</td>
<td>0.1</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 breakthrough 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: 1180–1280 °C (2156–2336 °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.
Trade name: d.SIGN 53

- 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.
Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 12/21/2012  Reviewed on 12/21/2012
Version number 4

Trade name: d.SIGN 53

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35.0.51

· 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.
· 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.
· UN "Model Regulation": -

(Contd. on page 7)
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
### Trade name: d.SIGN 53

**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)