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

- **Product identifier**
  - Trade name: d.SIGN 84

- **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

- **Signal word** Danger

(Contd. on page 2)
Safety Data Sheet
acc. to ISO/DIS 11014

Trade name: d.SIGN 84

· 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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-05-3 palladium</td>
<td>25-100%</td>
</tr>
<tr>
<td>7440-22-4 silver</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>7440-74-6 indium</td>
<td>1-&lt;10%</td>
</tr>
<tr>
<td>7440-55-3 gallium</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:
  - 7440-22-4 silver
    - PEL (m) 0.01 mg/m³
      - metal and soluble compounds (as Ag)
    - REL (m) 0.01 mg/m³
    - TLV (m) 0.1 mg/m³
      - metal: dust and fume

(Contd. on page 4)
7440-74-6 indium

REL () 0.1 mg/m³

and compounds, as In

TLV () 0.1 mg/m³

- 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: 1140–1335 °C (2084–2435 °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): 11.3 g/cm³ (94.299 lbs/gal)
- Relative density Not determined.
Trade name: d.SIGN 84

- 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.
- 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
Trade name: d.SIGN 84

- 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
  - 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": -

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.
Trade name: d.SIGN 84

- **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).

- **Signal word** Danger

- **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.
Trade name: d.SIGN 84

(Contd. of page 7)

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)