1 Identification of the substance or mixture and of the supplier

- **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

  - **Importer:** Ivoclar Vivadent Ltd.
    12 Omega St, Rosedale, Auckland
    New Zealand
    Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990

- **Further information obtainable from:**
  - Regulatory Affairs
    sds@ivoclarvivadent.com

- **Emergency telephone number:** 0800 764 766 (National Poison Centre - 24 hours / 7 days)

2 Hazards identification

- **Classification of the substance or mixture**
  - Ox. Sol. 2 H272 May intensify fire; oxidiser.

- **Label elements**
  - **GHS label elements**
    The product is classified and labelled according to the Globally Harmonised System (GHS).

- **Hazard pictograms**
  - GHS03

- **Signal word** Danger

- **Hazard statements**
  May intensify fire; oxidiser.

- **Precautionary statements**
  Keep away from heat. - No smoking.
  Keep/Store away from clothing/combustible materials.
  Take any precaution to avoid mixing with combustibles.
  Wear protective gloves/protective clothing/eye protection/face protection.
  In case of fire: Use to extinguish: 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.
3 Composition/Information on ingredients

- Chemical characterisation: Mixtures
- Description: Dental alloy
- Dangerous components:
  - CAS: 7440-22-4, EINECS: 231-131-3, silver, 25-50%
  - CAS: 7440-31-5, EINECS: 231-141-8, tin, 2.5-10%
  - CAS: 7440-74-6, EINECS: 231-180-0, indium, 2.5-10%
- Additional information: For the wording of the listed hazard phrases refer to section 16.

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.
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 fire - and explosion protection: 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 facilities: No further data; see item 7.

- Control parameters
  - Ingredients with limit values that require monitoring at the workplace:
    - CAS: 7440-22-4 silver
      - WES Long-term value: 0.1* 0.01** mg/m³
        *metal; **soluble compds., as Ag
    - CAS: 7440-31-5 tin
      - WES Long-term value: 2 mg/m³
    - CAS: 7440-74-6 indium
      - WES Long-term value: 0.1 mg/m³
        as In

- Additional information: The lists valid during the making were used as basis.

- Exposure controls
- Personal protective equipment:
  - General protective and hygienic measures:
    Usual hygienic measures for dental practice and dental laboratories.
  - Respiratory protection: 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 material 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.
9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:** Solid
    - **Colour:** White
    - **Odour:** Odourless
    - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.

- **Change in condition**
  - **Melting point/freezing point:** 1230–1280 °C
  - **Initial boiling point and boiling range:** Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Not determined.

- **Auto-ignition temperature:** Product is not self-igniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**
  - **Lower:** Not determined.
  - **Upper:** Not determined.

- **Vapour pressure:** Not applicable.

- **Density at 20 °C:** 10.7 g/cm³
  - **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.
Safety Data Sheet
in accordance with HSNO

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- Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

- Information on toxicological effects
  - Acute toxicity
    - Skin corrosion/irritation No irritant effect.
    - Serious eye damage/irritation No irritating effect.
  - Respiratory or skin sensitisation No sensitising effects known.
- Additional toxicological information:
  Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

12 Ecological information

- Toxicity
  - Aquatic toxicity: No further relevant information available.
  - Persistence and degradability No further relevant information available.
  - Behaviour in environmental systems:
    - Bioaccumulative potential No further relevant information available.
    - Mobility in soil No further relevant information available.
- Additional ecological information:
  - General notes: 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 packaging:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - ADR/RID/ADN, ADN, IMDG, IATA Void
- UN proper shipping name
  - ADR/RID/ADN, ADN, IMDG, IATA Void
- Transport hazard class(es)
  - ADR/RID/ADN, ADN, IMDG, IATA
    - Class Void
- Packing group
  - ADR/RID/ADN, IMDG, IATA Void

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- Environmental hazards:
  - Marine pollutant: No

- Special precautions for user
  - Not applicable.

- Transport in bulk according to Annex II of Marpol 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": Void

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - New Zealand Inventory of Chemicals
    - CAS: 7440-22-4 silver
    - CAS: 7440-31-5 tin
    - CAS: 7440-74-6 indium

  - HSNO Approval numbers
    - CAS: 7440-22-4 silver HSR003077
    - CAS: 7440-31-5 tin HSR002803
    - CAS: 7440-74-6 indium HSR003007

- GHS label elements
  - The product is classified and labelled according to the Globally Harmonised System (GHS).

- Hazard pictograms
  - GHS03

- Signal word Danger

- Hazard statements
  - May intensify fire; oxidiser.

- Precautionary statements
  - Keep away from heat. - No smoking.
  - Keep/Store away from clothing/combustible materials.
  - Take any precaution to avoid mixing with combustibles.
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - In case of fire: Use to extinguish: CO2, powder or water spray.
  - Dispose of contents/container in accordance with local/regional/national/international regulations.

- Directive 2012/18/EU
  - Named dangerous substances - ANNEX I None of the ingredients is listed.
  - Seveso category P8 OXIDISING LIQUIDS AND SOLIDS
  - Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t
  - Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t

- National regulations:
  - Other regulations, limitations and prohibitive regulations
    - The product is a medical device according to the Directive 93/42/EEC.
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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
IATA: International Air Transport Association
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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Ox. Sol. 2: Oxidizing solids – Category 2