1 Identification

- **Product identifier**
- **Trade name:** Midigold 50
- **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 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 SDS Assistance:
  US: 1-800-533-6825
  Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
  The product is not classified according to the Globally Harmonized System (GHS).
- **Label elements**
  - **GHS label elements** Void
  - **Hazard pictograms** Void
  - **Signal word** Void
  - **Hazard statements** Void
- **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

(Contd. on page 2)
Trade name: **Midigold 50**

- **HMIS-ratings (scale 0 - 4)**
  - **HEALTH**
    - Health = 0
  - **FIRE**
    - Fire = 0
  - **REACTIVITY**
    - 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:**
  - 7440-22-4 silver 25-50%
  - 7440-50-8 copper 2.5-<10%
  - 7440-05-3 palladium 2.5-<10%
  - 7440-74-6 indium 1-<2.5%

### 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.
Trade name: *Midigold 50*

(Contd. of page 2)

**40.1.5**

- **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 Long-term value: 0.01 mg/m³</th>
<th>REL Long-term value: 0.01 mg/m³</th>
<th>TLV Long-term value: 0.1 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-22-4 silver</td>
<td></td>
<td></td>
<td>metal: dust and fume</td>
</tr>
<tr>
<td>7440-50-8 copper</td>
<td>PEL Long-term value: 1* 0.1** mg/m³ as Cu</td>
<td>REL Long-term value: 1* 0.1** mg/m³ as Cu</td>
<td>TLV Long-term value: 1* 0.2** mg/m³ as Cu</td>
</tr>
<tr>
<td>7440-74-6 indium</td>
<td>REL Long-term value: 0.1 mg/m³ as In</td>
<td>TLV Long-term value: 0.1 mg/m³ as In</td>
<td></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.

(Contd. on page 4)
### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
  - **Appearance:**
    - **Form:** Solid
    - **Color:** Yellow
  - **Odor:** Odorless
  - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.
- **Change in condition**
  - **Melting point/Melting range:** 825 – 915 °C (1517 – 1679 °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):** 13.2 g/cm³ (110.154 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 %

(Contd. on page 5)
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:
    - 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
- 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.
Trade name: Midigold 50

- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
- DOT
- ADR, ADN, IMDG, IATA
  - DOT
  - Class
  - Label
- ADR, ADN, IMDG, IATA
- Class
- UN proper shipping name
- ADR, ADN, IMDG, IATA
- Transport hazard class(es)
  - DOT
  - Class
  - Label
- ADR, ADN, IMDG, IATA
- Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
- 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.
  - 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
    - 7440-74-0 indium
### 40.1.5

#### 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.

- **GHS label elements**
  - Void
- **Hazard pictograms**
  - Void
- **Signal word**
  - Void
- **Hazard statements**
  - Void

#### 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.

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### 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** 06/23/2015 / 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)