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

- Product identifier
- Trade name: **Y-Lite**
- 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)
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
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:
7440-05-3 palladium 10-<25%
7440-22-4 silver 1-≤2.5%
7440-74-6 indium 1-≤2.5%
7440-31-5 tin 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.
Trade name: Y-Lite

- 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>Substance</th>
<th>PEL (mg/m³)</th>
<th>REL (mg/m³)</th>
<th>TLV (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>silver</td>
<td>0.01</td>
<td>0.01</td>
<td>0.1</td>
</tr>
<tr>
<td>metal and soluble</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>compounds (as Ag)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>metal: dust and fume</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Contd. on page 4)
Trade name: Y-Lite

7440-74-6 indium
REL (TWA) 0.1 mg/m³
and compounds, as In
TLV (TWA) 0.1 mg/m³
7440-31-5 tin
PEL (TWA) 2 mg/m³
metal
REL (TWA) 2 mg/m³
TLV (TWA) 2 mg/m³
metal

- 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: Yellow
  - Odor: Odorless
  - Odour threshold: Not determined.
- pH-value: Not applicable.
- Change in condition
  - Melting point/Melting range: 1150–1250 °C (2102–2282 °F)
  - Boiling point/Boiling range: Undetermined.
- Flash point: Not applicable.
- Flammability (solid, gaseous): Not determined.
- Auto igniting: Product is not self-igniting.
- Danger of explosion: Product does not present an explosion hazard.
Trade name: Y-Lite

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

- Vapor pressure: Not applicable.

- Density at 20 °C (68 °F):
  - 16.1 g/cm³ (134.355 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: 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

Trade name: Y-Lite

- **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**: 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.
  - **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

(Contd. on page 8)
35.0.51

· 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)