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

- Product identifier
  - Trade name: Brite Gold XH
- 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
Trade name: **Brite Gold XH**

- **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:**
  - 7440-06-4 platinum 1-<10%

### 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.
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:
    - 7440-06-4 platinum
      - PEL (soluble salts, as Pt) 0.002 mg/m³
      - REL (1* 0.002** mg/m³)
        - Metal *soluble salts, as Pt
      - TLV (1* 0.002** mg/m³)
        - Metal **soluble salts, as Pt

- Additional information: The lists that were valid during the creation were used as basis.
### 35.0.51

#### 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance:</strong></td>
<td></td>
</tr>
<tr>
<td>Form</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>Yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Melting point/Melting range:</strong></td>
<td>1080–1150 °C (1976–2102 °F)</td>
</tr>
<tr>
<td><strong>Boiling point/Boiling range:</strong></td>
<td>Undetermined.</td>
</tr>
<tr>
<td><strong>Flash point:</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Flammability (solid, gaseous):</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Auto igniting:</strong></td>
<td>Product is not self-igniting.</td>
</tr>
<tr>
<td><strong>Danger of explosion:</strong></td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td><strong>Explosion limits:</strong></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Upper</td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Vapor pressure:</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Density at 20 °C (68 °F):</strong></td>
<td>18.8 g/cm³ (156.886 lbs/gal)</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Vapour density</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Solubility in / Miscibility with:</strong></td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>Insoluble.</td>
</tr>
</tbody>
</table>
10 Stability and reactivity

- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - Dynamic: Not applicable.
  - Kinematic: Not applicable.
- **Solvent content:** 100%
- **Other information**
  - No further relevant information available.

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.
- **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
    - 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

(Contd. on page 7)
Trade name: Brite Gold XH

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>7440-50-8</td>
<td>copper</td>
</tr>
<tr>
<td>7440-06-4</td>
<td>platinum</td>
</tr>
<tr>
<td>7440-74-6</td>
<td>indium</td>
</tr>
<tr>
<td>7439-88-3</td>
<td>iridium</td>
</tr>
</tbody>
</table>

- **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
- **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.
Trade name: Brite Gold XH

- 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)