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

- **Product identifier**
- **Trade name**: BioUniversal

**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 - Inforac: 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).

- **Signal word** Danger
Trade name: BioUniversal

- **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](image)
  ![Fire: 0](image)
  ![Reactivity: 0](image)
  Health = 0
  Fire = 0
  Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**
  ![Health: 0](image)
  ![Fire: 0](image)
  ![Reactivity: 0](image)
  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:**
  7440-05-3 palladium 25-50%

### 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.
Trade name: BioUniversal

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:
    The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
  - 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.

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Trade name: BioUniversal

- Material of gloves
  Mechanical processing:
  Leather gloves
  Strong 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.
- 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: 1020–1100 °C (1868–2012 °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): 14.5 g/cm³ (121.003 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 %
## 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
  - **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.
**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
    - Class: 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

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- 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.

  - 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)