**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

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

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **1.3 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
  - **Further information obtainable from:**
    Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein
    Regulatory Affairs
    sds@ivoclarvivadent.com
  - **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**
    - Ox. Sol. 2 H272 May intensify fire; oxidiser.

- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**
    - The product is classified and labelled according to the CLP regulation.
  - **Hazard pictograms**
    - GHS03

- **Signal word** Danger
- **Hazard statements**
  - H272 May intensify fire; oxidiser.
- **Precautionary statements**
  - P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  - P221 Take any precaution to avoid mixing with combustibles.
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
  - P220 Keep/Store away from clothing/combustible materials.
  - P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.
  - P501 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.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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**SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterisation: Mixtures**
  - **Description:** Dental alloy
  - **Dangerous components:**
    - CAS: 7440-05-3
    - EINECS: 231-115-6
    - Palladium Self-heat. 2, H252; Ox. Sol. 2, H272 25-50%
  - **Additional information:** For the wording of the listed risk phrases refer to section 16.

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**SECTION 4: First aid measures**

- **4.1 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.

- **4.2 Most important symptoms and effects, both acute and delayed**
  - No further relevant information available.

- **4.3 Indication of any immediate medical attention and special treatment needed**
  - No further relevant information available.

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**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
  - Suitable extinguishing agents: The product is not flammable.
- **5.2 Special hazards arising from the substance or mixture**
  - No further relevant information available.
- **5.3 Advice for firefighters**
  - **Protective equipment:** Do not inhale explosion gases or combustion gases.

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**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**
  - Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 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.

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**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**
  - Extractors are required on all machines used for thermal processing or splinter removal processes.
40.1.5

- Information about fire - and explosion protection: No special measures required.

- 7.2 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.

- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.

- 8.1 Control parameters
  - Ingredients 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 valid during the making were used as basis.

- 8.2 Exposure controls
  - Personal protective equipment:
    - General protective and hygienic measures: Usual hygienic measures for dental practice.
    - 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.
    - Eye protection:
      Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

SECTION 9: Physical and chemical properties

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

- Change in condition
  - Melting point/Melting range: 1020–1100 °C
  - Boiling point/Boiling range: Undetermined.

- Flash point: Not applicable.
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- Flammability (solid, gaseous): Not determined.
- Self-igniting: Product is not selfigniting.
- Danger of explosion: Product does not present an explosion hazard.

- Explosion limits:
  Lower: Not determined.
  Upper: Not determined.
- Vapour pressure: Not applicable.
- Density at 20 °C: 14.5 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 %
- 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability Stable under normal handling and storage conditions.
- 10.3 Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.4 Possibility of hazardous reactions No dangerous reactions known.
- 10.5 Conditions to avoid No further relevant information available.
- 10.6 Incompatible materials: No further relevant information available.
- 10.7 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity:
    - Primary irritant effect:
      - on the skin: No irritant effect.
      - on the eye: No irritating effect.
    - Sensitisation: No sensitising effects known.
  - Additional toxicological information:
    Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity: No further relevant information available.

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12.2 Persistence and degradability
No further relevant information available.

12.3 Bioaccumulative potential
No further relevant information available.

12.4 Mobility in soil
No further relevant information available.

Additional ecological information:
- General notes: Generally not hazardous for water

12.5 Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.

12.6 Other adverse effects
No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
- Recommendation
  Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

European waste catalogue
- 20 00 40 metals

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

SECTION 14: Transport information

14.1 UN-Number
- ADR, ADN, IMDG, IATA  Void

14.2 UN proper shipping name
- ADR, ADN, IMDG, IATA  Void

14.3 Transport hazard class(es)
- ADR, ADN, IMDG, IATA  Void
- Class  Void

14.4 Packing group
- ADR, IMDG, IATA  Void

14.5 Environmental hazards:
- Marine pollutant:  No

14.6 Special precautions for user
- Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 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":  -

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- National regulations:
- Other regulations, limitations and prohibitive regulations
  The product is a medical device according to the Directive 93/42/EEC.
· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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.

· Relevant phrases
  H252 Self-heating in large quantities; may catch fire.
  H272 May intensify fire; oxidiser.

· 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
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  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)
  Self-heat. 2: Self-Heating Substances and Mixtures, Hazard Category 2
  Ox. Sol. 2: Oxidising Solids, Hazard Category 2

· * Data compared to the previous version altered.