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

- **Product identifier**
  - **Trade name:** Ultrapro™ Tx Prophy Paste Pure
  - **Article number:** 8325
  - **Index number:** SDS 339-001.04
  - **Relevant identified uses of the substance or mixture and uses advised against:** Professional Dental Prophy Paste
  - **Application of the substance / the mixture:** Professional Dental Prophy Paste

- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**
    Ultradent Products Inc.
    505 W. Ultradent Drive (10200 S)
    South Jordan, UT 84095-3942
    USA
    onlineordersupport@utradent.com

EC Responsible Person
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDe@utradent.com
Emergency Phone: +49(0)2203-35-92-0

- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
  - CHEMTREC (NORTH AMERICA) : (800) 424-9300
  - (INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**
    The product is not classified, according to the CLP regulation.

- **Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**
    The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

- **Hazard pictograms:** Void
- **Signal word:** Void
- **Hazard statements:** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterisation:** Mixtures
- **Description:** Mixture of substances listed below with nonhazardous additions.
4 First aid measures

- Description of first aid measures
  - General information: No special measures required.
  - After inhalation: This product is a thick paste, therefore inhalation is extremely unlikely.
  - After skin contact: If skin irritation continues, consult a doctor.
  - After eye contact: Rinse opened eye for several minutes under running water.
  - After swallowing: If symptoms persist consult doctor.
- 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:
    Foam
    Water spray
    Carbon dioxide
  - Use fire extinguishing methods suitable to surrounding conditions.
- Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters:
  - Protective equipment:
    Wear self-contained respiratory protective device.
    Wear fully protective suit.
- Additional information Cool endangered receptacles with water spray.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Dilute with plenty of water.
- Methods and material for containment and cleaning up:
  - Wipe up and discard in a suitable container.
  - Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- 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: No special measures required.
  - Information about fire - and explosion protection: No special measures required.
8 Exposure controls/personal protection

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

- 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.

- Exposure controls
  - Personal protective equipment:
  - General protective and hygienic measures:
    The usual precautionary measures are to be adhered to when handling chemicals.
  - Respiratory protection: Not required.

- Protection of hands:
  - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
  - Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
  - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
  - Material of gloves
    The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
  - 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: Goggles recommended during refilling
  - Body protection: Protective work clothing

9 Physical and chemical properties

- Information on basic physical and chemical properties
  - General Information
    - Appearance:
      - Form: Paste
      - Colour: Light grey
      - Odour: Odourless
      - Odour threshold: Not determined.
    - pH-value: Not determined.

- Change in condition
  - Melting point/freezing point: Not determined
  - Initial boiling point and boiling range: Not determined
10 Stability and reactivity

- Reactivity No further relevant information available.
- Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- Possibility of hazardous reactions:
  Reacts with acids.
  Reacts with oxidising agents.
- Conditions to avoid: No further relevant information available.
- Incompatible materials: No further relevant information available.
- Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- Information on toxicological effects
  - Acute toxicity Based on available data, the classification criteria are not met.
  - Primary irritant effect:
    - Skin corrosion/irritation Irritant effect on the skin
    - Serious eye damage/irritation Contact may cause mild irritation with redness and tearing.
  - Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
  - CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
  - Germ cell mutagenicity Based on available data, the classification criteria are not met.
12 Ecological information

- Toxicity
  - Aquatic toxicity: No further relevant information available.
  - Persistence and degradability: No further relevant information available.
  - Behaviour in environmental systems:
    - Bioaccumulative potential: No further relevant information available.
    - Mobility in soil: No further relevant information available.
  - Additional ecological information:
    - General notes: Not known to be hazardous to 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: Smaller quantities can be disposed of with household waste.
  - Uncleaned packaging:
    - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number: not regulated
  - ADR, ADN, IMDG, IATA: not regulated
- UN proper shipping name: not regulated
  - ADR, ADN, IMDG, IATA: not regulated
- Transport hazard class(es)
  - ADR, ADN, IMDG, IATA: not regulated
  - Class: not regulated
- Packing group
  - ADR, IMDG, IATA: not regulated
- Environmental hazards:
  - Not applicable.
- Special precautions for user
  - Not applicable.

- Transport in bulk according to Annex II of Marpol and the IBC Code:
  - Not applicable.
15 Regulatory information

- Chemical safety assessment:
  Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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.

- Department issuing SDS: Regulatory Affairs
- Contact: Customer Service
- 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)
  - VOC: Volatile Organic Compounds (USA, EU)
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative