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

- **Product identifier**

- **Trade name:** Vit-l-escence™

- **Article number:**

- **Index number:** SDS 143-001.04

- **Relevant identified uses of the substance or mixture and uses advised against**

  Professional Dental Esthetic Restorative Material

- **Application of the substance / the mixture**

  Professional Dental Esthetic Restorative Material

- **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@ultradent.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**
  
  ![GHS07]

  Skin Sens. 1 H317 May cause an allergic skin reaction.

- **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** GHS07
  
  - **Signal word** Warning

  - **Hazard-determining components of labelling**
    Tetramethylene Dimethacrylate

(Contd. on page 2)
3 Composition/information on ingredients

- Chemical characterisation: Mixtures
- Description: Mixture of substances listed below with nonhazardous additions.

- Dangerous components:

  | CAS: 2082-81-7 | Tetramethylene Dimethacrylate | Skin Sens. 1, H317; STOT SE 3, H335 |
  | EINECS: 218-218-1 | >2.5-≤10% |

- Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- Description of first aid measures
- General information: Immediately remove any clothing soiled by the product.
- After inhalation: Supply fresh air and to be sure call for a doctor.
- After skin contact:
  - Immediately wash with water and soap and rinse thoroughly.
  - If skin irritation continues, consult a doctor.
- After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing: Do not induce vomiting; call for medical help immediately.
- 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
  - Fire-extinguishing powder
  - Water haze
  - Carbon dioxide
  - Use fire extinguishing methods suitable to surrounding conditions.
- Special hazards arising from the substance or mixture No further relevant information available.
6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures: Not required.
- Environmental precautions: Do not allow to enter sewers/surface or ground water.
- Methods and material for containment and cleaning up:
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Dispose contaminated material as waste according to item 13.
  Ensure adequate ventilation.
- Reference to other sections
  No dangerous substances are released.
  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:
    Keep receptacles tightly sealed.
    Ensure good ventilation/exhaustion at the workplace.
    Prevent formation of aerosols.
  - Information about fire - and explosion protection: No special measures required.
- Conditions for safe storage, including any incompatibilities
- Storage:
  - Requirements to be met by storerooms and receptacles: See product labeling.
  - Information about storage in one common storage facility: Store away from foodstuffs.
  - Further information about storage conditions: See product labelling.
- Specific end use(s) Professional Dental Esthetic Restorative Material

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:
    Immediately remove all soiled and contaminated clothing.
    Wash hands before breaks and at the end of work.
  - Respiratory protection:
    In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
Trade name: Vit-l-escence™

- **Protection of hands:**
  - Protective gloves and protective skin cream

  **Protective gloves**

  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**
  - Natural rubber, NR
  
  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**
  - 0.1 - 0.2mm
  - Penetration time: 5 min
  
  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:** Different according to colouring
      - **Odour:** Weak, characteristic
      - **Odour threshold:** Not determined.

    - **pH-value:** Not determined.

    - **Change in condition**
      - **Melting point/freezing point:** Undetermined.
      - **Initial boiling point and boiling range:** Undetermined.

    - **Flash point:** 101 °C

    - **Flammability (solid, gas):** Not applicable.

    - **Ignition temperature:** >370 °C

    - **Decomposition temperature:** Not determined.

    - **Auto-ignition temperature:** Product is not selfigniting.

    - **Explosive properties:** Product does not present an explosion hazard.

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

    - **Vapour pressure:** 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:
  Photoreactive.
  Danger of polymerisation.
· Conditions to avoid: No further relevant information available.
· Incompatible materials:
  In presence of radical formers (e.g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.
· 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: Based on available data, the classification criteria are not met.
    · Serious eye damage/irritation: Based on available data, the classification criteria are not met.
  · Respiratory or skin sensitisation
    May cause an allergic skin reaction.
  · CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
  · Germ cell mutagenicity: Based on available data, the classification criteria are not met.
  · Carcinogenicity: Based on available data, the classification criteria are not met.
  · Reproductive toxicity: Based on available data, the classification criteria are not met.
  · STOT-single exposure: Based on available data, the classification criteria are not met.
  · STOT-repeated exposure: Based on available data, the classification criteria are not met.
  · Aspiration hazard: 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: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
      Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
    - 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**
  Must be specially treated adhering to official regulations.
  Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**
  - HP 13 Sensitising
  - Uncleaned packaging:
    - **Recommendation**: Packagings that may not be cleansed are to be disposed of in the same manner as the product.
    - **Recommended cleansing agents**: Alcohol

14 Transport information

- **UN-Number**
  - ADR, ADN, IMDG, IATA: not regulated
- **UN proper shipping name**
  - ADR, ADN, IMDG, IATA: not regulated
- **Transport hazard class(es)**
  - ADR, ADN, IMDG, IATA: 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.
Trade name: Vit-l-escence™

UN "Model Regulation": not regulated

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- REGULATION (EC) No 1907/2006 ANNEX XVII
- Conditions of restriction: 3
- 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.

- Relevant phrases
  H317 May cause an allergic skin reaction.
  H335 May cause respiratory irritation.

- 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
  Skin Sens. 1: Skin sensitisation – Category 1
  STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

GB2