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

· Product identifier
  · Trade name: DeOx™
  · Article number: DX/11101
  · Index number: SDS 77-001.07
· Relevant identified uses of the substance or mixture and uses advised against
  Professional Dental Oxygen Barrier
· Application of the substance / the mixture
  Professional Dental Oxygen Barrier
· 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@ultradent.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
    The product is not classified, according to the CLP regulation.
· Label elements
  · Labelling according to Regulation (EC) No 1272/2008 Void
  · 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.

· Dangerous components:
  
  | CAS: 56-81-5 | Glycerine | substance with a Community workplace exposure limit |
  | EINECS: 200-289-5 | | >50-%100% |

(Contd. on page 2)
4 First aid measures

- Description of first aid measures
  - General information: No special measures required.
  - After inhalation: Supply fresh air; consult doctor in case of complaints.
  - After skin contact: Generally the product does not irritate the skin.
  - 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: 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: No special measures required.

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).
- 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.
  - Conditions for safe storage, including any incompatibilities: No special measures required.

  - 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)
    - Professional Dental Oxygen Barrier

8 Exposure controls/personal protection

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

- Control parameters
  - Ingredients with limit values that require monitoring at the workplace:
    - 56-81-5 Glycerine
      - WEL (Great Britain) Long-term value: 10 mg/m³
  - 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: Viscous Liquid
      - Colour: Colourless
    - Odour: Mild
    - Odour threshold: Not determined.
  - pH-value: Not determined.

- Change in condition
  - Melting point/freezing point: 19-20 °C
  - Initial boiling point and boiling range: 290 °C

- Flash point: 160 °C

- Flammability (solid, gas): Not applicable.

- Ignition temperature: 370-392 °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:

- Vapour pressure at 20 °C: 0 hPa
- Density at 20 °C: 1.26126 g/cm³
- Relative density: Not determined.
- Vapour density: Not determined.
- Evaporation rate: Not determined.

- Solubility in / Miscibility with water: Not miscible or difficult to mix.
- Partition coefficient: n-octanol/water: Not determined.
- Viscosity:
  - Dynamic: Not determined.
  - Kinematic: Not determined.
- Solvent content:
  - Organic solvents: 99.1 %
  - VOC (EC): 0.00 %
- Solids content: <1.0 %
- Other information: No further relevant information available.

## 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: No dangerous reactions known.
- 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.

- LD/LC50 values relevant for classification:

### ATE (Acute Toxicity Estimates)

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalative</td>
<td>LC50/4 h</td>
</tr>
</tbody>
</table>

### 56-81-5 Glycerine

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>LD50</td>
</tr>
<tr>
<td>Oral</td>
<td>LC50 Fish</td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
</tr>
<tr>
<td>Inhalative</td>
<td>LC50/4 h</td>
</tr>
</tbody>
</table>
Trade name: DeOx™

- 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: Based on available data, the classification criteria are not met.
- CMR effects (carcinogenity, 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:
    - 56-81-5 Glycerine
      - EC50 >10,000 mg/l (Bacteria)
      - >10,000 mg/l (daphnia)
  - 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: 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
  - ADR, ADN, IMDG, IATA: not regulated

- UN proper shipping name
  - ADR, ADN, IMDG, IATA: not regulated
48.0

· Transport hazard class(es)
  · ADR, ADN, IMDG, IATA
  · 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.

· UN "Model Regulation": not regulated

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)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative