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

· Product identifier
  · Trade name: Opalescence™ 10% Bleaching Gel (All Flavors)
  · Article number: 10320, 11592
  · Index number: SDS 9-001.12

· Relevant identified uses of the substance or mixture and uses advised against
  Professional Dental Teeth Whitening Gel

· Application of the substance / the mixture
  Professional Dental Teeth Whitening Gel

· 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:
  · 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

  Acute Tox. 4 H332 Harmful if inhaled.
  Skin Irrit. 2 H315 Causes skin irritation.
  Eye Irrit. 2 H319 Causes serious eye irritation.

· 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 cosmetic in the finished state used in direct physical contact with the human body according to Art. 1.5 (c). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6b), 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:
  Carbamide Peroxide
  Sodium Hydroxide

(Contd. on page 2)
Trade name: Opalescence™ 10% Bleaching Gel (All Flavors)

- **Hazard statements**
  - H332 Harmful if inhaled.
  - H315 Causes skin irritation.
  - H319 Causes serious eye irritation.
- **Precautionary statements**
  - P101 If medical advice is needed, have product container or label at hand.
  - P102 Keep out of reach of children.
  - P103 Read label before use.
  - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  - P264 Wash thoroughly after handling.
  - P271 Use only outdoors or in a well-ventilated area.
  - P280 Wear protective gloves / eye protection / face protection.
  - P302+P352 IF ON SKIN: Wash with plenty of water.
  - P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
  - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P312 Call a POISON CENTER/doctor if you feel unwell.
  - P321 Specific treatment (see on this label).
  - P362+P364 Take off contaminated clothing and wash it before reuse.
  - P332+P313 If skin irritation occurs: Get medical advice/attention.
  - P337+P313 If eye irritation persists: Get medical advice/attention.

- **Additional information:**
  - Contains Oils, Peppermint. May produce an allergic reaction.

- **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 | >50-≤100% |
| EINECS: 200-289-5 | | | |

| CAS: 124-43-6 | Carbamide Peroxide | | <12% |
| EINECS: 204-701-4 | | | |

| CAS: 1310-73-2 | Sodium Hydroxide | | <5% |
| EINECS: 215-185-5 | | | |

| CAS: 8006-90-4 | Oils, Peppermint | | <1% |
| EINECS: 282-015-4 | | | |

- **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.
  - Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

(Contd. on page 3)
Trade name: Opalescence™ 10% Bleaching Gel (All Flavors)

- **After inhalation:**
  This product is a viscous gel, therefore chance of inhalation is extremely low.
  Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- **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. If symptoms persist, consult a doctor.
- **After swallowing:**
  If swallowed in large quantities seek medical attention.
- **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:** Water spray
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:**
  **Protective equipment:**
  Wear fully protective suit.
  Mouth respiratory protective device.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
  Wear protective equipment. Keep unprotected persons away.
- **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). Ensure adequate ventilation.
- **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:**
  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:** No special requirements.
  **Information about storage in one common storage facility:** Not required.
  **Further information about storage conditions:**
  See product labelling.
  Keep container tightly sealed.
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Opalescence™ 10% Bleaching Gel (All Flavors)

8 Exposure controls/personal protection

- Specific end use(s) Professional Dental Teeth Whitening Gel

- 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:

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Substance</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5</td>
<td>Glycerine</td>
<td>WEL (Great Britain)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Long-term value: 10 mg/m³</td>
</tr>
<tr>
<td>1310-73-2</td>
<td>Sodium Hydroxide</td>
<td>WEL (Great Britain)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Short-term value: 2 mg/m³</td>
</tr>
</tbody>
</table>

- Additional information: The lists valid during the making were used as basis.

- Exposure controls
- Personal protective equipment:
  - General protective and hygienic measures:
    - Keep away from foodstuffs, beverages and feed.
    - Immediately remove all soiled and contaminated clothing.
    - Wash hands before breaks and at the end of work.
    - Avoid contact with the eyes and skin.
  - 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.
  - Protection of hands:

    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

    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:

    Tightly sealed goggles

    Body protection: Protective work clothing
9 Physical and chemical properties

- Information on basic physical and chemical properties
  - General Information
    - Appearance:
      - Form: Gel
      - Colour: Colourless
    - Odour:
      - Odour: Product specific
      - Odour threshold: Not determined.
  - pH-value at 20 °C: 6.1-6.7

- Change in condition
  - Melting point/freezing point: Undetermined.
  - Initial boiling point and boiling range: Undetermined.
  - Flash point: Not applicable.
  - Flammability (solid, gas): Not applicable.
  - 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.
    - Density at 20 °C: 1.2-1.3 g/cm³
    - Relative density: Not determined.
    - Vapour density: Not determined.
    - Evaporation rate: Not determined.
    - Solubility in / Miscibility with water: Partly soluble.
    - Partition coefficient: n-octanol/water: Not determined.
    - Viscosity:
      - Dynamic: \(\leq 3,762,000\) cps
      - Kinematic: Not determined.
    - Solvent content:
      - Organic solvents: <70 %
      - Water: <40 %
      - VOC (EC): 0.00 %
    - Other information: No further relevant information available.

10 Stability and reactivity

- Reactivity: Stable
- 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: Excess heat
- Incompatible materials: Strong caustics, most metals
11 Toxicological information

- Information on toxicological effects
  
  - Acute toxicity
    Harmful if inhaled.

  - LD/LC50 values relevant for classification:

    **ATE (Acute Toxicity Estimates)**

    | Route   | LD50      | LC50/4 h       |
    |---------|-----------|----------------|
    | Oral    | 4,808-12,374 mg/kg | >0.272 mg/l (rat) |
    | Dermal  | 49,926 mg/kg (rabbit) | >21,900 mg/kg (rat) |
    | Inhalative | >0.272 mg/l (rat) | >160 mg/l (Fish) |

    **56-81-5 Glycerine**

    | Route   | LD50      | LC50/4 h       |
    |---------|-----------|----------------|
    | Oral    | 7,750 mg/kg (Guinea pig) | >0.1425 mg/l (rat) |
    | Dermal  | >21,900 mg/kg (rat) | 180 ppm (Fish) |
    | Inhalative | >0.1425 mg/l (rat) | >5,000 mg/l (Fish) |

    **124-43-6 Carbamide Peroxide**

    | Route   | LD50      | Absolute lethal concentration |
    |---------|-----------|-------------------------------|
    | Oral    | >2,000 mg/kg (rat) | 180 ppm (Fish) |

    **1310-73-2 Sodium Hydroxide**

    | Route   | LD50      | Absolute lethal concentration |
    |---------|-----------|-------------------------------|
    | Oral    | 130-340 mg/kg (rat) | 160 mg/l (Fish) |
    | Dermal  | 1,350 mg/kg (rabbit) | 180 ppm (Fish) |

    **8006-90-4 Oils, Peppermint**

    | Route   | LD50      | Absolute lethal concentration |
    |---------|-----------|-------------------------------|
    | Oral    | 2,490 mg/kg (mouse) | 180 ppm (Fish) |

- Primary irritant effect:
  
  - Skin corrosion/irritation
    Causes skin irritation.
  
  - Serious eye damage/irritation
    Causes serious eye irritation.
  
  - Respiratory or skin sensitisation
    Based on available data, the classification criteria are not met.
  
  - CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
    Based on available data, the classification criteria are not met.
  
  - 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)
    - **1310-73-2 Sodium Hydroxide**
      - EC50: 40.38 mg/l (Water Flea)

- **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 2 (German Regulation) (Self-assessment): hazardous for water.
    Do not allow product to reach ground water, water course or sewage system.
    Danger to drinking water if even small quantities leak into the ground.

- **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**
  Do not allow product to reach sewage system.

- **European waste catalogue**
  - **HP8**: Corrosive

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

14 Transport information

- **UN-Number**
  - **ADR, IMDG, IATA**
    not regulated

- **UN proper shipping name**
  - **ADR, 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.
Trade name: Opalescence™ 10% Bleaching Gel (All Flavors)

- **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**

- **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**: The product meets the toxicological profile required for cosmetics per the EU cosmetic regulation, Regulation (EC) No. 1223/2009.

**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**
  - H272 May intensify fire; oxidiser.
  - H301 Toxic if swallowed.
  - H304 May be fatal if swallowed and enters airways.
  - H312 Harmful in contact with skin.
  - H314 Causes severe skin burns and eye damage.
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
  - H411 Toxic to aquatic life with long lasting effects.

- **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
  - Ox. Sol. 3: Oxidizing solids – Category 3
  - Acute Tox. 3: Acute toxicity - oral – Category 3
  - Acute Tox. 4: Acute toxicity - dermal – Category 4
  - Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  - Skin Corr. 1B: Skin corrosion/irritation – Category 1B
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  - Skin Sens. 1: Skin sensitisation – Category 1
  - Asp. Tox. 1: Aspiration hazard – Category 1
  - Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2