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

· Product identifier
  · Trade name: Opalescence Go™ 6%
  · Article number: 71162
  · Index number: SDS 131-001.14
  · 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@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

  GHS07

  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

· Hazard statements
  H315 Causes skin irritation.
Trade name: Opalescence Go™ 6%

4.3.1 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.
P264 Wash thoroughly after handling.
P280 Wear protective gloves / eye protection / face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
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 | >25-%<50% |
| EINECS: 200-289-5 | | |
| CAS: 124-43-6 | Carbamide Peroxide | >2.5-%<8% |
| EINECS: 204-701-4 | Ox. Sol. 3, H272; Skin Corr. 1B, H314 | |
| CAS: 7722-84-1 | Hydrogen Peroxide | >2.5-%<5% |
| EINECS: 231-765-0 | Ox. Liq. 1, H271; Skin Corr. 1A, H314; Acute Tox. 4, H332 | |
| CAS: 1310-73-2 | Sodium Hydroxide | ≤2% |
| EINECS: 215-185-3 | Acute Tox. 3, H301; Skin Corr. 1A, H314; Acute Tox. 4, H312 | |
| CAS: 8006-90-4 | Oils, Peppermint | ≤1.0% |
| EINECS: 282-015-4 | Asp. Tox. 1, H304; Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | |
| CAS: 7681-49-4 | Sodium Fluoride | 0.25% |
| EINECS: 231-667-8 | Acute Tox. 3, H301; Acute Tox. 2, H310; Skin Irrit. 2, H315; Eye Irrit. 2, H319 | |
| CAS: 7757-79-1 | Potassium Nitrate | ≤0.5% |
| EINECS: 231-818-8 | Ox. Sol. 2, H272; Skin Irrit. 2, H315; STOT SE 3, H335-H336 | |

· 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:
This product is a thick paste, therefore inhalation is extremely unlikely.
Provide fresh air. Seek medical attention if problems persist.
5 Firefighting measures

· Extinguishing media
· Suitable extinguishing agents:
  CO₂ powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  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: Avoid contact with eyes, skin, and clothing.
· 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.
· Specific end use(s) Professional Dental Teeth Whitening Gel

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:

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Substance</th>
<th>WEL (Great Britain)</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5</td>
<td>Glycerine</td>
<td>Long-term value: 10 mg/m³</td>
</tr>
<tr>
<td>7722-84-1</td>
<td>Hydrogen Peroxide</td>
<td>Short-term value: 2.8 mg/m³, 2 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Long-term value: 1.4 mg/m³, 1 ppm</td>
</tr>
<tr>
<td>1310-73-2</td>
<td>Sodium Hydroxide</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: Not required.
  - 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: Whitish
### 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:**
  - Metal Oxides
  - Strong Alkalis

---

**Trade name: Opalescence Go™ 6%**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour</td>
<td>Mint</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not determined</td>
</tr>
<tr>
<td>pH-value at 20 °C</td>
<td>4.6-6.6</td>
</tr>
<tr>
<td>Change in condition</td>
<td></td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Undetermined</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Undetermined</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not determined</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Product is not selfigniting</td>
</tr>
<tr>
<td><strong>Explosion limits:</strong></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>Not determined</td>
</tr>
<tr>
<td>Upper</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapour pressure at 20 °C</td>
<td>23.3 hPa</td>
</tr>
<tr>
<td>Density</td>
<td>1.2</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not determined</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not determined</td>
</tr>
<tr>
<td>Solubility in / Miscibility with water</td>
<td>Fully miscible</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not determined</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Dynamic</td>
<td>Not determined</td>
</tr>
<tr>
<td>Kinematic</td>
<td>Not determined</td>
</tr>
<tr>
<td>Solvent content</td>
<td></td>
</tr>
<tr>
<td>Organic solvents</td>
<td>&lt;50 %</td>
</tr>
<tr>
<td>Water</td>
<td>&lt;60 %</td>
</tr>
<tr>
<td>VOC (EC)</td>
<td>0.00 %</td>
</tr>
<tr>
<td>Solids content</td>
<td>&lt;30.0 %</td>
</tr>
<tr>
<td>Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>
Trade name: Opalescence Go™ 6%

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>Mode</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50</td>
<td>4,498-6,621 mg/kg</td>
</tr>
<tr>
<td>Dermal LD50</td>
<td>39,375 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Inhalative LC50/4 h</td>
<td>&gt;0.35 mg/l</td>
</tr>
</tbody>
</table>

  **56-81-5 Glycerine**
  
<table>
<thead>
<tr>
<th>Mode</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50</td>
<td>7,750 mg/kg (Guinea pig)</td>
</tr>
<tr>
<td>Dermal LC50</td>
<td>&gt;5,000 mg/l (Fisch)</td>
</tr>
<tr>
<td>Dermal LD50</td>
<td>27,000 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Inhalative LC50/4 h</td>
<td>&gt;0.1425 mg/l (rat)</td>
</tr>
</tbody>
</table>

  **124-43-6 Carbamide Peroxide**
  
<table>
<thead>
<tr>
<th>Mode</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50</td>
<td>&gt;2,000 mg/kg (rat)</td>
</tr>
</tbody>
</table>

  **7722-84-1 Hydrogen Peroxide**
  
<table>
<thead>
<tr>
<th>Mode</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LC50</td>
<td>16.4 mg/l (Fisch)</td>
</tr>
</tbody>
</table>

  **1310-73-2 Sodium Hydroxide**
  
<table>
<thead>
<tr>
<th>Mode</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50</td>
<td>130-340 mg/kg (rat)</td>
</tr>
<tr>
<td>Dermal LC50</td>
<td>160 mg/l (Fisch)</td>
</tr>
<tr>
<td>Dermal LD50</td>
<td>1,350 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Absolute lethal concentration</td>
<td>180 ppm (Fish)</td>
</tr>
</tbody>
</table>

  **8006-90-4 Oils, Peppermint**
  
<table>
<thead>
<tr>
<th>Mode</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50</td>
<td>2,490 mg/kg (mouse)</td>
</tr>
</tbody>
</table>

  **7681-49-4 Sodium Fluoride**
  
<table>
<thead>
<tr>
<th>Mode</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50</td>
<td>52 mg/kg (mouse)</td>
</tr>
<tr>
<td>Oral LC50</td>
<td>17 mg/l (Fisch)</td>
</tr>
<tr>
<td>Dermal LD50</td>
<td>175 mg/kg (rat)</td>
</tr>
</tbody>
</table>

- **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)**
  - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
  - **Carcinogenicity** Based on available data, the classification criteria are not met.
### 12 Ecological information

**· Toxicity**

**· Aquatic toxicity:**

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5 Glycerine</td>
<td>&gt;10,000 mg/l (Bacteria)</td>
</tr>
<tr>
<td></td>
<td>&gt;10,000 mg/l (daphnia)</td>
</tr>
<tr>
<td>7722-84-1 Hydrogen Peroxide</td>
<td>1.38 mg/l (Algae)</td>
</tr>
<tr>
<td></td>
<td>2.4 mg/l (daphnia)</td>
</tr>
<tr>
<td>1310-73-2 Sodium Hydroxide</td>
<td>40.38 mg/l (Water Flea)</td>
</tr>
<tr>
<td>7681-49-4 Sodium Fluoride</td>
<td>272 mg/kg (Algae)</td>
</tr>
<tr>
<td></td>
<td>98 mg/kg (daphnia)</td>
</tr>
</tbody>
</table>

**· 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**
  - Not regulated

- **UN proper shipping name**
  - Not regulated

- **Transport hazard class(es)**
  - Not regulated

- **Packing group**
  - 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

- **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**
  H271 May cause fire or explosion; strong oxidiser.
  H272 May intensify fire; oxidiser.
  H301 Toxic if swallowed.
  H302 Harmful if swallowed.
  H304 May be fatal if swallowed and enters airways.
  H310 Fatal in contact with skin.
  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.
  H332 Harmful if inhaled.
  H335 May cause respiratory irritation.
  H336 May cause drowsiness or dizziness.
  H411 Toxic to aquatic life with long lasting effects.

- **Department issuing SDS**: Regulatory Affairs

- **Contact**: Customer Service

(Contd. on page 9)
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. Liq. 1: Oxidizing liquids – Category 1
Ox. Sol. 2: Oxidizing solids – Category 2
Ox. Sol. 3: Oxidizing solids – Category 3
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 2: Acute toxicity – Category 2
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
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Asp. Tox. 1: Aspiration hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2