# 1 Identification

- **Product identifier**
  - **Trade name**: Opalescence™ 35% CP Mint
  - **Article number**: 1007932
  - **Index number**: SDS 448-001.01
- **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
  - **Information department**: Customer Service
  - **Emergency telephone number**:
    - CHEMTREC (NORTH AMERICA) : (800) 424-9300
    - (INTERNATIONAL) : +(703) 527-3887

# 2 Hazard(s) identification

- **Classification of the substance or mixture**
  - GHS07
  - Acute Tox. 4  H302  Harmful if swallowed.
  - Acute Tox. 4  H332  Harmful if inhaled.
  - Skin Irrit. 2  H315  Causes skin irritation.
  - Eye Irrit. 2A  H319  Causes serious eye irritation.
  - Skin Sens. 1  H317  May cause an allergic skin reaction.
- **Label elements**
  - **GHS label elements**
    - Medical Devices, Cosmetics, and Drugs are exempt from the labeling requirements of the Globally Harmonized System (GHS).
  - **Hazard pictograms** GHS07
  - **Signal word** Warning
- **Hazard-determining components of labeling**:
  - Carbamide Peroxide
  - Hydrogen Peroxide
  - Sodium Hydroxide
  - Oils, Peppermint
  - **Hazard statements**
    - Harmful if swallowed or if inhaled.
    - Causes skin irritation.
    - Causes serious eye irritation.
    - May cause an allergic skin reaction.
- **Precautionary statements**
  - **P261**  Avoid breathing dust/fume/gas/mist/vapors/spray
  - **P264**  Wash thoroughly after handling.
  - **P270**  Do not eat, drink or smoke when using this product.

(Contd. on page 2)
Trade name: Opalescence™ 35% CP Mint

P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves / eye protection / face protection.
P301+P312 If swallowed: Call a poison center/doctor if you feel unwell.
P330 Rinse mouth.
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.
P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system:

- NFPA ratings (scale 0 - 4)
  - Health = 2
  - Fire = 0
  - Reactivity = 0

- HMIS-ratings (scale 0 - 4)
  - Health = *3
  - Fire = 0
  - Reactivity = 0

Other hazards:

- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

3 Composition/information on ingredients

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

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5 Glycerin</td>
<td>&gt;25-≤50%</td>
</tr>
<tr>
<td>Eye Irrit. 2B, H320</td>
<td></td>
</tr>
<tr>
<td>124-43-6 Carbamide Peroxide</td>
<td>&gt;10-≤20%</td>
</tr>
<tr>
<td>Ox. Sol. 3, H272; Skin Corr. 1B, H314; Eye Dam. 1, H318</td>
<td></td>
</tr>
<tr>
<td>9003-01-4 Polyacrylic Acid</td>
<td>&gt;2.5-≤10%</td>
</tr>
<tr>
<td>7722-84-1 Hydrogen Peroxide</td>
<td>≥2.5-≤10%</td>
</tr>
<tr>
<td>Ox. Liq. 1, H271; Skin Corr. 1A, H314; Acute Tox. 4, H302; Acute Tox. 4, H332</td>
<td></td>
</tr>
<tr>
<td>25322-68-3 Polyethylene Glycol</td>
<td>&gt;2.5-≤10%</td>
</tr>
<tr>
<td>1310-73-2 Sodium Hydroxide</td>
<td>&lt;3%</td>
</tr>
<tr>
<td>Acute Tox. 3, H301; Met. Corr.1, H290; Skin Corr. 1A, H314; Eye Dam. 1, H318; Acute Tox. 4, H312</td>
<td></td>
</tr>
<tr>
<td>8006-90-4 Oils, Peppermint</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Asp. Tox. 1, H304; Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317; Flam. Liq. 4, H227</td>
<td></td>
</tr>
</tbody>
</table>
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 viscous gel, therefore chance of inhalation is extremely low.
  - **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
  - **After eye contact:** Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
  - **After swallowing:** Immediately call a 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 Fire-fighting measures

- **Extinguishing media**
  - **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
  - **Special hazards arising from the substance or mixture** No further relevant information available.
  - **Advice for firefighters**
    - **Protective equipment:** 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).
    - Dispose contaminated material as waste according to item 13.
    - 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.

- **Protective Action Criteria for Chemicals**

<table>
<thead>
<tr>
<th>PAC-1:</th>
<th>PAC-2:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
</tr>
<tr>
<td>45 mg/m³</td>
<td>180 mg/m³</td>
</tr>
<tr>
<td>Carbamide Peroxide</td>
<td>124-43-6</td>
</tr>
<tr>
<td>1.2 mg/m³</td>
<td>13 mg/m³</td>
</tr>
<tr>
<td>Hydrogen Peroxide</td>
<td>7722-84-1</td>
</tr>
<tr>
<td>10 ppm</td>
<td>50 ppm</td>
</tr>
<tr>
<td>Polyethylene Glycol</td>
<td>25322-68-3</td>
</tr>
<tr>
<td>30 mg/m³</td>
<td>1,300 mg/m³</td>
</tr>
<tr>
<td>Edetate Disodium</td>
<td>6381-92-6</td>
</tr>
<tr>
<td>30 mg/m³</td>
<td>330 mg/m³</td>
</tr>
</tbody>
</table>
Trade name: Opalescence™ 35% CP Mint

7 Handling and storage

· Handling:
  · Precautions for safe handling
    Ensure good ventilation/exhaustion at the workplace.
    Prevent formation of aerosols.
  · Information about protection against explosions and fires: 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 receptacle tightly sealed.
  · Specific end use(s) Professional Dental Teeth Whitening Gel

8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see item 7.
· Control parameters
· Components with limit values that require monitoring at the workplace:
  At this time, the other constituents have no known exposure limits.

<table>
<thead>
<tr>
<th>PAC-3:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5</td>
<td>Glycerin</td>
</tr>
<tr>
<td>124-43-6</td>
<td>Carbamide Peroxide</td>
</tr>
<tr>
<td>7722-84-1</td>
<td>Hydrogen Peroxide</td>
</tr>
<tr>
<td>25322-68-3</td>
<td>Polyethylene Glycol</td>
</tr>
<tr>
<td>6381-92-6</td>
<td>Edetate Disodium</td>
</tr>
</tbody>
</table>

56-81-5 Glycerin

<table>
<thead>
<tr>
<th>PEL</th>
<th>Long-term value: 15* 5** mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>mist; *total dust **respirable fraction</td>
<td></td>
</tr>
<tr>
<td>TLV</td>
<td>TLV withdrawn-insufficient data human occup. exp.</td>
</tr>
<tr>
<td>TWA</td>
<td>Short-term value: 15 mg/m³</td>
</tr>
</tbody>
</table>

9003-01-4 Polyacrylic Acid

| TWA | Short-term value: 0.05 mg/m³ |

7722-84-1 Hydrogen Peroxide

| PEL | Long-term value: 1.4 mg/m³, 1 ppm |
| REL | Long-term value: 1.4 mg/m³, 1 ppm |
| TLV | Long-term value: 1.4 mg/m³, 1 ppm |

25322-68-3 Polyethylene Glycol

| WEEL | Long-term value: 10 mg/m³ |
| (H); MW>200 |

1310-73-2 Sodium Hydroxide

| PEL | Long-term value: 2 mg/m³ |
51.1.24

REL Ceiling limit value: 2 mg/m³
TLV Ceiling limit value: 2 mg/m³

· Additional information: The lists that were valid during the creation 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.
· Breathing equipment:
  In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
· 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 is based 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
  Color: Clear
  Odor: Mint
  Odor threshold: Not determined.
· pH-value at 20 °C: 5-7
· Change in condition
  Melting point/Melting range: Undetermined.
### 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**: Excess heat
  - **Incompatible materials**: Strong caustics, Most Metals
  - **Hazardous decomposition products**: No dangerous decomposition products known.
## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**

<table>
<thead>
<tr>
<th>ATE (Acute Toxicity Estimate)</th>
<th>Oral LD50</th>
<th>Oral LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal LD50</td>
<td>&gt;1,885-2,546 mg/kg</td>
<td>46,552 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Inhalative LC50/4 h</td>
<td>&gt;0.479 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

### 56-81-5 Glycerin

<table>
<thead>
<tr>
<th>Oral LD50</th>
<th>Oral LC50/4 h</th>
<th>Oral LD50</th>
<th>Oral LC50/4 h</th>
<th>Oral LD50</th>
<th>Oral LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal LD50</td>
<td>7,750 mg/kg (Guinea pig)</td>
<td>&gt;1,885-2,546 mg/kg</td>
<td>4,100 mg/kg (mouse)</td>
<td>5,570 mg/kg (rat)</td>
<td></td>
</tr>
<tr>
<td>Inhalative LC50/4 h</td>
<td>&gt;0.479 mg/l</td>
<td>&gt;21,900 mg/kg (rat)</td>
<td>10,000 mg/kg (rabbit)</td>
<td>&gt;0.1425 mg/l (rat)</td>
<td></td>
</tr>
</tbody>
</table>

### 124-43-6 Carbamide Peroxide

<table>
<thead>
<tr>
<th>Oral LD50</th>
<th>Oral LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal LD50</td>
<td>&gt;2,000 mg/kg (rat)</td>
</tr>
<tr>
<td>Inhalative LC50/4 h</td>
<td></td>
</tr>
</tbody>
</table>

### 9003-01-4 Polyacrylic Acid

<table>
<thead>
<tr>
<th>Oral LC50 Fish</th>
<th>Oral LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>580 mg/l (Fish)</td>
</tr>
</tbody>
</table>

### 7722-84-1 Hydrogen Peroxide

<table>
<thead>
<tr>
<th>Oral LC50 Fish</th>
<th>Oral LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>16.4 mg/l (Fish)</td>
</tr>
</tbody>
</table>

### 25322-68-3 Polyethylene Glycol

<table>
<thead>
<tr>
<th>Oral LD50</th>
<th>Oral LC50/4 h</th>
<th>Oral LD50</th>
<th>Oral LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal LD50</td>
<td>19,600 mg/kg (Guinea pig)</td>
<td>&gt;1,885-2,546 mg/kg</td>
<td>4,100 mg/kg (mouse)</td>
</tr>
<tr>
<td>Inhalative LC50/4 h</td>
<td>&gt;0.479 mg/l</td>
<td>&gt;21,900 mg/kg (rat)</td>
<td>10,000 mg/kg (rabbit)</td>
</tr>
</tbody>
</table>

### 1310-73-2 Sodium Hydroxide

<table>
<thead>
<tr>
<th>Oral LD50</th>
<th>Oral LC50/4 h</th>
<th>Oral LD50</th>
<th>Oral LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal LD50</td>
<td>130-340 mg/kg (rat)</td>
<td>&gt;1,885-2,546 mg/kg</td>
<td>4,100 mg/kg (mouse)</td>
</tr>
<tr>
<td>Inhalative LC50/4 h</td>
<td>&gt;0.479 mg/l</td>
<td>&gt;21,900 mg/kg (rat)</td>
<td>10,000 mg/kg (rabbit)</td>
</tr>
</tbody>
</table>

### 8006-90-4 Oils, Peppermint

<table>
<thead>
<tr>
<th>Oral LD50</th>
<th>Oral LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal LD50</td>
<td>2,490 mg/kg (mouse)</td>
</tr>
<tr>
<td>Inhalative LC50/4 h</td>
<td>&gt;0.479 mg/l</td>
</tr>
</tbody>
</table>

- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
51.1.24

Additional toxicological information:
The product shows the following dangers according to internally approved calculation methods for preparations:
- Harmful
- Irritant

Carcinogenic categories

IARC (International Agency for Research on Cancer)
- 9003-01-4 Polyacrylic Acid 3
- 7722-84-1 Hydrogen Peroxide 3

NTP (National Toxicology Program)
None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients is listed.

Germ cell mutagenicity Does not meet the classification criteria for this hazard class.

Carcinogenicity
Hydrogen Peroxide & Polyacrylic Acid are listed on the IARC Group 3 carcinogens. These items are not classifiable as to its carcinogenicity to humans.

Reproductive toxicity Does not meet the classification criteria for this hazard class.

Specific target organ toxicity - single exposure Does not meet the classification criteria for this hazard class.

Specific target organ toxicity - repeated exposure Does not meet the classification criteria for this hazard class.

Aspiration hazard Does not meet the classification criteria for this hazard class.

12 Ecological information

Toxicity

Aquatic toxicity:

56-81-5 Glycerin
- EC50 >10,000 mg/l (Bacteria)
- >10,000 mg/l (daphnia)

9003-01-4 Polyacrylic Acid
- EC50 174 mg/kg (daphnia)

7722-84-1 Hydrogen Peroxide
- EC50 1.38 mg/l (Algae)
- 2.4 mg/l (daphnia)

1310-73-2 Sodium Hydroxide
- EC50 40.38 mg/l (Water Flea)

Persistence and degradability No further relevant information available.

Behavior 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 (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.
**Trade name:** Opalescence™ 35% CP Mint

- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
  - **Recommendation:** Dispose of contents/container in accordance with local/regional/national/international regulations. Do not allow product to reach sewage system.
- **Uncleaned packagings**:
  - **Recommendation:** Disposal must be made according to official regulations.
  - **Recommended cleansing agent:** Water, if necessary with cleansing agents.

### 14 Transport information

- **UN-Number**
  - DOT, IMDG, IATA: not regulated
- **UN proper shipping name**
  - DOT, IMDG, IATA: Not Regulated
- **Transport hazard class(es)**
  - DOT, IMDG, IATA: not regulated
- **Packing group**
  - DOT, IMDG, IATA: not regulated
- **Environmental hazards**: Not applicable.
- **Special precautions for user**: Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 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**
  - **Sara**
  - **Section 355 (extremely hazardous substances):**
    - 7722-84-1 Hydrogen Peroxide
  - **Section 313 (Specific toxic chemical listings):**
    - None of the ingredients is listed.
  - **TSCA (Toxic Substances Control Act):**
    - All components have the value ACTIVE.
  - **Hazardous Air Pollutants**
    - None of the ingredients is listed.
Trade name: Opalescence™ 35% CP Mint

- Proposition 65
  - Chemicals known to cause cancer:
    None of the ingredients is listed.
  - Chemicals known to cause reproductive toxicity for females:
    None of the ingredients is listed.
  - Chemicals known to cause reproductive toxicity for males:
    None of the ingredients is listed.
  - Chemicals known to cause developmental toxicity:
    None of the ingredients is listed.

- Carcinogenic categories
  - EPA (Environmental Protection Agency)
    None of the ingredients is listed.
  - TLV (Threshold Limit Value established by ACGIH)
    7722-84-1 Hydrogen Peroxide A3
  - NIOSH-Ca (National Institute for Occupational Safety and Health)
    None of the ingredients is listed.

- 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: Environmental, Health & Safety
- Contact: Customer Service
- Date of preparation / last revision 11/11/2020 / -
- Abbreviations and acronyms:
  IMDG: International Maritime Code for Dangerous Goods
  DOT: US Department of Transportation
  IATA: International Air Transport Association
  ACGIH: American Conference of Governmental Industrial Hygienists
  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)
  NFPA: National Fire Protection Association (USA)
  HMIS: Hazardous Materials Identification System (USA)
  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
  NIOSH: National Institute for Occupational Safety
  OSHA: Occupational Safety & Health
  TLV: Threshold Limit Value
  PEL: Permissible Exposure Limit
  REL: Recommended Exposure Limit
  Flamm. Liq. 4: Flammable liquids – Category 4
  Ox. Liq. 1: Oxidizing liquids – Category 1
  Ox. Sol. 3: Oxidizing solids – Category 3
  Met. Corr. 1: Corrosive to metals – Category 1
  Acute Tox. 3: Acute toxicity – Category 3
  Acute Tox. 4: Acute toxicity – Category 4
  Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  Skin Corr. 1B: Skin corrosion/irritation – Category 1B
### Trade name: Opalescence™ 35% CP Mint

Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Dam. 1: Serious eye damage/eye irritation – Category 1  
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A  
Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B  
Skin Sens. 1: Skin sensitisation – Category 1  
Asp. Tox. 1: Aspiration hazard – Category 1