1 Identification

- **Product identifier**
  - **Trade name:** Opalescence™ F 15% Melon
  - **Article number:** 39305
  - **Index number:** SDS 16-001.11
  - **Application of the substance / the mixture** Professional Dental Teeth Bleaching 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
  - 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**
    Cosmetics 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
  - Artificial Watermelon
  - Sodium Hydroxide

- **Hazard statements**
  - Causes skin irritation.
  - Causes serious eye irritation.
  - May cause an allergic skin reaction.

- **Precautionary statements**
  - Avoid breathing dust/fume/gas/mist/vapors/spray
  - Wash thoroughly after handling.
  - Contaminated work clothing must not be allowed out of the workplace.
  - Wear protective gloves / eye protection / face protection.
  - If on skin: Wash with plenty of water.
  - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
  - Continue rinsing.
  - Take off contaminated clothing and wash it before reuse.

(Contd. on page 2)
Safety Data Sheet
acc. to OSHA HCS

Trade name: Opalescence™ F 15% Melon

(Contd. of page 1)

If skin irritation or rash occurs: Get medical advice/attention.
Specific treatment (see on this label).
If eye irritation persists: Get medical advice/attention.
Wash contaminated clothing before reuse.
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
  - FIRE
  - REACTIVITY
    - 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.

· Dangerous components:
  - 56-81-5 Glycerine <40%
  - 124-43-6 Carbamide Peroxide <16%
  - 25322-68-3 Polyethylene Glycol <10%
  - 9003-01-4 Polyacrylic Acid <10%
  - 1310-73-2 Sodium Hydroxide ≤2%
  - Artificial Watermelon ≤2%
  - 7681-49-4 Sodium Fluoride 0.25%

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.
  Seek medical treatment in case of complaints.
· 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.

(Contd. on page 3)
Trade name: Opalescence™ F 15% Melon

- Indication of any immediate medical attention and special treatment needed
  No further relevant information available.

5 Fire-fighting 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:
    - Mouth respiratory protective device.
    - Wear fully protective suit.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
  Wear protective equipment.

- 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

  - PAC-1:
    - 56-81-5 Glycerine 45 mg/m³
    - 124-43-6 Carbamide Peroxide 1.2 mg/m³
    - 25322-68-3 Polyethylene Glycol 30 mg/m³
    - 7681-49-4 Sodium Fluoride 17 mg/m³

  - PAC-2:
    - 56-81-5 Glycerine 180 mg/m³
    - 124-43-6 Carbamide Peroxide 13 mg/m³
    - 25322-68-3 Polyethylene Glycol 1,300 mg/m³
    - 7681-49-4 Sodium Fluoride 90 mg/m³

  - PAC-3:
    - 56-81-5 Glycerine 1,100 mg/m³
    - 124-43-6 Carbamide Peroxide 79 mg/m³
    - 25322-68-3 Polyethylene Glycol 7,700 mg/m³
    - 7681-49-4 Sodium Fluoride 1,100 mg/m³

7 Handling and storage

- Handling:
  - Precautions for safe handling
    Ensure good ventilation/exhaustion at the workplace.
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:
    The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
    At this time, the other constituents have no known exposure limits.

| 56-81-5 Glycerine |  
|-----------------|------------------------------------------|
| PEL  | Long-term value: 15* 5** mg/m³  
mist: *total dust **respirable fraction |
| TLV  | TLV withdrawn-insufficient data human occup. exp. |
| TWA  | Short-term value: 15 mg/m³ |

| 25322-68-3 Polyethylene Glycol |  
|-----------------|------------------------------------------|
| WEEL | Long-term value: 10 mg/m³  
(H); MW>200 |

| 9003-01-4 Polyacrylic Acid |  
|-----------------|------------------------------------------|
| TWA  | Short-term value: 0.05 mg/m³ |

| 1310-73-2 Sodium Hydroxide |  
|-----------------|------------------------------------------|
| PEL  | Long-term value: 2 mg/m³  
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 cannot 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:

<table>
<thead>
<tr>
<th>Form</th>
<th>Gel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>Watermelon</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not determined.</td>
</tr>
</tbody>
</table>

· pH-value at 20 °C:

6-7.2

· Change in condition

| Melting point/Melting range: | Undetermined.      |
| Boiling point/Boiling range: | Undetermined       |

· Flash point:

Not applicable

· Flammability (solid, gaseous):

Not applicable.

· Decomposition temperature:

Not determined.

· Auto igniting:

Product is not selfigniting.

· Danger of explosion:

Product does not present an explosion hazard.

· Explosion limits:

| Lower: | Not determined. |
| Upper:  | Not determined. |

· Vapor pressure:

Not determined.
### Trade name: Opalescence™ F 15% Melon

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Density at 20 °C:</strong></td>
<td>1.2-1.3 g/cm³</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Vapor density</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Solubility in / Miscibility with Water:</strong></td>
<td>Partly soluble</td>
</tr>
<tr>
<td><strong>Partition coefficient (n-octanol/water):</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Viscosity:</strong></td>
<td></td>
</tr>
<tr>
<td>Dynamic</td>
<td>Not determined</td>
</tr>
<tr>
<td>Kinematic</td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Solvent content:</strong></td>
<td></td>
</tr>
<tr>
<td>Organic solvents:</td>
<td>&lt;50 %</td>
</tr>
<tr>
<td>Water:</td>
<td>&lt;40 %</td>
</tr>
<tr>
<td>VOC content:</td>
<td>0.00 %</td>
</tr>
<tr>
<td></td>
<td>0.0 g/l / 0.00 lb/gal</td>
</tr>
<tr>
<td>VOC (EC)</td>
<td>0.00 %</td>
</tr>
<tr>
<td><strong>Solids content:</strong></td>
<td>&lt;50.0 %</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

### 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
- **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:

- **ATE (Acute Toxicity Estimate)**
  - Oral LD50: >2,594-3,443 mg/kg
  - Dermal LD50: 67,500 mg/kg (rabbit)
  - Inhalative LC50/4 h: >0.439 mg/l (rat)

- **56-81-5 Glycerine**
  - Oral LD50: 7,750 mg/kg (Guinea pig)
  - 4,100 mg/kg (mouse)
  - 5,570 mg/kg (rat)
  - 27,000 mg/kg (rabbit)
  - LC50 Fish: >5,000 mg/l (Fish)
Trade name: Opalescence™ F 15% Melon

<table>
<thead>
<tr>
<th>Substance</th>
<th>LD50/Dermal LD50</th>
<th>LC50/Inhalative LC50/4h</th>
<th>Oral LD50</th>
<th>LC50 Fish</th>
<th>Dermal LD50</th>
<th>LC50 (Daphnia magna)</th>
<th>Oral LC50 Fish</th>
<th>Absolute lethal concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>124-43-6 Carbamide Peroxide</strong></td>
<td>&gt;21,900 mg/kg (rat)</td>
<td>&gt;0.1425 mg/l (rat)</td>
<td>&gt;2,000 mg/kg (rat)</td>
<td>&gt;10,000 mg/kg (rat)</td>
<td>&gt;10,000 mg/kg (rat)</td>
<td>&gt;10,000 mg/l (Water Flea) (Toxicity to aquatic invertebrates)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>25322-68-3 Polyethylene Glycol</strong></td>
<td>19,600 mg/kg (Guinea pig)</td>
<td>&gt;100 mg/l (Fish)</td>
<td>&gt;20,000 mg/kg (rabbit)</td>
<td>&gt;10,000 mg/l (Daphnia magna)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>9003-01-4 Polyacrylic Acid</strong></td>
<td>130-340 mg/kg (rat)</td>
<td>160 mg/l (Fish)</td>
<td>1,350 mg/kg (rabbit)</td>
<td>180 ppm (Fish)</td>
<td></td>
<td></td>
<td></td>
<td></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.

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

- **Carcinogenic categories**
  - IARC (International Agency for Research on Cancer)
    - 9003-01-4 Polyacrylic Acid 3
    - 7681-49-4 Sodium Fluoride 3
  - NTP (National Toxicology Program)
    - None of the ingredients is listed.
  - OSHA-Ca (Occupational Safety & Health Administration)
    - None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**
  - **Aquatic toxicity:**
    - 56-81-5 Glycerine
      - EC50 >10,000 mg/l (Bacteria)
      - >10,000 mg/l (daphnia)
    - 9003-01-4 Polyacrylic Acid
      - EC50 174 mg/kg (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.
  - Other adverse effects: No further relevant information available.

### 13 Disposal considerations

- Waste treatment methods
  - Recommendation: Do not allow product to reach sewage system.
- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

### 14 Transport information

- UN-Number
  - DOT, IMDG, IATA: not regulated
- UN proper shipping name
  - DOT, IMDG, IATA: not regulated
- Transport hazard class(es)
  - DOT, ADN, IMDG, IATA: not regulated
- Class
  - 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):
    None of the ingredients is listed.
  
  · 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.
  
  · Proposition 65
    None of the ingredients is listed.
  
  · 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
    None of the ingredients is listed.
  
  · EPA (Environmental Protection Agency)
    None of the ingredients is listed.
  
  · TLV (Threshold Limit Value established by ACGIH)
    7681-49-4 Sodium Fluoride A4
  
  · NIOSH-Ca (National Institute for Occupational Safety and Health)
    None of the ingredients is listed.
  
  · GHS label elements
    Cosmetics 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
    Artificial Watermelon
    Sodium Hydroxide
  
  · Hazard statements
    Causes skin irritation.
    Causes serious eye irritation.
    May cause an allergic skin reaction.
  
  · Precautionary statements
    Avoid breathing dust/fume/gas/mist/vapors/spray
    Wash thoroughly after handling.
    Contaminated work clothing must not be allowed out of the workplace.
    Wear protective gloves / eye protection / face protection.
    If on skin: Wash with plenty of water.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Take off contaminated clothing and wash it before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
Specific treatment (see on this label).
If eye irritation persists: Get medical advice/attention.
Wash contaminated clothing before reuse.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Chemical safety assessment:**
  This product meets the toxicologic requirements of cosmetics per the US Food, Drug, and Cosmetic Act.

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### 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
- **Date of preparation / last revision** 11/22/2019 / -
- **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
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
  - Skin Sens. 1: Skin sensitisation – Category 1