Opalescence® F 15% Melon

SECTION 1: Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code: OF/39305
Product name: Opalescence® F 15% Melon
Product description: Dental Teeth Bleaching Gel

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Professional Dental Teeth Bleaching Gel

1.3. Details of the supplier of the safety data sheet

Manufacturer
Ultradent Products, Inc.
505 W. 10200 S.
South Jordan, UT 84095

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

1.4. Emergency telephone number

CHEMTREC (NORTH AMERICA): (800) 424 - 9300
(INTERNATIONAL): +1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

Health: Eye Irritation, Category 2
       Skin Irritation, Category 2
       Acute Toxicity (Inhalation), Category 3

2.2. Label elements

Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictogram(s):

Exclamation mark

Signal Word: DANGER

Hazard statement(s):
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Precautionary statement(s):
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Date Issued : 02/02/2006
SDS No : 16-001.10
Date Revised : 11/03/2016
Revision No : 9

Opalescence® F 15% Melon

Response
P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P315: Get immediate medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P332+P313: If skin irritation occurs: Get medical advice/attention.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Storage
P273: Avoid release to the environment.

Disposal

2.3. Other hazards
Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients
3.1. Substances
Not Applicable
3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamide Peroxide</td>
<td>000124-43-6</td>
<td>204-701-4</td>
<td>≤ 20</td>
<td>Skin Irr., Cat. 2; EYE DMG., Cat. 1; STOT SE, Cat. 3; Oxid. Liq., Cat 3; H272; H315; H318; H335</td>
</tr>
<tr>
<td>Sodium Fluoride</td>
<td>007681-49-4</td>
<td>231-667-8</td>
<td>0.25</td>
<td>Skin Irr., Cat. 2; Eye Irr., Cat. 2A; Acute Tox. (O), Cat 3; H301; H315; H319</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>&lt; 5</td>
<td>Skin Corr., Cat. 1B; Eye Irr., Cat. 1; Cor. Metal, Cat. 1; H314; H290</td>
</tr>
<tr>
<td>Poly Acrylic acid</td>
<td>9003-01-4</td>
<td>N/A</td>
<td>&lt; 10</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures
4.1. Description of first aid measures
Following eyes: Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.
Following skin: Wash with soap and water. Get medical attention if irritation develops or persists.
Following ingestion: If swallowed in small quantity the product is harmless, otherwise consult a doctor.
Following inhalation: No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

4.2. Most important symptoms and effects, both acute and delayed
Opalescence® F 15% Melon

Eyes : Irritating to eyes.
Skin : May cause skin irritation.
Ingestion : May be harmful if swallowed in large quantities.
Inhalation : May be harmful if inhaled.

4.3. Indication of any immediate medical attention and special treatment needed
Notes to physician : Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media
Extinguishing media : Water Spray Only

5.2. Special hazards arising from the substance or mixture
Hazardous combustion products : None

5.3. Advice for firefighters
Fire fighting procedures : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
General procedures : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions
Water spill : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up
Small spill : Wipe up with cloth, soap and water.
Large spill : Absorb with inert, damp non-combustible material, then flush area with water.

6.4. Reference to other sections
Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling
General procedures : Avoid contact with eyes, skin and clothing.
Handling : Use suitable protective equipment.
Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities
Shelf life : See product labeling

7.3. Specific end use(s)
Specific end use(s) : Professional Dental Teeth Bleaching Gel

SECTION 8: Exposure controls / personal protection

8.1. Control parameters
### Opalescence® F 15% Melon

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>TWA 2.5 mg/m(^3) F TWA 2.5 mg/m(^3) dust (vacated) TWA 2.5 mg/m(^3)</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>TWA 2.5 mg/m(^3) F</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>TWA 2.5 mg/m(^3)</td>
</tr>
<tr>
<td>NIOSH IDLH</td>
<td>250 mg/m(^3) F TWA: 2.5 mg/m(^3) F</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sodium Hydroxide CAS: 1310-73-2</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Exposure Limit</th>
<th>Limit Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA Permissible Exposure Limit(PEL)- General Industry</td>
<td>2mg/m(^3) TWA</td>
</tr>
<tr>
<td>OSHA PEL - Construction Industry</td>
<td>2mg/m(^3) TWA</td>
</tr>
<tr>
<td>OSHA PEL - Shipyard Employment</td>
<td>2mg/m(^3) TWA</td>
</tr>
<tr>
<td>National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit(REL)</td>
<td>2mg/m(^3) Ceiling</td>
</tr>
<tr>
<td>CAL/OSHA PEL</td>
<td>2mg/m(^3) Ceiling</td>
</tr>
<tr>
<td>American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) (2001)</td>
<td>2mg/m(^3) Ceiling</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>International Regulations</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>Exposure Limits</th>
<th>Limit Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Peak limitation(199)</td>
<td>2mg/m(^3)</td>
</tr>
<tr>
<td>Federal Republic of Germany</td>
<td>Short term level</td>
<td>2mg/m(^3), 4mg/m(^3), 5 minutes. 8 times per shift(1990)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>10 min Short term exposure limit (STEL)</td>
<td>2mg/m(^3) (1991)</td>
</tr>
</tbody>
</table>

8.2. Exposure controls

- **Eye/face protection**: Wear eye protection
- **Skin protection**: Wear suitable protective clothing and gloves.
## 9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Clear viscous gel which may contain bubbles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Colorless</td>
</tr>
<tr>
<td>Odour</td>
<td>Watermelon</td>
</tr>
<tr>
<td>pH</td>
<td>6.0 to 7.2</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>1.2 - 1.3</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>Partially Soluble</td>
</tr>
</tbody>
</table>

### 9.2. Other information

- Percent volatile: Not Volatile

## 10. Stability and reactivity

### 10.1. Reactivity

- Reactivity: Stable

### 10.2. Chemical stability

- Chemical stability: Stable when stored and handled under recommended conditions.

### 10.3. Possibility of hazardous reactions

- Hazardous polymerization: None

### 10.4. Conditions to avoid

- Conditions to avoid: Avoid strong bases, metals, excess heat, exposure to moist air or water.

### 10.5. Incompatible materials

- Incompatible materials: Strong caustics, most metals.

### 10.6. Hazardous decomposition products

- Hazardous decomposition products: None known.

## 11. Toxicological information

### 11.1. Information on toxicological effects

#### Acute

- **Dermal LD$_{50}$**: > 5000 mg/kg Rabbit/Rat
- **Notes**: ~ 20% of the mixture consists of components of unknown toxicity (Dermal).
- **Oral LD$_{50}$**: > 2000 mg/kg Mouse/Rat/Rabbit
- **Notes**: There are no components of unknown toxicity (Oral).
- **Inhalation LC$_{50}$**: > 0.5 mg/L/4H Dust/Mist Rat
- **Notes**: ~ 22% of the mixture consists of components of unknown toxicity (Inhalation).
- **Other information**: This product meets the toxicologic profile required for cosmetics per the EU cosmetic regulation, Regulation (EC) No. 1223/3009.
### Section 12: Ecological Information

12.1. Toxicity

Aquatic toxicity (acute): Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability

Persistence and degradability: Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential: Not classified

12.4. Mobility in soil

Mobility in soil: Not Available

12.5. Results of PBT and vPvB Assessment

Results of PBT and vPvB Assessment: Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data: Do not flush to sewer.

### Section 13: Disposal Considerations

13.1. Waste treatment methods


### Section 14: Transport Information

14.1. UN number

UN number: NAP

14.2. UN proper shipping name

UN proper shipping name: Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification: NAP

14.4. Packing group

Packing group: NAP

14.5. Environmental hazards

Marine pollutant #1: NAP

14.6. Special precautions for user

ADR - road: NAP
RID - rail: NAP
IMDG - sea: NAP
IATA - air: NAP

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Opalescence® F 15% Melon

Transport in bulk : NAP

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

General comments : Please refer to Regulation 1223/2009 on Cosmetics

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65. This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant H-statements (number and full text) : Acute Tox. (O), Cat 3: Acute Toxicity (Oral), Category 3
Cor. Metal, Cat. 1: Corrosive to Metals, Category 1
EYE DMG., Cat. 1: Eye Damage, Category 1
Eye Irr., Cat. 1: Eye Irritation, Category 1
Eye Irr., Cat. 2A: Eye Irritation, Category 2A
Oxid. Liq., Cat 3: Oxidizing Liquids, Category 3
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
Skin Irr., Cat. 2: Skin Irritation, Category 2
H272: May intensify fire; oxidizer.
H290: May be corrosive to metals.
H301: Toxic if swallowed.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 11/25/2015 SDS. Revised: Section 1: GENERAL USE, MSDS No, PRODUCT CODE/ PART #. Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. Section 4: SIGNS AND SYMPTOMS OF OVEREXPOSURE - INHALATION. Section 5: EXTINGUISHING MEDIA, FIRE FIGHTING EQUIPMENT. Section 7: Section 8: PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY. Section 9: ODOR, PHYSICAL STATE, SPECIFIC GRAVITY. Section 11: ACUTE ( DERMAL LD50 (rabbit), DERMAL LD50 (rabbit), DERMAL LD50 (rabbit), ORAL LD50 (rat), INHALATION LC50 (rat), ORAL LD50 (rat), INHALATION LC50 (rat), INHALATION LC50 (rat), ORAL LD50 (rat) ), GENERAL COMMENTS. Section 12: CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC50, 96-HOUR EC50 ), SECTION 12: Ecological information. Section
Opalescence® F 15% Melon

14: ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE
POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS
SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. Section 15: COMMENTS, GENERAL COMMENTS, RoHS, SECTION 15: Regulatory information. Section 16: GENERAL STATEMENTS.

General statements
NAP = Not Applicable
NE = Not Established
TLV = Threshold Limit Value
PEL = Permissible exposure limits
MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average
PPE = Personal Protective Equipment
AMU = Atomic Mass Unit

Manufacturer disclaimer
FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.