Opalescence® PF Regular, Mint or Melon 35% Bleaching Gel

1.1. Product identifier
- **Product code**: FA/15059, FB/15060, FC/15061
- **Product name**: Opalescence® PF Regular, Mint or Melon 35% Bleaching Gel
- **Product description**: Dental Bleaching Gel

1.2. Relevant identified uses of the substance or mixture and uses advised against
- **Relevant identified uses**: Professional Dental Teeth Whitening Gel

1.3. Details of the supplier of the safety data sheet
- **Manufacturer**: Ultradent Products, Inc.
  505 W. 10200 S.
  South Jordan, UT 84095

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 Directive 1999/45/EC**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

- **Danger symbols**: Xi
- **R phrases**: R36/38

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

- **Health**: Eye Irritation, Category 2
  Skin Irritation, Category 2

2.2. Label elements

**Classification according to Directive 1999/45/EC**

- **Hazard pictogram(s)**: Xi
  - [Irritant]

- **R&S statement(s)**: R36/38: Irritating to eyes and skin.
SAFETY DATA SHEET
described in Regulation (EC) No. 453/2010

Opalescence® PF Regular, Mint or Melon 35% Bleaching Gel

Hazard pictogram(s):

Exclamation mark

Signal Word: DANGER

Hazard statement(s):
H319: Causes serious eye irritation.
H315: Causes skin irritation.

Precautionary statement(s)

Prevention:
P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response:
P305: IF IN EYES:
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P332+P313: If skin irritation occurs: Get medical advice/attention.
P315: Get immediate medical advice/attention.

Storage:
P273: Avoid release to the environment.

Disposal:

2.3. Other hazards

Immediate concerns: None

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 Directive 67/548/EEC</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>Xi; R36</td>
<td>Skin Corr.,Cat. 1B; Oxid. Sol.,Cat. 3; H272; H314</td>
</tr>
<tr>
<td>Hydrogen Peroxide</td>
<td>007722-84-1</td>
<td>231-765-0</td>
<td>&lt; 10</td>
<td>Xi; R36</td>
<td>EYE DMG., Cat. 1; H319</td>
</tr>
<tr>
<td>Sodium Fluoride</td>
<td>007681-49-4</td>
<td>231-667-8</td>
<td>0.25</td>
<td>T, Xi; R25; R32; R36/38</td>
<td>Eye Irr., Cat. 2; Skin Irr., Cat. 2; Acute Tox. (O), Cat 3; EUH032; H301;</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**
according to Regulation (EC) No. 453/2010

**Opalescence® PF Regular, Mint or Melon 35% Bleaching Gel**

| Sodium Hydroxide | 1310-73-2 | 215-185-5 | < 5 | C; R34 | Skin Corr., Cat. 1B; H314 |

For full text of H-statements and R-phrases: 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

**Eyes**
- Irritating to eyes.

**Skin**
- May cause skin irritation.

**Ingestion**
- May be harmful if swallowed in large quantities.

**Inhalation**
- None expected for this product.

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**
- Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

**Hazardous combustion products**
- None known.

**Explosion hazards**
- None

**Fire explosion**
- None

**Sensitive to static discharge**
- None

**Sensitivity to impact**
- None

5.3. Advice for firefighters

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

**Fire fighting equipment**
- Water spray only.
**Opalescence® PF Regular, Mint or Melon 35% Bleaching Gel**

**SECTION 6: Accidental release measures**

<table>
<thead>
<tr>
<th>6.1. Personal precautions, protective equipment and emergency procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General procedures</strong></td>
</tr>
<tr>
<td>Refer to Section 8 for Personal Protective Equipment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6.2. Environmental precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Water spill</strong></td>
</tr>
<tr>
<td>Do not allow to enter sewers or drains that may lead to waterways.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6.3. Methods and material for containment and cleaning up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Small spill</strong></td>
</tr>
<tr>
<td>Wipe up with cloth, soap and water.</td>
</tr>
<tr>
<td><strong>Large spill</strong></td>
</tr>
<tr>
<td>Absorb with inert, damp non-combustible material, then flush area with water.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6.4. Reference to other sections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference to other sections</td>
</tr>
<tr>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

**SECTION 7: Handling and storage**

<table>
<thead>
<tr>
<th>7.1. Precautions for safe handling</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General procedures</strong></td>
</tr>
<tr>
<td>Avoid contact with eyes, skin and clothing.</td>
</tr>
<tr>
<td><strong>Handling</strong></td>
</tr>
<tr>
<td>Use suitable protective equipment.</td>
</tr>
<tr>
<td><strong>Storage</strong></td>
</tr>
<tr>
<td>See product labeling.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.2. Conditions for safe storage, including any incompatibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shelf life</strong></td>
</tr>
<tr>
<td>See product labeling</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.3. Specific end use(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specific end use(s)</strong></td>
</tr>
<tr>
<td>Professional Dental Teeth Whitening Gel</td>
</tr>
</tbody>
</table>

**SECTION 8: Exposure controls / personal protection**

<table>
<thead>
<tr>
<th>8.1. Control parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control parameters</td>
</tr>
<tr>
<td>Not Determined</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8.2. Exposure controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eye/face protection</strong></td>
</tr>
<tr>
<td>Wear eye protection</td>
</tr>
<tr>
<td><strong>Skin protection</strong></td>
</tr>
<tr>
<td>Wear suitable protective clothing and gloves.</td>
</tr>
<tr>
<td><strong>Respiratory protection</strong></td>
</tr>
<tr>
<td>Good general ventilation should be sufficient to control airborne levels.</td>
</tr>
</tbody>
</table>

**SECTION 9: Physical and chemical properties**

<table>
<thead>
<tr>
<th>9.1. Information on basic physical and chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical state</strong></td>
</tr>
<tr>
<td>Gel</td>
</tr>
<tr>
<td><strong>Colour</strong></td>
</tr>
<tr>
<td>Colorless</td>
</tr>
<tr>
<td><strong>Odour</strong></td>
</tr>
<tr>
<td>Flavor dependent</td>
</tr>
<tr>
<td><strong>pH</strong></td>
</tr>
<tr>
<td>5.6 to 7.2</td>
</tr>
<tr>
<td><strong>Solubility in water</strong></td>
</tr>
<tr>
<td>Partially Soluble</td>
</tr>
</tbody>
</table>
Opalescence® PF Regular, Mint or Melon 35% Bleaching Gel

9.2. Other information
Percent volatile : Not Volatile

SECTION 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.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Acute
Notes : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity
Toxicity : Not Determined

Aquatic toxicity (acute)
96-hour LC_{50} : Not Determined
48-hour EC_{50} : Not Determined
96-hour EC_{50} : Not Determined

12.2. Persistence and degradability
Persistence and degradability : Not Determined

12.3. Bioaccumulative potential
Bioaccumulative potential : Not Determined

12.4. Mobility in soil
Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment
Opalescence® PF Regular, Mint or Melon 35% Bleaching Gel

Results of PBT and vPvB assessment

12.6. Other adverse effects

Environmental data

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal method


SECTION 14: Transport information

14.1. UN number

UN number

: N/A

14.2. UN proper shipping name

UN proper shipping name

: Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification

: N/A

14.4. Packing group

Packing group

: N/A

14.5. Environmental hazards

Marine pollutant #1

: N/A

14.6. Special precautions for user

ADR - road

: Not Dangerous Goods

RID - rail

: Not Dangerous Goods

IMDG - sea

: Not Dangerous Goods

IATA - air

: Not Dangerous Goods

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk

: Not Dangerous Goods

SECTION 15: Regulatory information

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

RoHS


15.2. Chemical safety assessment

Chemical safety assessment

: See Section 11

Additional information

: This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full

R25: Toxic if swallowed.

R32: Contact with acids liberates very toxic gas.
Opalescence® PF Regular, Mint or Melon 35% Bleaching Gel

R34: Causes burns.
R36/38: Irritating to eyes and skin.
R36: Irritating to eyes.
Acute Tox. (O), CAT 3: Acute Toxicity (Oral), Category 3
EYE DMG., Cat. 1: Eye Damage, Category 1
Eye Irr., Cat. 2: Eye Irritation, Category 2
Oxid. Sol., Cat. 3: Oxidizing Solids, Category 3
Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
Skin Irr., Cat. 2: Skin Irritation, Category 2
EUH032: Contact with acids liberates very toxic gas.
H272: May intensify fire; oxidizer.
H301: Toxic if swallowed.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H319: Causes serious eye irritation.

Prepared by: Anu Kattoju

Revision summary: This SDS replaces the 09/09/2014 SDS. Revised:

Section 1: General statements
N/A= Not Applicable

Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS.

Section 5: EXPLOSION HAZARDS, FIRE EXPLOSION, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT.

Section 8: PERSONAL PROTECTIVE EQUIPMENT - SKIN.

Section 9: PERCENT VOLATILE.

Section 10: HAZARDOUS POLYMERIZATION, STABLE.

Section 11: ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE.

Section 14: VESSEL (IMO/IMDG) - MARINE POLLUTANT #1.

Section 15: COMMENTS, RoHS, SECTION 15: Regulatory information.

Section 16: GENERAL STATEMENTS.

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.