Opalescence® PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

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

1.1. Product identifier


Product name: Opalescence® PF, 10-20% Bleaching Gel (Regular, Mint or 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 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
- Acute Toxicity (Oral), Category 4
- Acute Toxicity (Inhalation), Category 3

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s): Xi

R& statement(s): R36/38: Irritating to eyes and skin.
Opalescence® PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

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.
H302: Harmful if swallowed.
H335: May cause respiratory irritation.

Precautionary statement(s)

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

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.
P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P304+P312: IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

Opalescence® PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</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 Irr., Cat. 2; EYE DMG., Cat. 1; STOT SE, Cat. 3; Oxd. Liq., Cat. 3; H272; H372; H315; H318; H335</td>
</tr>
<tr>
<td>Poly Acrylic acid</td>
<td>9003-01-4</td>
<td>N/A</td>
<td>&lt; 10</td>
<td>Xi; R36/37/38</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium Hydioxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>&lt; 5</td>
<td>C; R34</td>
<td>Skin Corr., Cat. 1B; Eye Irr., Cat. 1; Cor. Metal, Cat. 1; H314; H290</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>Skin Irr., Cat. 2; Eye Irr., Cat. 2A; Acute Tox. (O), Cat. 3; H301; H315; H319</td>
</tr>
</tbody>
</table>

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

SECTION 4: First aid measures

4.1. Description of first aid measures

After eye contact: Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.

After skin contact: Wash with soap and water. Get medical attention if irritation develops or persists.

After ingestion: If swallowed in small quantity the product is harmless, otherwise consult a doctor.

After 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

General notes: Irritating to eyes.

: May cause skin irritation.

: Maybe harmful if swallowed in large quantities.

: Maybe 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 known.

5.3. Advice for firefighters

Fire fighting procedures: General: Evacuate all personnel; use protective equipment for fire-fighting. Use
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
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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

Control parameters: Sodium Fluoride CAS: 7681-49-4

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>TWA 2.5 mg/m³ F TWA 2.5 mg/m³ dust (vacated) TWA 2.5 mg/m³</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>TWA 2.5 mg/m³ F</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>TWA 2.5 mg/m³</td>
</tr>
<tr>
<td>NIOSH IDLH</td>
<td>250 mg/m³ F TWA: 2.5 mg/m³ F</td>
</tr>
</tbody>
</table>

8.2. Exposure controls

Eye/face protection: Wear eye protection
Skin protection: Wear suitable protective clothing and gloves.
Respiratory protection: Good general ventilation should be sufficient to control airborne levels. In case
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
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Opalescence® PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Gel</td>
</tr>
<tr>
<td>Appearance</td>
<td>Clear viscous gel which may contain bubbles</td>
</tr>
<tr>
<td>Colour</td>
<td>Colorless</td>
</tr>
<tr>
<td>Odour</td>
<td>Flavor dependent</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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent volatile</td>
<td>Not Volatile</td>
</tr>
</tbody>
</table>

SECTION 10: Stability and reactivity

10.1. Reactivity

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Stable</td>
</tr>
</tbody>
</table>

10.2. Chemical stability

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability</td>
<td>Stable when stored and handled under recommended conditions.</td>
</tr>
</tbody>
</table>

10.3. Possibility of hazardous reactions

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous polymerization</td>
<td>None</td>
</tr>
</tbody>
</table>

10.4. Conditions to avoid

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conditions to avoid</td>
<td>Avoid strong bases, metals, excess heat, exposure to moist air or water.</td>
</tr>
</tbody>
</table>

10.5. Incompatible materials

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incompatible materials</td>
<td>Strong caustics, most metals.</td>
</tr>
</tbody>
</table>

10.6. Hazardous decomposition products

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous decomposition products</td>
<td>None known.</td>
</tr>
</tbody>
</table>

SECTION 11: Toxicological information

11.1. Information on toxicological effects

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td></td>
</tr>
<tr>
<td>Dermal LD$_{50}$</td>
<td>&gt; 3800 mg/kg Rabbit/Rat</td>
</tr>
<tr>
<td>Notes</td>
<td>~22% of the mixture consists of components of unknown toxicity (Dermal).</td>
</tr>
<tr>
<td>Oral LD$_{50}$</td>
<td>&gt; 1200 mg/kg Mouse/Rat/Rabbit</td>
</tr>
<tr>
<td>Inhalation LC$_{50}$</td>
<td>&gt; 0.5 mg/L/4H Dust/Mist Rat</td>
</tr>
<tr>
<td>Notes</td>
<td>~26% of the mixture consists of components of unknown toxicity (Inhalation).</td>
</tr>
<tr>
<td>Other information</td>
<td>The 10-16% CP products meet the toxicological profile required for cosmetics per the EU Cosmetic Regulation, Regulation (EC) No. 1223/2009.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
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### 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

**Disposal method**


### 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

**Transport in bulk**

- NAP
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according to Regulation (EC) No. 453/2010
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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 R-phrases and/or H-statements (number and full text)

: R25: Toxic if swallowed.
R32: Contact with acids liberates very toxic gas.
R34: Causes burns.
R36/37/38: Irritating to eyes, respiratory system and skin.
R36/38: Irritating to eyes and skin.
R36: Irritating to eyes.
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 03/18/2015 SDS. Revised: Section 1: GENERAL USE, MSDS No. Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. Section 3: Wt.% Section 4: SIGNS AND SYMPTOMS OF OVEREXPOSURE - INHALATION Section 5: EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. Section 7: Section 8: PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY Section 9: APPEARANCE, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. Section 11: ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit),
Opalescence® PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, COMMENTS, 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 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 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

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.