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

Opalescence® 10% Bleaching Gel (All Flavors)

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

1.1. Product identifier
Product code : OE/10320, OM/11592
Product name : Opalescence® 10% Bleaching Gel (All Flavors)
Product description : Dental Teeth Whitening 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
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

Classification according to Regulation(EC) No 1272/2008 [CLP]
Health
: Eye Irritation, Category 2
Skin Irritation, Category 2
Acute Toxicity (Inhalation), Category 4

2.2. Label elements
Classification according to Directive 1999/45/EC
Hazard pictogram(s) : Xi

R& statement(s) : R36: Irritating to eyes.

Classification according to Regulation(EC) No 1272/2008 [CLP]
Opalescence® 10% Bleaching Gel (All Flavors)

Hazard pictogram(s) : Exclamation mark

Signal Word : DANGER

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

Precautionary statement(s)
Response : P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P315: Get immediate medical advice/attention.
P306+P360: IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.
P363: Wash contaminated clothing before reuse.
P304+P341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

Storage : P273: Avoid release to the environment.

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 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>124-43-6</td>
<td>204-701-4</td>
<td>10</td>
<td>Xi; R41</td>
<td>Skin Corr.,Cat. 1B; Oxid. Sol.,CAT 3; H272; H314</td>
</tr>
<tr>
<td>Sodium Hydroxide</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>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>
</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: Immediately flush skin with plenty of water. Remove clothing. Get medical attention immediately. Wash clothing separately before reuse.

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.

: Irritating to skin.

: May be harmful if swallowed in large quantities.

: 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 known.

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
Opalescence® 10% Bleaching Gel (All Flavors)

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 Whitening Gel

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters: Sodium Hydroxide CAS: 1310-73-2

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL General Industry</td>
<td>2 mg/m³ TWA</td>
</tr>
<tr>
<td>OSHA PEL - Construction Industry</td>
<td>2 mg/m³ TWA</td>
</tr>
<tr>
<td>OSHA PEL - Shipyard Employment</td>
<td>2 mg/m³ TWA</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>2 mg/m³ Ceiling</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>2 mg/m³ Ceiling</td>
</tr>
<tr>
<td>CAL/OSH A PEL</td>
<td>2 mg/m³ Ceiling</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 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>Physical state</th>
<th>Clear gel with bubbles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Colorless</td>
</tr>
<tr>
<td>Odour</td>
<td>Mint or odorless</td>
</tr>
<tr>
<td>pH</td>
<td>6.1 - 6.7</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>
<tr>
<td>Viscosity</td>
<td>≤ 3,762,000 cp</td>
</tr>
</tbody>
</table>

9.2. Other information

Percent volatile: Not Volatile

SECTION 10: Stability and reactivity
## Opalescence® 10% Bleaching Gel (All Flavors)

### 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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>&gt; 7800 mg/kg Rabbit</td>
</tr>
<tr>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>&gt; 2500 mg/kg Rat/Mouse</td>
</tr>
<tr>
<td>Inhalation LC&lt;sub&gt;50&lt;/sub&gt;</td>
<td>&gt; 1.0 mg/L/4H Dust/Mist Rat</td>
</tr>
</tbody>
</table>

**Notes:**
- ~7% of the mixture consists of components of unknown toxicity (Dermal).
- There are no components of unknown toxicity (Oral).
- ~10% 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
Opalescence® 10% Bleaching Gel (All Flavors)

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

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 R-phrases and/or H-statements (number and full text) : R34: Causes burns.
R36/37/38: Irritating to eyes, respiratory system and skin.
R41: Risk of serious damage to eyes.
Cor. Metal, Cat. 1: Corrosive to Metals, Category 1
Opalescence® 10% Bleaching Gel (All Flavors)

Eye Irr., Cat. 1: Eye Irritation, Category 1
Oxid. Sol., CAT 3: Oxidizing Solids, Central Nervous System Category 3
Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
H272: May intensify fire; oxidizer.
H290: May be corrosive to metals.
H314: Causes severe skin burns and eye damage.

Prepared by: Anu Kattoju
Revision summary: This SDS replaces the 10/29/2015 SDS. Revised: Section 1: SDS 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 8: PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY. Section 9: ODOR, pH, PHYSICAL STATE, SPECIFIC GRAVITY, VISCOSITY. Section 11: ACUTE (DERMAL LD$_{50}$ (rabbit), DERMAL LD$_{50}$ (rabbit), DERMAL LD$_{50}$ (rabbit), ORAL LD$_{50}$ (rat), INHALATION LC$_{50}$ (rat), ORAL LD$_{50}$ (rat), ORAL LD$_{50}$ (rat), INHALATION LC$_{50}$ (rat), INHALATION LC$_{50}$ (rat), INHALATION LC$_{50}$ (rat), ORAL LD$_{50}$ (rat)) ACUTE, GENERAL COMMENTS. Section 12: CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC$_{50}$, 96-HOUR EC$_{50}$), 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.