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

Opalescence® Endo  

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

1.1. Product identifier  

- Product code: OY/35263  
- Product name: Opalescence® Endo  
- Product description: Dental Walking Bleach  

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

Relevant identified uses: Professional Dental 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  
- Distributor: 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: Xn  
- R phrases: R41,R22  

Classification according to Regulation (EC) No 1272/2008 [CLP]  
- Health: Skin Corrosion, Category 1A  
  Acute Toxicity (Dermal), Category 4  
  Acute Toxicity (Oral), Category 4  
- Environmental: Oxidizing Liquids, Category 1  

2.2. Label elements  

Classification according to Directive 1999/45/EC  
- Hazard pictogram(s): Xn  
  Harmful  
- R&S statement(s): R41: Risk of serious damage to eyes.
Opalescence® Endo

R22: Harmful if swallowed.

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

Hazard pictogram(s) : Exclamation mark

Signal Word : WARNING

Hazard statement(s) : H318: Causes serious eye damage.
H302: Harmful if swallowed.

Precautionary statement(s)


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.

Storage : P273: Avoid release to the environment.


2.3. Other hazards

Immediate concerns : Harmful if swallowed. Risk of serious damage to eyes.

SECTION 3: Composition / information on ingredients

3.1. Substances
Not Applicable

3.2. Mixtures
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according to Regulation (EC) No. 453/2010
Dental Use

Date Issued: 12/12/2006
SDS No: 74-001.7
Date Revised: 04/15/2015
Revision No: 7

Opalescence® Endo

<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>Hydrogen Peroxide</td>
<td>7722-84-1</td>
<td>231-765-0</td>
<td>&lt; 40</td>
<td>Xn; R41; R22</td>
<td>Oxid. Liq., Cat. 1; Acute Tox. (D), Cat. 4; Acute Tox. (O), Cat. 4; Skin Corr., Cat. 1A; H271; H302; H314; H332</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

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: Causes eye burns.

Skin: Causes 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: Can cause serious damage to eyes.

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
**SAFETY DATA SHEET**
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**Opalescence® Endo**

<table>
<thead>
<tr>
<th>Explosion hazards</th>
<th>: Not Determined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fire explosion</td>
<td>: Not Determined</td>
</tr>
<tr>
<td>Sensitive to static discharge</td>
<td>: Not Determined</td>
</tr>
<tr>
<td>Sensitivity to impact</td>
<td>: Not Determined</td>
</tr>
</tbody>
</table>

**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.

**Fire fighting equipment**

: Water spray only.

**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**

**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 Bleaching Gel

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

**8.1. Control parameters**

**Control parameters**

: Not Determined

**8.2. Exposure controls**

**Eye/face protection**

: Wear eye protection

**Skin protection**

: Wear suitable protective clothing and gloves.
Opalescence® Endo

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Gel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Clear to milky</td>
</tr>
<tr>
<td>Odour</td>
<td>Odorless or no characteristic odor</td>
</tr>
<tr>
<td>pH</td>
<td>3.0 to 5.0</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>Partially Soluble</td>
</tr>
</tbody>
</table>

9.2. Other information

| Percent volatile | Not Determined |

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 | Product contains high levels of hydrogen peroxide, which has a known toxicological profile. Product is only to be used by licensed dental professionals using the specified engineering controls. |

SECTION 12: Ecological information

12.1. Toxicity

| Toxicity | Not Determined |
### Opalescence® Endo

**Aquatic toxicity (acute)**

<table>
<thead>
<tr>
<th>Time</th>
<th>LC$<em>{50}$/EC$</em>{50}$</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>96-hour</td>
<td>LC$_{50}$</td>
<td>Not Determined</td>
</tr>
<tr>
<td>48-hour</td>
<td>EC$_{50}$</td>
<td>Not Determined</td>
</tr>
<tr>
<td>96-hour</td>
<td>EC$_{50}$</td>
<td>Not Determined</td>
</tr>
</tbody>
</table>

**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**

Results of PBT and vPvB assessment: Not Determined

**12.6. Other adverse effects**

Environmental data: Not Available

### SECTION 13: Disposal considerations

**13.1. Waste treatment methods**


### SECTION 14: Transport information

**14.1. UN number**

UN number: 3139

**14.2. UN proper shipping name**

UN proper shipping name: Oxidizing Liquid, N.O.S. (Hydrogen Peroxide Mixture)

**14.3. Transport hazard class(es)**

<table>
<thead>
<tr>
<th>Hazard class/division</th>
<th>Hazard classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>5.1</td>
</tr>
</tbody>
</table>

**14.4. Packing group**

Packing group: II

**14.5. Environmental hazards**

Marine pollutant #1: N/A

**14.6. Special precautions for user**

- ADR - road: N/A
- RID - rail: N/A
- IMDG - sea: N/A
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IATA - air : N/A

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

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment
Chemical safety assessment : See Section 11

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text)
: R22: Harmful if swallowed.
    R41: Risk of serious damage to eyes.
    Acute Tox. (D), Cat. 4: Acute Toxicity (Dermal), Category 4
    Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
    Oxid. Liq., Cat. 1: Oxidizing Liquids, Category 1
    Skin Corr., Cat. 1A: Skin Corrosion, Category 1A
    H271: May cause fire or explosion; strong oxidizer.
    H302: Harmful if swallowed.
    H314: Causes severe skin burns and eye damage.
    H332: Harmful if inhaled.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 11/06/2014 SDS. Revised: Section 1:
    Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. Section 8: PERSONAL PROTECTIVE EQUIPMENT - SKIN. Section 10: HAZARDOUS POLYMERIZATION, STABLE. Section 11: ACUTE ( ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. Section 15: SECTION 15: Regulatory information. Section 16: GENERAL STATEMENTS.

General statements : N/A= Not Applicable

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.