Opalescence® Whitening Toothpaste

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

1.1. Product identifier

Product code : TF/11577
Product name : Opalescence® Whitening Toothpaste
Product description : Whitening Toothpaste

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

Relevant identified uses : Toothpaste

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. This material is not considered hazardous to health.

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

Health : Not Classified

2.2. Label elements

Classification according to Directive 1999/45/EC: This material is not considered to be hazardous for the health. Please note that this material is not considered hazardous for the health according to the Classification according to Regulation(EC) No 1272/2008[CLP]

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

Precautionary statement(s)


Response : P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P337+P313: If eye irritation persists: Get medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.

Storage : P273: Avoid release to the environment.
Opalescence® Whitening Toothpaste

**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>Methyl Salicylate</td>
<td>119-36-8</td>
<td>204-317-7</td>
<td>&lt; 3</td>
<td>Xi; R22; R36/37/38</td>
<td>Acute Tox. (O), Cat. 4; H302</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; H315; H319</td>
</tr>
<tr>
<td>Poloxamer</td>
<td>9003-11-6</td>
<td>N/A</td>
<td>&lt; 5</td>
<td>Xi; R36/37/38/38</td>
<td>Aquatic Tox., Chronic 3; H412</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. Get medical attention, if irritation persists.
- **Following skin**: Wash with soap and water.
- **Following ingestion**: Swallowing less than an ounce will not cause significant harm. For larger amounts, do not induce vomiting, but give one or two glasses of water to drink and get medical attention.
- **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® Whitening Toothpaste

Eyes
: Mildly irritating to eyes.

Skin
: None expected for this product.

Ingestion
: None expected for this product.

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

Explosion hazards
: Not Determined

Fire explosion
: Not Determined

Sensitive to static discharge
: Not Determined

Sensitivity to impact
: Not Determined

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, fog, or mist, foam, dry chemical, carbon dioxide(CO₂)

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
: Not Available

6.3. Methods and material for containment and cleaning up

Small spill
: Pick up wash liquid with additional absorbent and place in a disposable container.

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
: Store at local atmospheric pressure.

Storage
: See product labeling.
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Opalescence® Whitening Toothpaste

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

<table>
<thead>
<tr>
<th>7.3. Specific end use(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific end use(s) : Toothpaste</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 : Not Determined</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8.2. Exposure controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye/face protection : Wear eye protection.</td>
</tr>
<tr>
<td>Skin protection : None Required</td>
</tr>
<tr>
<td>Respiratory protection : 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>Physical state : Gel</td>
</tr>
<tr>
<td>Colour : Blue green</td>
</tr>
<tr>
<td>Odour : Mint</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9.2. Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent volatile : Not Volatile</td>
</tr>
</tbody>
</table>

SECTION 10: Stability and reactivity

<table>
<thead>
<tr>
<th>10.1. Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity : Stable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.2. Chemical stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability : Stable when stored and handled under recommended conditions.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.3. Possibility of hazardous reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous polymerization : None</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.4. Conditions to avoid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conditions to avoid : Heat, flames, and ignition sources</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.5. Incompatible materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incompatible materials : None known.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.6. Hazardous decomposition products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous decomposition products : None known.</td>
</tr>
</tbody>
</table>

SECTION 11: Toxicological information
## Opalescence® Whitening Toothpaste

### 11.1. Information on toxicological effects

**Acute**

| Notes | This product meets the toxicologic profile required for cosmetics per the EU cosmetic regulation, Regulation (EC) No. 1223/2009. |

### SECTION 12: Ecological information

#### 12.1. Toxicity

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Not Available</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Aquatic toxicity (acute)</th>
</tr>
</thead>
<tbody>
<tr>
<td>96-hour LC&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td>48-hour EC&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td>96-hour EC&lt;sub&gt;50&lt;/sub&gt;</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 | Non-combustible. |

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods


### 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)

| Primary hazard class/division | N/A |
| Hazard classification | N/A |

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

Date Issued: 01/26/2006
SDS No: 12-001.7
Date Revised: 08/25/2015
Revision No: 7

Opalescence® Whitening Toothpaste

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 : Please refer to Regulation 1223/2009 on Cosmetics

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 text)

: R22: Harmful if swallowed.
R25: Toxic if swallowed.
R32: Contact with acids liberates very toxic gas.
R36/37/38: Irritating to eyes, respiratory system and skin.
R36/38: Irritating to eyes and skin.
Acute Tox. (O), CAT 3: Acute Toxicity (Oral), Category 3
Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
Aquatic Tox., Chronic 3: Aquatic Toxicity, Chronic. 3
Eye Irr., Cat. 2: Eye Irritation, Category 2
Skin Irr., Cat. 2: Skin Irritation, Category 2
EUH032: Contact with acids liberates very toxic gas.
H301: Toxic if swallowed.
H302: Harmful if swallowed.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H412: Harmful to aquatic life with long lasting effects.

Prepared by : Anu Kattoju
Revision summary : This SDS replaces the 05/20/2014 SDS. Revised: Section 1: Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. Section 3: Wt.% Section 9: PERCENT VOLATILE. Section 10: HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABILITY, STABLE. Section 11: ACUTE ( ORAL LD50 (rat), INHALATION LC50 (rat) ACUTE. Section 14: ROAD
Opalescence® Whitening Toothpaste

AND RAIL (ADR/RID) - PROPER SHIPPING NAME ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA - air. Section 15: COMMENTS, 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.