

**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****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)**

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

**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.

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**Disposal** : P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

**2.3. Other hazards**

**Immediate concerns** : None

**SECTION 3: Composition / information on ingredients**

**3.1. Substances**

Not Applicable

**3.2. Mixtures**

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Methyl Salicylate	119-36-8	204-317-7	< 3	Xi; R22; R36/37/38	Acute Tox. (O),Cat. 4; H302
Sodium Fluoride	007681-49-4	231-667-8	0.25	T, Xi; R25; R32; R36/38	Eye Irr.,Cat. 2; Skin Irr.,Cat. 2; Acute Tox. (O),CAT 3; EUH032; H301; H315; H319
Poloxamer	9003-11-6	N/A	< 5	Xi; R36/37/38; R22	Aquatic Tox.,Chronic 3; H412

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**

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<b>Eyes</b>	: Mildly irritating to eyes.
<b>Skin</b>	: None expected for this product.
<b>Ingestion</b>	: None expected for this product.
<b>Inhalation</b>	: 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(CO<sub>2</sub>)**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.

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**Opalescence® Whitening Toothpaste****7.2. Conditions for safe storage, including any incompatibilities**

**Shelf life** : See product labeling

**7.3. Specific end use(s)**

**Specific end use(s)** : Toothpaste

**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** : None Required

**Respiratory protection** : Good general ventilation should be sufficient to control airborne levels.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

**Physical state** : Gel

**Colour** : Blue green

**Odour** : Mint

**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** : Heat, flames, and ignition sources

**10.5. Incompatible materials**

**Incompatible materials** : None known.

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** : None known.

**SECTION 11: Toxicological information**

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**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**

**Toxicity** : Not Available

**Aquatic toxicity (acute)**

**96-hour LC<sub>50</sub>** : Not Determined

**48-hour EC<sub>50</sub>** : Not Determined

**96-hour EC<sub>50</sub>** : 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**

**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**

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**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**

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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 LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat) ACUTE. **Section 14:** ROAD

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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.