

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 1/26/2006

SDS No : 12-001.6

Date Revised : 5/20/2014

Revision No : 6

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

UP Dental GmbH
 Am Westhover Berg 30
 51149 Cologne Germany
 Email: info@updental.de
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

2.2. Label elements

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

Hazard statement(s) : 9502HLMN: This Material is not considered to be hazardous for the health.

2.3. Other hazards

Immediate concerns : No adverse human effects

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



Date Issued : 1/26/2006
 SDS No : 12-001.6
 Date Revised : 5/20/2014
 Revision No : 6

Opalescence® Whitening Toothpaste

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Directive 67/548/EEC
Methyl Salicylate	119-36-8	204-317-7	< 5	Xi; R22; R36/37/38
Sodium Fluoride	007681-49-4	231-667-8	0.25	T, Xi; R25; R32; R36/38
Poloxamer	9003-11-6	- -	< 5	Xi; R36/37/38; R22

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

- 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

SAFETY DATA SHEET

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



Date Issued : 1/26/2006
SDS No : 12-001.6
Date Revised : 5/20/2014
Revision No : 6

Opalescence® Whitening Toothpaste

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.

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

SAFETY DATA SHEET

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



Date Issued : 1/26/2006
SDS No : 12-001.6
Date Revised : 5/20/2014
Revision No : 6

Opalescence® Whitening Toothpaste

Colour : Blue green

Odour : Mint

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable : Yes

10.2. Chemical stability

Chemical stability : Stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization : No

10.4. Conditions to avoid

Conditions to avoid : Heat, flames, ignition sources, and incompatibles.

10.5. Incompatible materials

Incompatible materials : Not Determined

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : Not Determined

Oral LD₅₀ : Not Determined

Inhalation LC₅₀ : Not Determined

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Not Available

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

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



Date Issued : 1/26/2006
 SDS No : 12-001.6
 Date Revised : 5/20/2014
 Revision No : 6

Opalescence® Whitening Toothpaste

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 classified

14.3. Transport hazard class(es)

Primary hazard class/division : N/A

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

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

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 Regulation 1223/2009 on Cosmetics

15.2. Chemical safety assessment

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



Date Issued : 1/26/2006
 SDS No : 12-001.6
 Date Revised : 5/20/2014
 Revision No : 6

Opalescence® Whitening Toothpaste

Chemical safety assessment : Not Determined

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.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 11/27/2011 SDS.

General statements : NA = Not Applicable

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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.