

SAFETY DATA SHEET

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



Date Issued : 01/26/2006
SDS No : 12-001.8
Date Revised : 10/14/2016
Revision No : 8

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

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 Regulation(EC) No 1272/2008 [CLP]

: 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.

Health : Not Classified

2.2. Label elements

This material is not considered hazardous to the health 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.

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

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

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properties.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

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

For full text of H-statements: 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. Get medical attention, if irritation persists.
- After skin contact** : Wash with soap and water.
- After 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.
- 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** : Mildly irritating to eyes.
: None expected for this product.
: None expected for this product.
: 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** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO₂)

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : None known.

5.3. Advice for firefighters

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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 : 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 : Sodium Fluoride CAS: 7681-49-4

Control Parameters	Exposure Limits
OSHA PEL	TWA 2.5 mg/m ³ F TWA 2.5 mg/m ³ dust (vacated) TWA 2.5 mg/m ³
ACGIH TLV	TWA 2.5 mg/m ³ F
NIOSH REL	TWA 2.5 mg/m ³
NIOSH IDLH	250 mg/m ³ F TWA: 2.5 mg/m ³ F

8.2. Exposure controls

Eye/face protection : Wear eye protection.

Skin protection : None Required

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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

Physical state : Gel
Appearance : Smooth Sparkling
Colour : Mint green
Odour : Mint
pH : 6.3 - 7.6

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 : Light & heat

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 6000 mg/kg Rabbit/Rat

Notes : ~18% of the mixture consists of components of unknown toxicity (Dermal).

Oral LD₅₀ : > 3500 mg/kg Mouse/Rat/Rabbit

Notes : < 1% of the mixture consists of components of unknown toxicity (oral).

Inhalation LC₅₀ : > 5.0 mg/L/4H Rat

Notes : ~20% 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.

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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

Environmental data : Do not flush to sewer.

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 : 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

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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 H-statements (number and full text) : 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. 2A: Eye Irritation, Category 2A
Skin Irr., Cat. 2: Skin Irritation, Category 2
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 08/25/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** WATER SPILL. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY. **Section 9:** APPEARANCE, COLOR, pH. **Section 10:** INCOMPATIBLE MATERIALS. **Section 11:** ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), 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, Primary hazard class/division, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.

General statements : NAP = Not Applicable

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NE = Not Established
TLV = Threshold Limit Value
PEL = Permittable 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.