

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 06/16/2011

SDS No : 223-001.5

Date Revised : 05/19/2015

Revision No : 4

Opalescence® PF Whitening Toothpaste

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

1.1. Product identifier

Product code : TV/71001
Product name : Opalescence® PF 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.

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

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

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.

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Storage : P273: Avoid release to the environment.
Disposal : P501: Dispose of in compliance with governmental regulation.
(EC1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns : No adverse human effects

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] |
|-------------------|-------------|------------|-------|--|---|
| Sodium Fluoride | 007681-49-4 | 231-667-8 | 0.25 | T, Xi; R25; R32; R36/38 | Acute Tox. (O), Cat. 3; Eye Irr., Cat. 2; Skin Irr., Cat. 2; H301; H315; H319 |
| Potassium Nitrate | 7757-79-1 | 231-818-8 | 5 | O, Xi; R36/37/38; R22 | Oxid. Sol., Cat. 3; H272 |

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 : 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

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| | |
|-------------------|--|
| Eyes | : May be mildly irritating to eyes. |
| Skin | : None Expected. |
| Ingestion | : May be harmful if swallowed in large quantities. |
| Inhalation | : None Expected. |

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

Hazardous combustion products : None known.

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 : No data 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.

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Opalescence® PF Whitening Toothpaste**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** : Paste**Colour** : White paste**Odour** : Vanilla mint**pH** : 6.0 to 7.0**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** : Product will not undergo polymerization.**10.4. Conditions to avoid****Conditions to avoid** : Heat, flames, and ignition sources**10.5. Incompatible materials****Incompatible materials** : Not Determined**10.6. Hazardous decomposition products****Hazardous decomposition products** : None known.

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SECTION 11: Toxicological information

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 : No data 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

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)

Hazard classification : N/A

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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

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
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 Oxid. Sol., Cat. 3: Oxidizing Solids, Category 3
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 H272: May intensify fire; oxidizer.
 H301: Toxic if swallowed.
 H315: Causes skin irritation.
 H319: Causes serious eye irritation.

Prepared by : Anu Kattoju**Revision summary** : This SDS replaces the 02/25/2015 SDS. Revised: **Section 1:** . **Section 2:** . **Section 8:** . **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT # 1.**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

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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.