

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 05/20/2014

SDS No : 366-001.3

Date Revised : 03/23/2016

Revision No : 2

Opalescence® Whitening Toothpaste - Sensitivity Relief

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

1.1. Product identifier

Product code : 2Q/1001303
 Product name : Opalescence® Whitening Toothpaste - Sensitivity Relief
 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 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.
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

Immediate concerns : None

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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]
Sodium Fluoride	007681-49-4	231-667-8	0.25	Eye Irr.,Cat. 2; Skin Irr.,Cat. 2; Acute Tox. (O),Cat. 3; EUH032; H301; H315; H319
Potassium Nitrate	7757-79-1	231-818-8	< 10	Oxid. Sol.,Cat. 2; Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; STOT SE,Cat 3; H272; H335; H315; H319
Methyl Salicylate	119-36-8	204-317-7	< 5	Acute Tox. (O),Cat. 4; H302
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

- 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** : Maybe harmful if swallowed in large quantities.
- 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** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO2)

5.2. Special hazards arising from the substance or mixture

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Hazardous combustion products : None known.

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.

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

Colour : Blue green

Odour : Mint

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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 : None known.

10.5. Incompatible materials

Incompatible materials : None known.

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

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 : 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

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

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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

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 : 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 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. 2: Eye Irritation, Category 2
Oxid. Sol., Cat. 2: Oxidizing Solids, Category 2

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STOT SE, Cat 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3

Skin Irr., Cat. 2: Skin Irritation, Category 2

EUH032: Contact with acids liberates very toxic gas.

H272: May intensify fire; oxidizer.

H301: Toxic if swallowed.

H302: Harmful if swallowed.

H315: Causes skin irritation.

H319: Causes serious eye irritation.

H335: May cause respiratory irritation.

H412: Harmful to aquatic life with long lasting effects.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 09/03/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** . **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 10:** CONDITIONS TO AVOID. **Section 15:** COMMENTS. **Section 16:** Revision Summary.

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.