

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/12/2014

SDS No : 372-001.2

Date Revised : 09/14/2015

Revision No : 1

Opalescence® Trèswhite® Supreme, Opalescence® Go™ (Mint, Peach, or Melon PF 10-15% HP)

SECTION 1 : Identification of the substance/preparation and of the company/undertaking**1.1. Product identifier**

Product code : TE/71048, TQ/15053, TR/15054, TS/15055
Product name : Opalescence® Trèswhite® Supreme, Opalescence® Go™ (Mint, Peach, or Melon PF 10-15% HP)
Product description : Dental Teeth Bleaching Gel

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Dental Teeth Whitening Gel

1.3. Details of the supplier of the safety data sheet**Manufacturer**

Ultradent Products, Inc.
 505 W. 10200 S.
 South Jordan, UT 84095

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.

Danger symbols : Xi

R phrases : R41

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

Health : Eye Damage, Category 1
 Acute Toxicity (Oral), Category 4

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : Xi



Irritant

R&S statement(s) : R41: Risk of serious damage to eyes.

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

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Hazard pictogram(s)



Exclamation mark

Signal Word

: DANGER

Hazard statement(s)

: H318: Causes serious eye damage.

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.
P315: Get immediate medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P332+P313: If skin irritation occurs: 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

: May cause serious damage to the eyes.

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]
Hydrogen Peroxide	7722-84-1	231-765-0	< 15	Xi; R41	EYE DMG.,Cat. 1; Acute Tox. (O),Cat. 4; H318; H302; H332
Sodium Hydroxide	1310-73-2	215-185-5	< 5	C; R34	Skin Corr.,Cat. 1B; H314
					Oxid. Sol.,Cat. 2; Skin Irr.,Cat.

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Potassium Nitrate	7757-79-1	231-818-8	≤ 3	O; Xi; R22; R36/37/38	2; Eye Irr.,Cat. 2; 2; STOT SE,Cat. 3; 3; H272; H335; H315; H319
Sodium Fluoride	007681-49-4	231-667-8	0.25	T; Xi; 00602RA7; R32; R25	Eye Irr.,Cat. 2; Skin Irr.,Cat. 2; Acute Tox. (O),CAT 3; EUH032; H301; H315; H319

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 with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and tested by medical personnel.
- Following skin** : Flush skin with large amounts of water. Seek medical attention if irritation develops and persists.
- 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

- Eyes** : May cause serious damage.
- Skin** : May cause skin irritation.
- 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** : May cause severe eye damage.

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** : None

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Fire explosion : None

Sensitive to static discharge : None

Sensitivity to impact : None

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 only.

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 : Wipe up with cloth, soap and water.

Large spill : Absorb with inert, damp non-combustible material, then wipe area with towel wetted with alcohol.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

General procedures : Avoid contact with eyes, skin and clothing.

Handling : Use suitable protective equipment.

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) : Professional Dental Teeth Whitening Gel

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 : Wear suitable protective clothing and gloves.

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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 : Colorless
Odour : Flavor dependent
pH : 5.0 to 7.4

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 : Strong acids, strong bases, and oxidizing agents.

10.5. Incompatible materials

Incompatible materials : Strong acids, Strong bases, and reducing agents.

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 Determined

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

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96-hour LC₅₀ : Not Determined48-hour EC₅₀ : Not Determined96-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 : Not defined

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 : Not Dangerous Goods

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

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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 : US Cosmetic (not sold in the EU)

15.2. Chemical safety assessment
Chemical safety assessment : Not Determined

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) : 00602RA7: R36/38: Irritating to eyes and skin.
 R22: Harmful if swallowed.
 R25: Toxic if swallowed.
 R32: Contact with acids liberates very toxic gas.
 R34: Causes burns.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 R41: Risk of serious damage to eyes.
 Acute Tox. (O), CAT 3: Acute Toxicity (Oral), Respiratory Tract Category 3
 Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
 EYE DMG., Cat. 1: Eye Damage, Category 1
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 Oxid. Sol., Cat. 2: Oxidizing Solids, Category 2
 STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
 Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
 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.
 H314: Causes severe skin burns and eye damage.
 H315: Causes skin irritation.
 H318: Causes serious eye damage.
 H319: Causes serious eye irritation.
 H332: Harmful if inhaled.
 H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 12/12/2014 SDS. Revised: **Section 1:** . **Section 2:** . **Section 3:** Wt.%. **Section 4:** NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - SKIN. **Section 5:** EXPLOSION HAZARDS, FIRE EXPLOSION, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 9:** PERCENT

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VOLATILE. **Section 10:** CONDITIONS TO AVOID, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABLE. **Section 12:** ECOTOXICOLOGICAL INFORMATION, AQUATIC TOXICITY (ACUTE). **Section 15:** COMMENTS. **Section 16:** Revision Summary.

General statements

: N/A= Not Applicable

Additional SDS information

: Revision #:1

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.