

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/20/2007

SDS No : 199-001.11

Date Revised : 10/29/2015

Revision No : 10

**Opalescence® Boost PF 38% and Opalescence® Boost PF 40% , Mixed****SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

**Product code** : XO/34567, XW/15083, XZ/71087  
**Product name** : Opalescence® Boost PF 38% and Opalescence® Boost PF 40% , Mixed  
**Product description** : Parts 1 and 2 , Mixed.

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

**Relevant identified uses** : Professional Dental Tooth Bleaching Gel

**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.

**Danger symbols** : O,Xi

**R phrases** : R41

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

**Health** : Serious Eye Damage, Category 1  
 Skin Irritation, Category 2  
 Acute Toxicity (Oral), Category 4

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

**Hazard pictogram(s)** :   
 Oxidizing      Irritant

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

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Hazard pictogram(s)

:

Exclamation  
mark

Signal Word

: DANGER

Hazard statement(s)

: H318: Causes serious eye damage.

H315: Causes skin irritation.

H302: Harmful if swallowed.

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.

P306+P360: IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.

P313: Get medical advice/attention.

P363: Wash contaminated clothing before reuse.

P301: IF SWALLOWED:

P310: Immediately call a POISON CENTER or doctor/physician.

P330: Rinse mouth.

P331: Do NOT induce vomiting.

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

: Risk of serious damage to eyes. Irritating to skin.

**SECTION 3: Composition / information on ingredients****3.1. Substances**

Not Applicable

**3.2. Mixtures**

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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	≤ 40	Xi; R41	EYE DMG.,Cat. 1; Skin Irr.,Cat. 2; Acute Tox. (O),Cat. 4; STOT SE,Cat. 3; H302; H315; H335; H318
Potassium Nitrate	7757-79-1	231-818-8	< 5	Not classified	Oxid. Sol.,Cat. 2; Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; STOT SE,Cat. 3; H272; H335; H315; H319
Potassium Hydroxide	1310-58-3	215-181-3	< 5	C; R34	Skin Corr.,Cat. 1B; Acute Tox. (O),Cat. 4; H302; H314
Sodium Fluoride	007681-49-4	231-667-8	1.1 - 1.5	T; Xi; R25; R32; R36/38	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 eyes with plenty of water for at least 15 minutes. Get immediate medical attention.

##### Following skin

: Immediately flush skin with plenty of water. Remove clothing. Get medical attention immediately. Wash clothing separately before reuse.

##### Following ingestion

: If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.

##### 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

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symptoms develop.

**4.2. Most important symptoms and effects, both acute and delayed**

- Eyes** : Causes severe eye irritation.  
**Skin** : Causes skin irritation.  
**Ingestion** : Harmful if swallowed.  
**Inhalation** : None expected for this product.

**4.3. Indication of any immediate medical attention and special treatment needed**

- Notes to physician** : Risk of serious damage to eyes. Irritating to skin.

**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** : 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 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 small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.  
**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** : Use suitable protective equipment.  
**Storage** : See product labeling.

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### 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 Tooth Bleaching Gel

## SECTION 8: Exposure controls / personal protection

### 8.1. Control parameters

Control parameters : Not Determined

### 8.2. Exposure controls

Eye/face protection : Use chemical splash goggles and face shield (ANSI Z87.1 or approved equivalent).

Skin protection : Wear suitable protective clothing and gloves.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Gel

Colour : Red

Odour : Odorless or no characteristic odor

pH : 6.0 to 8.5

### 9.2. Other information

Percent volatile : Not Determined

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Reactivity : Stable when stored and handled under recommended conditions.

### 10.2. Chemical stability

Chemical stability : Decomposes when exposed to heat.

### 10.3. Possibility of hazardous reactions

Hazardous polymerization : None

### 10.4. Conditions to avoid

Conditions to avoid : Organic materials.

### 10.5. Incompatible materials

Incompatible materials : Organic materials

### 10.6. Hazardous decomposition products

Hazardous decomposition products : Not Determined

## SECTION 11: Toxicological information

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**Notes** : Product contains high levels of hydrogen peroxide, which has a known toxicological profile. Product is only to be used by licensed dental professionals using the specified engineering controls.

**SECTION 12: Ecological information****12.1. Toxicity**

**Toxicity** : Biodegradability - Not established  
**Aquatic toxicity (acute)** : Do not allow to enter sewers or drains that may lead to waterways.  
**96-hour LC<sub>50</sub>** : Not Determined  
**48-hour EC<sub>50</sub>** : Not Determined  
**96-hour EC<sub>50</sub>** : 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 Determined

**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** : 3139

**14.2. UN proper shipping name**

**UN proper shipping name** : Oxidizing Liquid, N.O.S. (Hydrogen Peroxide Mixture)

**14.3. Transport hazard class(es)**

**Primary hazard class/division** : 5.1

**Hazard classification** : 5.1

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Packing group : II

**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 Medical Devices Directive 93/42/EEC

**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)** : R25: Toxic if swallowed.  
R32: Contact with acids liberates very toxic gas.  
R34: Causes burns.  
R36/38: Irritating to eyes and skin.  
R41: Risk of serious damage to eyes.  
Acute Tox. (O), Cat 3: Acute Toxicity (Oral), 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.  
H335: May cause respiratory irritation.

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<b>Prepared by</b>	: Anu Kattoju
<b>Revision summary</b>	: This SDS replaces the 08/25/2015 SDS. Revised: <b>Section 1:</b> Date-Revised.
<b>General statements</b>	: N/A= Not Applicable
<b>Manufacturer disclaimer</b>	: 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.