

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/20/2007

SDS No : 199-001.9

Date Revised : 03/18/2015

Revision No : 8

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

Environmental : Oxidizing Liquids, Category 1

2.2. Label elements

This mixture contains Hydrogen Peroxide, Potassium Nitrate, Potassium Hydroxide, and Sodium Fluoride. These materials are considered hazardous as defined by the OSHA Hazard Communication Standard (29 CFR 1819.1200)

Classification according to Directive 1999/45/EC

Hazard pictogram(s) :  
 Oxidizing Irritant

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

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

Hazard pictogram(s) :



Exclamation mark Flame over circle

Signal Word : WARNING

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.
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 : Causes severe eye irritation

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	O, Xi; R41; R37/38	Oxid. Liq., Cat. 1; Acute Tox. (O), Cat. 4; Skin Corr., Cat. 1A; H271; H314; H302; H332
Potassium Nitrate	7757-79-1	231-818-8	< 5	O, Xi; R36/37/38; R22	H271; H272; H302; H315; H319; H335; H361; H371; H373
Potassium Hydroxide	1310-58-3	215-181-3	< 5	C; R34	Skin Corr., Cat. 1A; Acute Tox. (D), Cat. 4; H302; H314
Sodium Fluoride	007681-49-4	231-667-8	1.1 - 1.5	T, Xi; R25; R32; R36/38	Acute Tox. (O), Cat. 3; Eye Irr., Cat. 2; Skin Irr., Cat. 2; 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

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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** : 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
- 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 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

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

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 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

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10.6. Hazardous decomposition products

Hazardous decomposition products : Not Determined

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

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 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 : 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

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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

14.4. Packing group

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) :

- 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.
- R36/38: Irritating to eyes and skin.
- R37/38: Irritating to respiratory system and skin.
- R41: Risk of serious damage to eyes.
- Skin Irr., Cat. 2: Skin Irritation, Category 2
- H271: May cause fire or explosion; strong oxidizer.
- 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.
- H319: Causes serious eye irritation.
- H332: Harmful if inhaled.

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H335: May cause respiratory irritation.

H361: Suspected of damaging fertility or the unborn child .

H371: May cause damage to organs .

H373: May cause damage to organs through prolonged or repeated exposure .

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 03/02/2015 SDS. Revised: **Section 1:**
Section 2: .

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.