

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/20/2007

SDS No : 198-001.5

Date Revised : 11/17/2014

Revision No : 5

Opalescence Boost 38% and 40% Bleaching Gel (46% HP)

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

1.1. Product identifier

Product code : XO/34567
Product name : Opalescence Boost 38% and 40% Bleaching Gel (46% HP)
Product description : Professional Use Tooth Bleaching Gel, Part 1 of 2

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

Relevant identified uses : Professional Use 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

Danger symbols : O, Xi
R phrases : R41, R38



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.
 R38: Irritating to skin.

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

Hazard pictogram(s) :  
 Flame over circle Exclamation mark

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Signal Word : WARNING
Hazard statement(s) : H318: Causes serious eye damage.
 H315: Causes skin irritation.

2.3. Other hazards

Immediate concerns : Causes severe eye irritation

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
Hydrogen Peroxide	7722-84-1	231-765-0	< 50	Xi;O; R41

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 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 : R41: Risk of serious damage to eyes.

SECTION 5: Fire fighting measures

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Opalescence Boost 38% and 40% Bleaching Gel (46% HP)**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**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 Teeth Whitening Gel**SECTION 8: Exposure controls / personal protection**

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Opalescence Boost 38% and 40% Bleaching Gel (46% HP)**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** : S36/37: Wear suitable protective clothing and gloves.**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** : Frosty white**Odour** : Odorless or no characteristic odor**pH** : 2 to 3**9.2. Other information****Percent volatile** : Not Determined**SECTION 10: Stability and reactivity****10.1. Reactivity****Stable** : Yes**10.2. Chemical stability****Chemical stability** : Decomposes when exposed to heat.**10.3. Possibility of hazardous reactions****Hazardous polymerization** : No**10.4. Conditions to avoid****Conditions to avoid** : Organic materials.**10.5. Incompatible materials****Incompatible materials** : Not Determined**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

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Opalescence Boost 38% and 40% Bleaching Gel (46% HP)Inhalation LC₅₀ : Not Determined**SECTION 12: Ecological information****12.1. Toxicity**

Toxicity : Biodegradability - Not established

Aquatic toxicity (acute)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 : 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)

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

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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 : Not Determined

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R41: Risk of serious damage to eyes.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 4/9/2014 SDS. Revised: **Section 1:** Date-Revised.

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 MSDS(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.

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Dental Use



Date Issued : 12/17/2007
 SDS No : 196-001.4
 Date Revised : 5/28/2014
 Revision No : 2

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

Product code : XW/15083, XZ/71087
Product name : Opalescence® Boost 38% and 40% Activator Gel
Product description : Hydrogen Peroxide Gel Activator. Part 2 of 2

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

Relevant identified uses : Professional Dental Tooth Whitening Activator

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

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

Distributor

UP Dental GmbH
 Am Westhover Berg 30
 51149 Cologne Germany
 Email: info@updental.de
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**



Danger symbols : C, Xn
R phrases : R35 R22

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

Hazard pictogram(s) :  
 Corrosive Harmful

R&S statement(s) : R35: Causes severe burns.
 R22: Harmful if swallowed.

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

Hazard pictogram(s) :  
 Corrosive Exclamation mark

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Date Issued : 12/17/2007
SDS No : 196-001.4
Date Revised : 5/28/2014
Revision No : 2

Opalescence® Boost 38% and 40% Activator Gel

Hazard statement(s) : H302: Harmful if swallowed.
H314: Causes severe skin burns and eye damage.

2.3. Other hazards

Immediate concerns : Corrosive. Will cause eye burns and permanent tissue damage.

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
Potassium Nitrate	7757-79-1	231-818-8	< 25	O, Xi; R36/37/38; R22
Potassium Hydroxide	1310-58-3	215-181-3	< 20	C, Xn; R35; R22
Sodium Fluoride	007681-49-4	231-667-8	3 - 10	T, Xi; R25; R32; R36/38

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 symptoms develop.

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

- Eyes** : Causes severe eye burns.
- Skin** : Corrosive, causes skin burning.
- Ingestion** : Harmful if swallowed.

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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 : 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, fog, or mist, foam, dry chemical, carbon dioxide.

Additional information : Do not use strong water jet for extinguishing - may cause spattering of burning material.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Special protective equipment : S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

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 : Clean up spills immediately, observing precautions in Protective Equipment section.

Large spill : Collect in tightly closed containers.

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.

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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 Whitening Activator

SECTION 8: Exposure controls / personal protection**8.1. Control parameters**

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear safety glasses with side shields (or goggles) and a face shield.

Skin protection : S36/37: Wear suitable protective clothing and gloves.

Respiratory protection : Good general ventilation should be sufficient to control airborne levels.

Other precautions : Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state : Gel

Colour : Orange to Dark Red

Odour : Odorless or no characteristic odor

pH : > 12

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity**10.1. Reactivity**

Stable : Yes

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : No

10.4. Conditions to avoid

Conditions to avoid : Heat, moisture, incompatibles.

10.5. Incompatible materials

Incompatible materials : Acids, flammable liquids, organic halogen compounds, trichloroethylene, nitromethane, aluminum, tin, zinc.

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Opalescence® Boost 38% and 40% Activator Gel**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 : Readily biodegradable.
 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 : Does not bioaccumulate.

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
 General comments : 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**

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Opalescence® Boost 38% and 40% Activator Gel

UN number : 1760

14.2. UN proper shipping name

UN proper shipping name : Corrosive liquid, N.O.S. (Potassium Hydroxide Mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 8

Hazard classification : 8

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 : Not Determined

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.
 R35: Causes severe burns.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 R36/38: Irritating to eyes and skin.

Prepared by : Anu Kattoju**Revision summary** : This SDS replaces the 11/1/2011 SDS.**General statements** : NA = Not Applicable**Manufacturer disclaimer** : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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

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