

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/17/2007

SDS No : 196-001.5

Date Revised : 08/25/2015

Revision No : 3

## 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

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** : C, Xn

**R phrases** : R22, R35

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

**Health** : Skin Corrosion, Category 1A  
 Eye Irritation, Category 2

**Environmental** : Oxidizing Solids, Category 2

#### 2.2. Label elements

##### Classification according to Directive 1999/45/EC

**Hazard pictogram(s)** : C Xn



Corrosive



Harmful

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

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/17/2007  
 SDS No : 196-001.5  
 Date Revised : 08/25/2015  
 Revision No : 3

**Opalescence® Boost 38% and 40% Activator Gel****Classification according to Regulation(EC) No 1272/2008 [CLP]****Hazard pictogram(s)****Signal Word**

: DANGER

**Hazard statement(s)**

: H302: Harmful if swallowed.  
 H314: Causes severe skin burns and 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**

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

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

Not Applicable

**3.2. Mixtures**

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/17/2007

SDS No : 196-001.5

Date Revised : 08/25/2015

Revision No : 3

**Opalescence® Boost 38% and 40% Activator Gel**

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Potassium Nitrate	7757-79-1	231-818-8	< 25	O, Xi; R36/37/38; R22	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	≤ 15	C; R35	Acute Tox. (O),Cat. 4; Skin Corr.,Cat. 1A; H302; H314
Sodium Fluoride	007681-49-4	231-667-8	5 - 10	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 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.
- Inhalation** : None expected for this product.

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



**Date Issued :** 12/17/2007  
**SDS No :** 196-001.5  
**Date Revised :** 08/25/2015  
**Revision No :** 3

**Opalescence® Boost 38% and 40% Activator Gel****4.3. Indication of any immediate medical attention and special treatment needed**

**Notes to physician** : Corrosive

**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** : 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.

**Storage** : See product labeling.

**7.2. Conditions for safe storage, including any incompatibilities**

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/17/2007  
 SDS No : 196-001.5  
 Date Revised : 08/25/2015  
 Revision No : 3

**Opalescence® Boost 38% and 40% Activator Gel**

**Shelf life** : See product labeling

**7.3. Specific end use(s)**

**Specific end use(s)** : Professional Dental Bleaching Gel, Part 2 of 2

**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** : 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**

**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** : Heat, moisture, incompatibles.

**10.5. Incompatible materials**

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

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** : None known.

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/17/2007

SDS No : 196-001.5

Date Revised : 08/25/2015

Revision No : 3

**Opalescence® Boost 38% and 40% Activator Gel****SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute**Dermal LD<sub>50</sub> : Not DeterminedOral LD<sub>50</sub> : Not DeterminedInhalation LC<sub>50</sub> : 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 LC<sub>50</sub> : Not Determined48-hour EC<sub>50</sub> : Not Determined96-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 : 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**

UN number : 1760

**14.2. UN proper shipping name**

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

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/17/2007  
 SDS No : 196-001.5  
 Date Revised : 08/25/2015  
 Revision No : 3

**Opalescence® Boost 38% and 40% Activator Gel****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.  
 Acute Tox. (O), CAT 3: Acute Toxicity (Oral), Category 3  
 Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4  
 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), Category 3  
 Skin Corr., Cat. 1A: Skin Corrosion, Category 1A  
 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.  
 H319: Causes serious eye irritation.

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/17/2007

SDS No : 196-001.5

Date Revised : 08/25/2015

Revision No : 3

**Opalescence® Boost 38% and 40% Activator Gel**

H335: May cause respiratory irritation.

**Prepared by**

: Anu Kattoju

**Revision summary**

: This SDS replaces the 05/28/2014 SDS. Revised: **Section 1:**  
 . **Section 2:** . **Section 4:** NOTES TO PHYSICIAN. **Section 10:**  
 HAZARDOUS POLYMERIZATION, STABLE.

**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.