

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

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) :  C  Xn
 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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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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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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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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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.