

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/20/2007

SDS No : 198-001.8

Date Revised : 08/29/2017

Revision No : 8

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 Dental Teeth Whitening Gel

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

Ultradent Products, Inc.
 505 W. Ultradent Drive (10200 South)
 South Jordan, UT 84095

EC Responsible Person

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

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

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

2.2. Label elements**Classification according to Regulation(EC) No 1272/2008 [CLP]**

Hazard pictogram(s) :



Exclamation
 mark

Corrosive

Signal Word : DANGER

Hazard statement(s) : H318: Causes serious eye damage.
 H302: Harmful if swallowed.
 H332: Harmful if inhaled.
 H315: Causes skin irritation.

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Precautionary statement(s)

- Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.
P264: Wash hands thoroughly after handling.
P270: Do not eat, drink or smoke when using this product.
P261: Avoid breathing vapours.
P260: Do not breathe dust/fume/gas/mist/vapours/spray.
P271: Use only outdoors or in a well-ventilated area.
- Response** : P302+P352: IF ON SKIN: Wash with plenty of soap & water.
P332+P313: If skin irritation occurs: Get medical advice/attention.
P362: Take off contaminated clothing.
P301+P312: IF SWALLOWED: Call a POISON CENTER/or doctor/physician if you feel unwell.
P330: Rinse mouth.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a POISON CENTER or doctor/physician.
- Storage** : P273: Avoid release to the environment.
- Disposal** : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Hydrogen Peroxide	7722-84-1	231-765-0	< 50	EYE DMG.,Cat. 1; Acute Tox. (O),Cat. 4; Skin Irr.,Cat. 2; STOT SE,Cat. 3; H318; H332; H302; H315

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

- Following eyes** : Remove contact lenses, if present and easy to do. Flush eyes with plenty of water for at least 15 minutes, opening the eyelids fully. Seek immediate medical advice.
- Following skin** : Remove contaminated clothing. Wash with soap and water. Get medical attention if irritation develops or persists.
- Following ingestion** : If swallowed in large quantities, rinse mouth out with water. Seek medical advice if you feel unwell.

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Following inhalation : If inhaled, remove to fresh air. Get medical attention if you feel unwell.

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

Eyes : Causes severe eye irritation.
Skin : Causes skin irritation.
Ingestion : May be harmful if swallowed in large quantities.
Inhalation : May be harmful if inhaled.

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

Notes to physician : Risk of serious damage to eyes.

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Water Spray Only

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.

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 : NAP

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General procedures : Avoid contact with eyes, skin and clothing.

Handling : Safety glasses should be used by the patient and doctor. Use equipment for eye protection tested and approved under appropriate government standards such as ANSI Z87.1.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

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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

8.1. Control parameters

Control parameters : Hydrogen Peroxide CAS: 7722-84-1

Control Parameters	Exposure Limits
OSHA PEL General Industry	1 ppm, 1.4 mg/m ³ TWA
OSHA PEL Construction Industry	1 ppm, 1.4 mg/m ³ TWA
OSHA PEL Maritime Industry	1ppm, 1.4 mg/m ³ TWA
ACGIH TLV	1ppm, 1.4 mg/m ³ TWA
NIOSH REL	1ppm, 1.4 mg/m ³ TWA

8.2. Exposure controls

Eye/face protection : Safety glasses (ANSI Z87.1 or equivalent) should be used by the doctor and patient.

Skin protection : 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 : 1.8 to 2.8
Specific gravity : 1.3

9.2. Other information

Additional information : No further relevant information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

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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 : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 6200 mg/kg Rabbit

Oral LD₅₀ : > 480 mg/kg Rat

Inhalation LC₅₀ : > 0.37 mg/L/4H Rat

Notes : ~ 8% of the mixture consists of components of unknown toxicity (Inhalation).
This is a viscous gel, therefore, chance of inhalation is extremely low.

Germ cell mutagenicity : The components in this product are not reported to produce mutagenic effects in humans.

Carcinogenicity : None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

Reproductive toxicity : The components in this product are not reported to cause reproductive effects in humans.

Other information : 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

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability

Persistence and degradability : Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

12.4. Mobility in soil

Mobility in soil : Not available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion: The substance does not fulfill the PBT and vPvB criteria for

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screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data : No further relevant information available.

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 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : NAP

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

General information : European Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC Substances.
CAN: All of the raw materials on the formulation list are on the Candian DSL list.

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.

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SECTION 16: Other information

- Relevant H-statements (number and full-text)** : Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
EYE DMG., Cat. 1: Eye Damage, Category 1
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
Skin Irr., Cat. 2: Skin Irritation, Category 2
H302: Harmful if swallowed.
H315: Causes skin irritation.
H318: Causes serious eye damage.
H332: Harmful if inhaled.
- Prepared by** : Anu Kattoju
- Revision summary** : This SDS replaces the 10/29/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** EYES, INGESTION, INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INHALATION), SKIN. **Section 5:** EXTINGUISHING MEDIA, FIRE FIGHTING EQUIPMENT. **Section 6:** . **Section 7:** HANDLING. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - EYES AND FACE . **Section 9:** COMMENTS, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. **Section 11:** ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.
- General statements** : NAP = Not Applicable
NE = Not Established
TLV = Threshold Limit Value
PEL = Permittable exposure limits
MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average
PPE = Personal Protective Equipment
- 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

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intended use and determine whether they are appropriate.