

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/12/2006

SDS No : 74-001.8

Date Revised : 01/17/2017

Revision No : 8

Opalescence® Endo**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : OY/35263
 Product name : Opalescence® Endo
 Product description : Dental Walking Bleach

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

Relevant identified uses : Professional Dental Bleaching 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
 Skin Irritation, Category 2
 Acute Toxicity (Inhalation), Category 4
 Target Organ Toxicity (Single exposure), Category 3
 Acute Toxicity (Oral), Category 4

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

Hazard pictogram(s) :



Exclamation
 mark

Signal Word : DANGER

Hazard statement(s) : H318: Causes serious eye damage.
 H335: May cause respiratory irritation.
 H315: Causes skin irritation.

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H302: Harmful if swallowed.

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.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P332+P313: If skin irritation occurs: Get medical advice/attention.
P301: IF SWALLOWED:
P330: Rinse mouth.
P312: Call a POISON CENTER or doctor/physician if you feel unwell.
P304+P341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

Storage : P273: Avoid release to the environment.

Disposal : P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)

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	< 40	EYE DMG.,Cat. 1; Skin Irr.,Cat. 2; Acute Tox. (O),Cat. 4; STOT SE,Cat. 3; H302; H315; H335; H318

For full text of H-statements: 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 : Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion : If swallowed rinse mouth out with water. Seek medical attention if you feel unwell.

Following inhalation : If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

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

Eyes : Causes eye irritation.

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Skin : Causes skin irritation.
Ingestion : May be harmful if swallowed.
Inhalation : May be harmful if inhaled.

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

Notes to physician : Irritating to eyes and skin.

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 : None known.

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 with cloth, soap and 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

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

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Bleaching Gel

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

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

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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	1 ppm, 1.4 mg/m ³ TWA
ACGIH TLV	1 ppm, 1.4 mg/m ³ TWA
NIOSH REL	1 ppm, 1.4 mg/m ³ TWA

8.2. Exposure controls

- Eye/face protection** : Wear eye protection .
- Skin protection** : Wear suitable protective clothing and gloves.
- Respiratory protection** : Good general ventilation should be sufficient to control airborne levels. In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state** : Gel
- Appearance** : Viscous
- Colour** : Colorless to white
- Odour** : Odorless or no characteristic odor
- pH** : 2.8 to 5.2
- Specific gravity** : 1.1 to 1.3
- Solubility in water** : Partially Soluble

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

- 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** : Avoid strong bases, metals, excess heat, exposure to moist air or water.

10.5. Incompatible materials

- Incompatible materials** : Strong caustics, most metals.

10.6. Hazardous decomposition products

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Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 5500 mg/kg Rabbit
Oral LD₅₀ : > 3300 mg/kg (Rat)
Inhalation LC₅₀ : > 1.0 mg/L/4H Rat
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 screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data : Do not flush to sewer.

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)

Primary hazard class/division : 5.1

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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 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.

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.
H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 04/15/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 3:** . **Section 4:** INGESTION, INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INGESTION, INHALATION). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 7:** GENERAL PROCEDURES. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** APPEARANCE, COLOR, COMMENTS,

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PERCENT VOLATILE, pH, SPECIFIC GRAVITY. **Section 11:** ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), 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
 AMU = Atomic Mass Unit

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.