

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/12/2006

SDS No : 74-001.7

Date Revised : 04/15/2015

Revision No : 7

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. 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 : Xn

R phrases : R41, R22

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

Health : Skin Corrosion, Category 1A
 Acute Toxicity (Dermal), Category 4
 Acute Toxicity (Oral), Category 4

Environmental : Oxidizing Liquids, Category 1

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xn



Harmful

R&S statement(s) : R41: Risk of serious damage to eyes.

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R22: Harmful if swallowed.

Classification according to Regulation (EC) No 1272/2008 [CLP]**Hazard pictogram(s)**

:

Exclamation
mark**Signal Word**

: WARNING

Hazard statement(s): H318: Causes serious eye damage.
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.**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**

: Harmful if swallowed. Risk of serious damage to eyes.

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

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Hydrogen Peroxide	7722-84-1	231-765-0	< 40	Xn; R41; R22	Oxid. Liq., Cat. 1; Acute Tox. (D), Cat. 4; Acute Tox. (O), Cat. 4; Skin Corr., Cat. 1A; H271; H302; H314; H332

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** : Wash with soap and water. Get medical attention if irritation develops or persists.
- Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.
- 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 eye burns.
- Skin** : Causes skin irritation.
- Ingestion** : May be harmful if swallowed in large quantities.
- Inhalation** : None expected for this product.

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

- Notes to physician** : Can cause serious damage to eyes.

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

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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 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

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 : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection
Skin protection : Wear suitable protective clothing and gloves.

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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 : Clear to milky
Odour : Odorless or no characteristic odor
pH : 3.0 to 5.0
Solubility in water : Partially Soluble

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 : 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

Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Notes : 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

Toxicity : Not Determined

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Aquatic toxicity (acute)

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 : 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 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)

Primary hazard class/division : 5.1

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

ADR - road : N/A

RID - rail : N/A

IMDG - sea : N/A

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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 : See Section 11

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R22: Harmful if swallowed.
 R41: Risk of serious damage to eyes.
 Acute Tox. (D), Cat. 4: Acute Toxicity (Dermal), Category 4
 Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
 Oxid. Liq., Cat. 1: Oxidizing Liquids, Category 1
 Skin Corr., Cat. 1A: Skin Corrosion, Category 1A
 H271: May cause fire or explosion; strong oxidizer.
 H302: Harmful if swallowed.
 H314: Causes severe skin burns and eye damage.
 H332: Harmful if inhaled.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 11/06/2014 SDS. Revised: **Section 1:**
 . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE
 CONCERNS. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT -
 SKIN. **Section 10:** HAZARDOUS POLYMERIZATION,
 STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀
 (rat) ACUTE. **Section 15:** SECTION 15: Regulatory
 information. **Section 16:** GENERAL STATEMENTS.

General statements : N/A= Not Applicable

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 recommendations are taken from sources (raw material SDS(s) and
 manufacturer's knowledge) believed to be accurate; however, the
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 recommendations in the specific context of the intended use and
 determine whether they are appropriate.