

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010
Dental Use

ULTRADENT
PRODUCTS, INC.

Date Issued : 09/24/2007
SDS No : 182-001.5
Date Revised : 12/15/2015
Revision No : 5

Opalescence® Xtra®

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : OX/ 31907
Product name : Opalescence® Xtra®
Product description : Professional Dental Tooth Bleaching Gel

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

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 : O, Xi

R phrases : R36


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

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


2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : O Xi



Oxidizing



Irritant

R&S statement(s) : R36: Irritating to eyes.

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


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Hazard pictogram(s)	:	 Exclamation mark
Signal Word	:	DANGER
Hazard statement(s)	:	H318: Causes serious eye damage. H315: Causes skin irritation. 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. P306+P360: IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes. 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 regulations(EC 1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns : Risk of serious damage to eyes. Irritating to skin.

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	Classification according to Regulation(EC) No 1272/2008 [CLP]
Hydrogen Peroxide	7722-84-1	231-765-0	35	Xi; R36	Acute Tox. (O), Cat. 4; EYE DMG., Cat. 1; Skin Irr., Cat. 2; H302; H318; H315

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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, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center if you feel unwell.
- 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 damage.
- Skin** : May cause skin irritation.
- Ingestion** : Harmful if swallowed.
- Inhalation** : None expected for this product.

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

- Notes to physician** : Risk of serious damage to eyes. Irritating to skin.

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** : 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.
- 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 small amounts with chemical resistant or damp rag which is washed

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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 : 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 : Not Determined

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Gel

Colour : Burgundy to reddish orange

pH : 3.0 to 5.0

Solubility in water : Partially Soluble

9.2. Other information

Percent volatile : Not Volatile

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable when stored and handled under recommended conditions.

10.2. Chemical stability

Chemical stability : Decomposes when exposed to heat.

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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 : Biodegradability - Not established
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 : 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)

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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 : Not Applicable

14.6. Special precautions for user

ADR - road : Not Applicable

RID - rail : Not Applicable

IMDG - sea : Not Applicable

IATA - air : Not Applicable

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

Transport in bulk : Not Applicable

SECTION 15: Regulatory information

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

RoHS : Please refer to the United States Food, Drug, and Cosmetic Act.

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) : R36: Irritating to eyes.
Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
EYE DMG., Cat. 1: Eye Damage, Category 1
Skin Irr., Cat. 2: Skin Irritation, Category 2
H302: Harmful if swallowed.
H315: Causes skin irritation.
H318: Causes serious eye damage.

Prepared by : Corey Jaseph

Revision summary : This SDS replaces the 12/12/2014 SDS. Revised: **Section 1:** MSDS No, PREPARED BY. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 4:** NOTES TO PHYSICIAN. **Section 5:** EXPLOSION HAZARDS, FIRE EXPLOSION, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** SMALL SPILL. **Section 7:** GENERAL

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PROCEDURES. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - SKIN. **Section 9:** COLOR, ODOR, PERCENT VOLATILE. **Section 10:** HAZARDOUS POLYMERIZATION, STABILITY, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 12:** ECOTOXICOLOGICAL INFORMATION, AQUATIC TOXICITY (ACUTE). **Section 15:** RoHS, SECTION 15: Regulatory information.

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.