

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/14/2013

SDS No : 350-001.6

Date Revised : 07/21/2015

Revision No : 6

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

Product code : 2E/71194
Product name : Opalescence® Office Gel
Product description : Hydrogen Peroxide Gel, Part 1 of 2

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

Relevant identified uses : Professional Dental Tooth Bleaching Gel, Part 1 of 2

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 : Xi

R phrases : R36

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

Health : Eye Irritation, Category 2

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : Xi



Irritant

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

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

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ULTRADENT
 PRODUCTS, INC.

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Hazard pictogram(s)



Exclamation
 mark

Signal Word

: DANGER

Hazard statement(s)

: H319: Causes serious eye irritation.

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.
 P337+P313: If eye irritation persists: Get medical advice/attention.
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.

Storage

: P273: Avoid release to the environment.

Disposal

: P501: Dispose of in compliance with governmental regulation.
 (EC1975L0442-10/11/2003)

2.3. Other hazards

Immediate concerns

: None

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	007722-84-1	231-765-0	< 8	Xi; R36	Eye Irr.,Cat. 2; H319
Sodium Fluoride	007681-49-4	231-667-8	0.3	T, Xi; R25; R32; R36/38	Eye Irr.,Cat. 2; Skin Irr.,Cat. 2; Acute Tox. (O),CAT 3; H301; EUH032; H315; H319

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

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SECTION 4: First aid measures

4.1. Description of first aid measures

- Following eyes** : Flush eyes with water for at least 15 minutes. Get medical attention if eye irritation develops or persists.
- Following skin** : Wash with soap and water.
- 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** : Irritating to eyes.
- Skin** : May cause mild skin irritation.
- Ingestion** : Maybe 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** : 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

- 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.

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6.3. Methods and material for containment and cleaning up

- Small spill** : Wipe up with cloth, soap and water.
Large spill : Absorb spill with an inert material (e.g. dry sand or earth), then place in a chemical waste container.

6.4. Reference to other sections

- Reference to other sections** : Please refer to Sections 4,5, and 7.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- General procedures** : Avoid contact with eyes, skin and clothing.
Handling : Use suitable protective clothing.
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 Bleaching Gel, Part 1 of 2

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** : Translucent gel
Colour : Frosty white
Odour : Odorless or no characteristic odor
Solubility in water : Partially soluble in water.

9.2. Other information

- Percent volatile** : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

- Reactivity** : Stable

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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 : This product meets the toxicologic profile required for cosmetics per the EU cosmetic regulation, Regulation (EC) No. 1223/2009.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Not Determined
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

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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 : N/A

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : Not Dangerous Goods

RID - rail : Not Dangerous Goods

IMDG - sea : Not Dangerous Goods

IATA - air : Not Dangerous Goods

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

Transport in bulk : Not Dangerous Goods

SECTION 15: Regulatory information

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

RoHS : Please refer to Regulation 1223/2009 on Cosmetics

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R25: Toxic if swallowed.
 R32: Contact with acids liberates very toxic gas.
 R36/38: Irritating to eyes and skin.
 R36: Irritating to eyes.
 Acute Tox. (O), CAT 3: Acute Toxicity (Oral), Category 3
 Eye Irr., Cat. 2: Eye Irritation, Category 2

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Skin Irr., Cat. 2: Skin Irritation, Category 2
 EUH032: Contact with acids liberates very toxic gas.
 H301: Toxic if swallowed.
 H315: Causes skin irritation.
 H319: Causes serious eye irritation.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 08/26/2014 SDS. Revised: **Section 1:** GENERAL USE. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 3:** Wt.%. **Section 4:** EYES, INGESTION, SIGNS AND SYMPTOMS OF OVEREXPOSURE (SKIN), SKIN. **Section 7:** . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY. **Section 10:** HAZARDOUS POLYMERIZATION, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1. **Section 15:** SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

General statements

: N/A= Not Applicable

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.