

# SAFETY DATA SHEET

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



Date Issued : 2/2/2006  
SDS No : 14-001.10  
Date Revised : 2/24/2014  
Revision No : 12

## Opalescence® and Opalescence® Oh! PF, Regular, Mint or Melon 10-20% Bleaching Gel

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

#### 1.1. Product identifier

**Product code** : FF/39025, FG/39029, FH/39013, FI/39019, FJ/39005, FK/39009, FP/13514, FQ/13509, FR/13518, SC/71178, SD/71179, SG/71180

**Product name** : Opalescence® and Opalescence® Oh! PF, Regular, Mint or Melon 10-20% Bleaching Gel

**Product description** : Carbamide Peroxide bleaching gel

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

**Relevant identified uses** : 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

UP Dental GmbH  
Am Westhover Berg 30  
51149 Cologne Germany  
**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

**Danger symbols** : Xi  
**R phrases** : R36/38

#### 2.2. Label elements

##### Classification according to Directive 1999/45/EC

**Hazard pictogram(s)** : Xi



Irritant

**R&S statement(s)** : R36/38: Irritating to eyes and skin.

#### 2.3. Other hazards

**Immediate concerns** : Not Applicable

### SECTION 3: Composition / information on ingredients

#### 3.1. Substances

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Not Applicable

### 3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC
Carbamide Peroxide	000124-43-6	204-701-4	< 21	Xi; R36
Sodium Fluoride	007681-49-4	231-667-8	< 0.3	T, Xi; R25; R32; R36/38
Sodium Hydroxide	1310-73-2	215-185-5	< 3	C; R34

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** : Irritating to eyes.
- Skin** : May cause skin irritation.
- Ingestion** : Maybe harmful if swallowed in large quantities.
- Inhalation** : None Expected.

#### 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

- Hazardous combustion products** : Not Determined
- Explosion hazards** : Not Determined

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**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

**General procedures** : Avoid contact with eyes, skin and clothing.  
**Handling** : Use suitable protective equipment.  
**Storage** : Keep refrigerated.

### 7.2. Conditions for safe storage, including any incompatibilities

**Shelf life** : 24 months

### 7.3. Specific end use(s)

**Specific end use(s)** : Not Applicable

## 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** : S36/37: 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** : Colorless  
**Odour** : Flavor dependent  
**pH** : ~ 6.5  
**Solubility in water** : Partially Soluble

#### 9.2. Other information

**Percent volatile** : Not Determined

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

**Stable** : Yes

#### 10.2. Chemical stability

**Chemical stability** : Stable when stored and handled under recommended conditions.

#### 10.3. Possibility of hazardous reactions

**Hazardous polymerization** : No

#### 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

**Dermal LD<sub>50</sub>** : Not Determined  
**Oral LD<sub>50</sub>** : Not Determined  
**Inhalation LC<sub>50</sub>** : Not Determined

### SECTION 12: Ecological information

#### 12.1. Toxicity

**Toxicity** : Not yet Determined

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**Aquatic toxicity (acute)** : Do not allow to enter sewers or drains that may lead to waterways.  
**96-hour LC<sub>50</sub>** : Not Determined  
**48-hour EC<sub>50</sub>** : Not Determined  
**96-hour EC<sub>50</sub>** : 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** : N/A

### 14.2. UN proper shipping name

**UN proper shipping name** : Not classified

### 14.3. Transport hazard class(es)

**Primary hazard class/division** : Not Applicable

**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** : 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 Regulation 1223/2009 on Cosmetics

### 15.2. Chemical safety assessment

Chemical safety assessment : Not Determined

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.  
R34: Causes burns.  
R36/38: Irritating to eyes and skin.  
R36: Irritating to eyes.

Prepared by : Anu Kattoju

Revision summary : This MSDS replaces the 11/26/2013 MSDS. Revised: **Section 1:** GENERAL USE. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 4:** INGESTION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE ( INGESTION, INHALATION, SKIN ). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, . **Section 7:** SHELF LIFE, . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** PERCENT VOLATILE. **Section 10:** HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, STABLE. **Section 11:** ACUTE ( ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat) ). **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 14:** AIR (ICAO/IATA) ( SPECIAL PROVISIONS ), ROAD AND RAIL (ADR/RID), ROAD AND RAIL (ADR/RID) ( PROPER SHIPPING NAME, UN NUMBER, PACKING GROUP ), VESSEL (IMO/IMDG) ( SPECIAL PROVISIONS ), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS. **Section 15:** RoHS, 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 MSDS(s) and

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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.