

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 02/02/2006
SDS No : 14-001.15
Date Revised : 10/14/2016
Revision No : 16

Opalescence® PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

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® PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

Product description : Dental Teeth Bleaching Gel

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

Relevant identified uses : Professional Dental Teeth 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

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 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 : R36/38

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

Health : Eye Irritation, Category 2
Skin Irritation, Category 2
Acute Toxicity (Oral), Category 4
Acute Toxicity (Inhalation), Category 3

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi



Irritant

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

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

Hazard pictogram(s)



Exclamation
mark

Signal Word

: DANGER

Hazard statement(s)

: H315: Causes skin irritation.
 H319: Causes serious eye irritation.
 H302: Harmful if swallowed.
 H335: May cause respiratory 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.
 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+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
 P304+P312: IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

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

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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]
Carbamide Peroxide	000124-43-6	204-701-4	≤ 20	Xi; R36	Skin Irr.,Cat. 2; EYE DMG.,Cat. 1; STOT SE,Cat. 3; Oxid. Liq.,Cat 3; H272; H315; H318; H335
Poly Acrylic acid	9003-01-4	N/A	< 10	Xi; R36/37/38	Not classified
Sodium Hydroxide	1310-73-2	215-185-5	< 5	C; R34	Skin Corr.,Cat. 1B; Eye Irr.,Cat. 1; Cor. Metal,Cat. 1; H314; H290
Sodium Fluoride	007681-49-4	231-667-8	0.25	T; Xi; R25; R32; R36/38	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2A; Acute Tox. (O),Cat 3; H301; H315; H319

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

SECTION 4: First aid measures

4.1. Description of first aid measures

- After eye contact.** : Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.
- After skin contact** : Wash with soap and water. Get medical attention if irritation develops or persists.
- After ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.
- After 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

- General notes** : Irritating to eyes.
: May cause skin irritation.
: Maybe harmful if swallowed in large quantities.
: May be harmful if inhaled.

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** : 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

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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 Teeth Bleaching Gel

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Sodium Fluoride CAS: 7681-49-4

Control Parameters	Exposure Limits
OSHA PEL	TWA 2.5 mg/m ³ F TWA 2.5 mg/m ³ dust (vacated) TWA 2.5 mg/m ³
ACGIH TLV	TWA 2.5 mg/m ³ F
NIOSH REL	TWA 2.5 mg/m ³
NIOSH IDLH	250 mg/m ³ F TWA: 2.5 mg/m ³ F

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

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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	: Clear viscous gel which may contain bubbles
Colour	: Colorless
Odour	: Flavor dependent
pH	: 6.0 to 7.2
Specific gravity	: 1.2 - 1.3
Solubility in water	: Partially Soluble

9.2. Other information

Percent volatile	: Not Volatile
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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.
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10.3. Possibility of hazardous reactions

Hazardous polymerization	: None
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10.4. Conditions to avoid

Conditions to avoid	: Avoid strong bases, metals, excess heat, exposure to moist air or water.
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10.5. Incompatible materials

Incompatible materials	: Strong caustics, most metals.
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10.6. Hazardous decomposition products

Hazardous decomposition products	: None known.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD ₅₀	: > 3800 mg/kg Rabbit/Rat
Notes	: ~22% of the mixture consists of components of unknown toxicity (Dermal).
Oral LD ₅₀	: > 1200 mg/kg Mouse/Rat/Rabbit
Inhalation LC ₅₀	: > 0.5 mg/L/4H Dust/Mist Rat
Notes	: ~26% of the mixture consists of components of unknown toxicity (Inhalation).
Other information	: The 10-16% CP products meet the toxicological profile required for cosmetics per the EU Cosmetic Regulation, Regulation (EC) No. 1223/2009.

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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 : NAP

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : NAP

14.4. Packing group

Packing group : NAP

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

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SECTION 15: Regulatory information

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

General comments : Please refer to Regulation 1223/2009 on Cosmetics

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.
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.
R36/37/38: Irritating to eyes, respiratory system and skin.
R36/38: Irritating to eyes and skin.
R36: Irritating to eyes.
Acute Tox. (O), Cat 3: Acute Toxicity (Oral), Category 3
Cor. Metal, Cat. 1: Corrosive to Metals, Category 1
EYE DMG., Cat. 1: Eye Damage, Category 1
Eye Irr., Cat. 1: Eye Irritation, Category 1
Eye Irr., Cat. 2A: Eye Irritation, Category 2A
Oxid. Liq., Cat 3: Oxidizing Liquids, Category 3
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
Skin Irr., Cat. 2: Skin Irritation, Category 2
H272: May intensify fire; oxidizer.
H290: May be corrosive to metals.
H301: Toxic if swallowed.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 03/18/2015 SDS. Revised: **Section 1:** GENERAL USE, MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 3:** Wt.%. **Section 4:** SIGNS AND SYMPTOMS OF OVEREXPOSURE - INHALATION. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 7:** . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** APPEARANCE, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. **Section 11:** ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit),

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INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, COMMENTS, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, 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

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.