

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/02/2006

SDS No : 14-001.16

Date Revised : 09/27/2017

Revision No : 17

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. Ultradent Drive (10200 South)
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 Regulation(EC) No 1272/2008 [CLP]

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Health : Eye Damage, Category 1
Skin Irritation, Category 2
Acute Toxicity (Oral), Category 4
Acute Toxicity (Inhalation), Category 3

2.2. Label elements

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

Hazard pictogram(s) :



Exclamation
mark

Signal Word : DANGER

Hazard statement(s) : H315: Causes skin irritation.
H302: Harmful if swallowed.
H335: May cause respiratory irritation.

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H318: Causes serious eye damage.

Precautionary statement(s)

Prevention

: P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response

: P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a POISON CENTER or doctor/physician.
P302+P352: IF ON SKIN: Wash with plenty of soap & 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. (EC1975L0442-20/11/2003)

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

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Regulation(EC) No 1272/2008 [CLP]
Carbamide Peroxide	000124-43-6	204-701-4	≤ 20	Skin Irr., Cat. 2; EYE DMG., Cat. 1; STOT SE, Cat. 3; Oxid. Sol., Cat 3; H272; H315; H318; H335
Poly Acrylic acid	9003-01-4	N/A	< 10	Not classified
Sodium Hydroxide	1310-73-2	215-185-5	< 5	Skin Corr., Cat. 1B; H314
Sodium Fluoride	7681-49-4	231-667-8	0.25	Skin Irr., Cat. 2; Eye Irr., Cat. 2A; Acute Tox. (O), Cat 3; H301; H315; H319

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes

: Remove contact lenses, if present and easy to do. Flush eyes with plenty of water for at least 15 minutes, opening the eyelids fully. Seek immediate medical advice.

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

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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 : May cause damage.
Skin : May cause skin irritation.
Ingestion : Maybe harmful if swallowed in large quantities.
Inhalation : May be harmful if inhaled.

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

Notes to physician : NAP

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 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 : NAP

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

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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

Sodium Hydroxide CAS: 1310-73-2

Exposure Limit	Limit Values
OSHA Permissible Exposure Limit(PEL)- General Industry	2 mg/m ³ TWA
OSHA PEL - Construction Industry	2 mg/m ³ TWA
OSHA PEL - Shipyard Employment	2 mg/m ³ TWA
National Institute for Occupational Safety and Health(NIOSH) Recommended Exposure Limit(REL)	2 mg/m ³ Ceiling
CAL/OSHA PEL	2 mg/m ³
American Conference of Governmental Industrial Hygienists(ACGIH) Threshold Limit Value (TLV) (2001)	2 mg/m ³ Ceiling

Sodium Hydroxide International Regulations

Country	Exposure Limits	Limit Values
Australia	Peak limitation(199)	2 mg/m ³
Federal Republic of Germany	Short term level	2 mg/m ³ , 4mg/m ³ , 5 minutes. 8 times per shift(1990)
United Kingdom	10 min Short term exposure limit (STEL)	2 mg/m ³ (1991)

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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 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

Additional information : No further relevant information available

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

Dermal LD₅₀ : > 3800 mg/kg Rabbit/Rat

Notes : ~22% of the mixture consists of components of unknown toxicity (Dermal).

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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).
Germ cell mutagenicity	: The components in this product are not reported to produce mutagenic effects in humans.
Carcinogenicity	: None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.
Reproductive toxicity	: The components in this product are not reported to cause reproductive effects in humans.
Other information	: The 10-16% CP products meet the toxicological profile required for cosmetics per the EU Cosmetic Regulation, Regulation (EC) No. 1223/2009.

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 : No further relevant information 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 : NAP

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : NAP

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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

SECTION 15: Regulatory information

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

General information : EU : Substances of very high concern (SVHC) according to REACH, Article 57; Contains no SVHC substances.
Canada : According to the New Substances Notification Regulations (Chemicals and Polymers): Required Information for Chemicals and Polymers other than Research and Development, Contained Site Limited Intermediate and Contained Export-Only Substances: Chemicals and Biochemicals on the NDSL that manufacture or import quantities greater than 1,000 kg and 10,000 kg must notify the Minister: Carbamide Peroxide is on the NDSL and is exempt from reporting requirements.

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 H-statements (number and full-text) : Acute Tox. (O), Cat 3: Acute Toxicity (Oral), Category 3
EYE DMG., Cat. 1: Eye Damage, Category 1
Eye Irr., Cat. 2A: Eye Irritation, Category 2A
Oxid. Sol., Cat 3: Oxidizing Solids, 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.
H301: Toxic if swallowed.
H314: Causes severe skin burns and eye damage.

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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 10/14/2016 SDS. Revised: **Section 1:** MSDS No. **Section 4:** EYES, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - EYES SKIN. **Section 6:** . **Section 9:** COMMENTS, PERCENT VOLATILE. **Section 11:** CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 12:** ENVIRONMENTAL DATA. **Section 15:** RoHS.

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
AMU = Atomic Mass Unit

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.