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 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: Professional Dental Teeth Whitening 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: 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

2.2. Label elements

This mixture contains Carbamide Peroxide, Poly Acrylic Acid, Sodium Hydroxide, and Sodium Fluoride. These materials are considered hazardous as defined by the OSHA Hazard Communication Standard (29 CFR 1819.1200)

Classification according to Directive 1999/45/EC
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Hazard pictogram(s) : Xi

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

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

Hazard pictogram(s) :

Exclamation mark

Signal Word : WARNING

Hazard statement(s) : H315: Causes skin irritation.

Precautionary statement(s)


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.

Storage : P273: Avoid release to the environment.


2.3. Other hazards

Immediate concerns : No other adverse human effects.

SECTION 3: Composition / information on ingredients

3.1. Substances
Not Applicable

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

### 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 | < 25 | Xi; R36 | H272; H314; H302; H315; H318; H335
Poly Acrylic acid | 9003-01-4 | NA | < 10 | Xi; R36/37/38 | H226; H290; H302; H312; H314; H317; H319; H332; H335; H340; H350; H400
Sodium Hydroxide | 1310-73-2 | 215-185-5 | < 5 | C; R34 | Eye Irr., Cat. 2; Skin Corr., Cat. 1A; H314
Sodium Fluoride | 007681-49-4 | 231-667-8 | 0.25 | T, Xi; R25; R32; R36/38 | Acute Tox. (O), Cat. 3; Eye Irr., Cat. 2; Skin Irr., Cat. 2; 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

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

Skin: May cause 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
Hazardous combustion products: Not Determined
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.

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

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 Whitening 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 : 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

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 : None known.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Notes: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute): Do not allow to enter sewers or drains that may lead to waterways.
96-hour LC_{50}: Not Determined
48-hour EC_{50}: Not Determined
96-hour EC_{50}: 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


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
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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 MARPOL 73/78 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

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.
Skin Irr., Cat. 2: Skin Irritation, Category 2
H226: Flammable liquid and vapour.
H272: May intensify fire; oxidizer.
H290: May be corrosive to metals.
H301: Toxic if swallowed.
H302: Harmful if swallowed.
H312: Harmful in contact with skin.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.
H332: Harmful if inhaled.
H335: May cause respiratory irritation.
H340: May cause genetic defects.
H350: May cause cancer.
H400: Very toxic to aquatic life.
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Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 02/27/2015 SDS. Revised: Section 1:
Section 2:

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.