

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 06.05.2020

Revision: 18.07.2019

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** *Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)*
- **Article number:** 13509, 13514, 13518, 39005, 39009, 39013, 39019, 39025, 39029, 71178, 71179, 71180
- **Index number:** SDS 14-001.18
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Teeth Whitening Gel
- **Application of the substance / the mixture** *Professional Dental Teeth Whitening Gel*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com*
-
- EC Responsible Person
Ultradent Products GmbH
Am Westhoyer Berg 30
51149 Cologne Germany
Email: infoDe@ultradent.com
Emergency Phone: +49(0)2203-35-92-0*
- **Further information obtainable from:** *Customer Service*
- **Emergency telephone number:**
*CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887*

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



*Acute Tox. 4 H332 Harmful if inhaled.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.*

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a cosmetic in the finished state used in direct physical contact with the human body according to Art. 1.5 (c). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6b), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- **Hazard pictograms** *GHS07*
- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
*Carbamide Peroxide
Sodium Hydroxide*

(Contd. on page 2)

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Revision: 18.07.2019

Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

(Contd. of page 1)

· **Hazard statements**

H332 Harmful if inhaled.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

· **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves / eye protection / face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312 Call a POISON CENTER/doctor if you feel unwell.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

· **Additional information:**

Contains Oils, Peppermint. May produce an allergic reaction.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	Glycerine substance with a Community workplace exposure limit	>25-≤50%
CAS: 124-43-6 EINECS: 204-701-4	Carbamide Peroxide ⚠ Ox. Sol. 3, H272; ⚠ Skin Corr. 1B, H314	>10-≤20%
CAS: 1310-73-2 EINECS: 215-185-5	Sodium Hydroxide ⚠ Acute Tox. 3, H301; ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H312	<5%
	Artificial Watermelon ⚠ Flam. Liq. 3, H226	≤2.5%
CAS: 8006-90-4 EINECS: 282-015-4	Oils, Peppermint ⚠ Asp. Tox. 1, H304; ⚠ Aquatic Chronic 2, H411; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≤2.5%
CAS: 7681-49-4 EINECS: 231-667-8	Sodium Fluoride ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	0.25%
CAS: 7757-79-1 EINECS: 231-818-8	Potassium Nitrate ⚠ Ox. Sol. 2, H272; ⚠ Skin Irrit. 2, H315; STOT SE 3, H335-H336	<3%

(Contd. on page 3)

Safety data sheet

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Revision: 18.07.2019

Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

(Contd. of page 2)

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

· **Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **After inhalation:**

This product is a viscous gel, therefore chance of inhalation is extremely low.

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** If swallowed in large quantities seek medical attention.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:** Water spray

· **Special hazards arising from the substance or mixture** No further relevant information available.

· **Advice for firefighters:**

· **Protective equipment:**

Wear fully protective suit.

Mouth respiratory protective device.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

· **Methods and material for containment and cleaning up:**

Dispose contaminated material as waste according to item 13.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Ensure adequate ventilation.

· **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

GB2

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 06.05.2020

Revision: 18.07.2019

Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

(Contd. of page 3)

7 Handling and storage

- **Handling:**
- **Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
See product labelling.
Keep container tightly sealed.
- **Specific end use(s)** Professional Dental Teeth Whitening Gel

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

56-81-5 Glycerine

WEL (Great Britain)	Long-term value: 10 mg/m ³
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1310-73-2 Sodium Hydroxide

WEL (Great Britain)	Short-term value: 2 mg/m ³
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- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 06.05.2020

Revision: 18.07.2019

Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

(Contd. of page 4)

· **Penetration time of glove material**

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Gel
· Colour:	Colourless
· Odour:	Product specific
· Odour threshold:	Not determined.

· **pH-value at 20 °C:** 5.3-7.5

· **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not applicable.

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.

· Density at 20 °C:	1.2-1.3 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

· **Solubility in / Miscibility with water:** Partly soluble.

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

· Dynamic:	Not determined.
· Kinematic:	Not determined.

· **Solvent content:**

· Organic solvents:	<60 %
· Water:	<50 %

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

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Revision: 18.07.2019

Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

(Contd. of page 5)

VOC (EC)	<1 %
Solids content:	<60.0 %
Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity Stable**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** Excess heat
- **Incompatible materials:**
Strong Alkalis
Metals
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
Harmful if inhaled.

· **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)		
Oral	LD50	3,688-7,498 mg/kg
Dermal	LD50	27,959 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.403 mg/l (rat)
56-81-5 Glycerine		
Oral	LD50	7,750 mg/kg (Guinea pig)
		4,100 mg/kg (mouse)
		5,570 mg/kg (rat)
		27,000 mg/kg (rabbit)
Dermal	LC50 Fish	>5,000 mg/l (Fish)
	LD50	>21,900 mg/kg (rat)
Inhalative	LC50/4 h	10,000 mg/kg (rabbit)
		>0.1425 mg/l (rat)
124-43-6 Carbamide Peroxide		
Oral	LD50	>2,000 mg/kg (rat)
1310-73-2 Sodium Hydroxide		
Oral	LD50	130-340 mg/kg (rat)
	LC50 Fish	160 mg/l (Fish)
Dermal	LD50	1,350 mg/kg (rabbit)
	Absolute lethal concentration	180 ppm (Fish)
8006-90-4 Oils, Peppermint		
Oral	LD50	2,490 mg/kg (mouse)

(Contd. on page 7)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 06.05.2020

Revision: 18.07.2019

Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

(Contd. of page 6)

		2,426 mg/kg (rat)
7681-49-4 Sodium Fluoride		
Oral	LD50	52 mg/kg (mouse)
	LC50 Fish (static)	17 mg/l (Fish)
Dermal	LD50	175 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological information

- **Toxicity**

· Aquatic toxicity:	
56-81-5 Glycerine	
EC50	>10,000 mg/l (Bacteria) >10,000 mg/l (daphnia)
1310-73-2 Sodium Hydroxide	
EC50	40.38 mg/l (Water Flea)
7681-49-4 Sodium Fluoride	
EC50	272 mg/kg (Algae) 98 mg/kg (daphnia)
Algae Toxicity (static)	7 mg/l (Algae)

- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

GB2

(Contd. on page 8)

Safety data sheet

according to 1907/2006/EC, Article 31

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Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

(Contd. of page 7)

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

HP8	Corrosive
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number
· ADR, IMDG, IATA | not regulated |
| · UN proper shipping name
· ADR, IMDG, IATA | not regulated |
| · Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | not regulated |
| · Packing group
· ADR, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | not regulated |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **Chemical safety assessment:**
The 10-16% products meet the toxicological profile required for cosmetics per the EU cosmetic regulation, Regulation (EC) No. 1223/2009.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
H226 Flammable liquid and vapour.

(Contd. on page 9)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 06.05.2020

Revision: 18.07.2019

Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

(Contd. of page 8)

H272 May intensify fire; oxidiser.
 H301 Toxic if swallowed.
 H304 May be fatal if swallowed and enters airways.
 H310 Fatal in contact with skin.
 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.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H336 May cause drowsiness or dizziness.
 H411 Toxic to aquatic life with long lasting effects.

· **Department issuing SDS:** Regulatory Affairs

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids – Category 3

Ox. Sol. 2: Oxidizing solids – Category 2

Ox. Sol. 3: Oxidizing solids – Category 3

Acute Tox. 3: Acute toxicity - oral – Category 3

Acute Tox. 2: Acute toxicity - dermal – Category 2

Acute Tox. 4: Acute toxicity - dermal – Category 4

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Asp. Tox. 1: Aspiration hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

GB2