Safety data sheet
according to UK REACH

Printing date 13.03.2025 Version number 1 Revision: 13.03.2025

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

· **Product identifier**

· **Trade name: Opalescence™ PF 35%-(All Flavors)**

· **Article number:** SDS 60-001.11R01, 15060, 15061, 5404-US, 5405-US, 15059
· **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 Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Office 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** Void
· **Hazard pictograms** GHS07
· **Signal word** Warning

· **Hazard-determining components of labelling:**
Hydrogen Peroxide
· **Hazard statements**
H332 Harmful if inhaled.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

(Contd. on page 2)

Safety data sheet
according to UK REACH

Printing date 13.03.2025 Version number 1 Revision: 13.03.2025

Trade name: Opalescence™ PF 35%-(All Flavors)

(Contd. of page 1)

· **Precautionary statements**

P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P103	Read carefully and follow all instructions.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves / eye protection / face protection.
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).

3 Composition/information on ingredients

· **Mixtures**

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

· **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	Glycerin substance with a Community workplace exposure limit	≥0-<40%
CAS: 124-43-6 EINECS: 204-701-4	Carbamide Peroxide Ox. Sol. 3, H272; Skin Corr. 1B, H314	>10-≤25%
CAS: 7722-84-1 EINECS: 231-765-0	Hydrogen Peroxide Ox. Liq. 1, H271; Skin Corr. 1A, H314; Acute Tox. 4, H302; Acute Tox. 4, H332 Specific concentration limits: Ox. Liq. 1; H271: C ≥ 70 % Ox. Liq. 2; H272: 50 % ≤ C < 70 % Skin Corr. 1A; H314: C ≥ 70 % Skin Corr. 1B; H314: 50 % ≤ C < 70 % Skin Irrit. 2; H315: 35 % ≤ C < 50 % Eye Dam. 1; H318: C ≥ 8 % Eye Irrit. 2; H319: 5 % ≤ C < 8 % STOT SE 3; H335: C ≥ 35 %	>1-<7%
CAS: 1310-73-2 EINECS: 215-185-5	Sodium Hydroxide Skin Corr. 1A, H314	≥1-<5%
	Artificial Watermelon Flam. Liq. 3, H226	≥1-<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	≥0.25-<1%
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, EUH032	≤0.25%

· **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.

(Contd. on page 3)

Safety data sheet
according to UK REACH

Printing date 13.03.2025 Version number 1 Revision: 13.03.2025

Trade name: Opalescence™ PF 35%-(All Flavors)

(Contd. of page 2)

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.*

· ***After eye contact:***
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· ***After swallowing:*** *If symptoms persist consult 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:*** *Use fire extinguishing methods suitable to surrounding conditions.*

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

· ***Advice for firefighters:***

· ***Protective equipment:*** *Mouth respiratory protective device.*

6 Accidental release measures

· ***Personal precautions, protective equipment and emergency procedures*** *Not required.*

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

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

7 Handling and storage

· ***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*

(Contd. on page 4)

Safety data sheet
according to UK REACH

Printing date 13.03.2025 Version number 1 Revision: 13.03.2025

Trade name: Opalescence™ PF 35%-(All Flavors)

(Contd. of page 3)

8 Exposure controls/personal protection

· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
56-81-5 Glycerin	
WEL	Long-term value: 10 mg/m³
7722-84-1 Hydrogen Peroxide	
WEL	Short-term value: 2.8 mg/m³, 2 ppm Long-term value: 1.4 mg/m³, 1 ppm
1310-73-2 Sodium Hydroxide	
WEL	Short-term value: 2 mg/m³

· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**
· **Appropriate engineering controls** No further data; see section 7.
· **Individual protection measures, such as 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.
· **Hand protection**

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.
· **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/face protection**

Tightly sealed goggles

· **Body protection:** Protective work clothing

(Contd. on page 5)

Safety data sheet
according to UK REACH

(Contd. of page 4)

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	Fluid
· **Colour:**	Colourless
· **Odour:**	Flavor Dependent
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Undetermined.
· **Boiling point or initial boiling point and boiling range**	Undetermined.
· **Flammability**	Not applicable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **pH at 20 °C**	5-7
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Dynamic:**	Not determined.
· **Solubility**	
· **water:**	Partly soluble.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density and/or relative density**	
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

· **Other information**	
· **Appearance:**	
· **Form:**	Gel
· **Important information on protection of health and environment, and on safety.**	
· **Ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Change in condition**	
· **Evaporation rate**	Not determined.

· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Void
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void

(Contd. on page 6)

Safety data sheet
according to UK REACH

(Contd. of page 5)

· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	Void

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **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:** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

· **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Harmful if inhaled.

· **LD/LC50 values relevant for classification:**		
ATE (Acute Toxicity Estimates)		
Oral	LD50	6,326 mg/kg
Dermal	LD50	70,000 mg/kg
Inhalative	LC50/4 h	200 mg/l
56-81-5 Glycerin		
Oral	LD50	7,750 mg/kg (guinea pig)
		4,100 mg/kg (mouse)
		5,570 mg/kg (rat)
		27,000 mg/kg (rabbit)
	LC50 Fish	>5,000 mg/l (Fish)
Dermal	LD50	>21,900 mg/kg (rat)
		10,000 mg/kg (rabbit)
124-43-6 Carbamide Peroxide		
Oral	LD50	>2,000 mg/kg (rat)
7722-84-1 Hydrogen Peroxide		
Oral	LC50 Fish	16.4 mg/l (Fish)
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)
		2,426 mg/kg (rat)

(Contd. on page 7)

Safety data sheet
according to UK REACH

Trade name: Opalescence™ PF 35%-(All Flavors)

(Contd. of page 6)

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.
· **Information on other hazards**

· **Endocrine disrupting properties**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**	
56-81-5 Glycerin	
EC50	>10,000 mg/kg (Bacteria)
7722-84-1 Hydrogen Peroxide	
EC50	1.38 mg/l (Algae)
	2.4 mg/l (daphnia)
1310-73-2 Sodium Hydroxide	
EC50	40.38 mg/kg (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.
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.
· **Other adverse effects**
· **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.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of contents/container in accordance with international, federal, state, and local regulations.

(Contd. on page 8)

Safety data sheet
according to UK REACH

(Contd. of page 7)

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN number or ID number**	
· **ADR, ADN, IMDG, IATA**	not regulated
· **UN proper shipping name**	
· **ADR, ADN, 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
· **Maritime transport in bulk according to IMO instruments**	Not applicable.
· **UN "Model Regulation":**	not regulated

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **Poisons Act**

· **Regulated explosives precursors**

7722-84-1	Hydrogen Peroxide	12%

· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

7757-79-1	Potassium Nitrate	Listed

· **Reportable poisons**

1310-73-2	Sodium Hydroxide	12% of total caustic alkalinity
7681-49-4	Sodium Fluoride	Listed

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.
· **Chemical safety assessment:**
Device is biocompatible when used as directed by dental professionals per ISO 10993-1

(Contd. on page 9)

Safety data sheet
according to UK REACH

(Contd. of page 8)

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 from Section 3**
H226 Flammable liquid and vapour.
H271 May cause fire or explosion; strong oxidiser.
H272 May intensify fire; oxidiser.
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H304 May be fatal if swallowed and enters airways.
H310 Fatal 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.
H411 Toxic to aquatic life with long lasting effects.
EUH032 Contact with acids liberates very toxic gas.

· **Department issuing SDS:** Environmental, Health, and Safety
· **Contact:** Customer Service
· **Abbreviations and acronyms:**
ADR: Accord relatif au transport international 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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
ATE: Acute toxicity estimate values
Flam. Liq. 3: Flammable liquids – Category 3
Ox. Liq. 1: Oxidizing liquids – Category 1
Ox. Sol. 3: Oxidizing solids – Category 3
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 2: Acute toxicity – Category 2
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
Asp. Tox. 1: Aspiration hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
· *** Data compared to the previous version altered.**