

Printing date 03/19/2025 Reviewed on 03/19/2025

#### 1 Identification

- · Product identifier
- · Trade name: Opalescence<sup>TM</sup> Quick PF 45%
- · Article number: SDS 89-001.12R01, 15073, 10817, 13691, 14544, 15292
- · 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

- · Information department: Customer Service
- · Emergency telephone number:

CHEMTREC (NORTH AMERICA): +1 (800) 424-9300 (INTERNATIONAL): +(703) 527-3887

#### 2 Hazard(s) identification

· Classification of the substance or mixture



GHS07

Acute Toxicity - Oral 4 H302 Harmful if swallowed. Skin Irritation 2 H315 Causes skin irritation.

Eye Irritation 2A H319 Causes serious eye irritation.

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

- · Label elements
- · GHS label elements Void
- · Hazard pictograms GHS07
- · Signal word Warning
- · Health Hazard-determining components of labeling:

Hydrogen Peroxide

Sodium Hydroxide

Sodium Fluoride

Oils, Peppermint

· Hazard statements

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapors/spray

*P264* Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P272 Contaminated work clothing must not be allowed out of the workplace.

*P280* Wear protective gloves / eye protection / face protection.

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# Safety Data Sheet acc. to OSHA HCS

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P301+P312 If swallowed: Call a poison center/doctor if you feel unwell.

*P330* Rinse mouth.

*P302+P352 If on skin: Wash with plenty of water.* 

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing.

P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P321 Specific treatment (see on this label).

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

*Wash contaminated clothing before reuse.* 

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· Classification system:

· NFPA ratings (scale 0 - 4)



Health = 2 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



#### 3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · **Description:** Mixture of the substances listed below with nonhazardous additions.
- · Dangerous components:

None

	Glycerin	>10-≤25%
124-43-6	Carbamide Peroxide	>10-≤25%
	Hydrogen Peroxide	≥8-<10%
	Polyacrylic Acid	1-10%
25322-68-3	Polyethylene Glycol	1-10%
	Sodium Hydroxide	≥3-<5%
7757-79-1	Potassium Nitrate	≥1-<10%
7681-49-4	Sodium Fluoride	≥1-<10%
8006-90-4	Oils, Peppermint	≥0.1-<1%

#### 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.

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· After inhalation:

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

Supply fresh air and to be sure call for a doctor.

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

· After skin contact:

If skin irritation continues, consult a doctor.

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 swallowed in large quantities seek medical attention.

Immediately call a doctor.

- · 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 Fire-fighting measures

- · Extinguishing media
- Suitable extinguishing agents:

Water spray

Use fire fighting measures that suit the environment.

- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: Wear self-contained 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).

Dispose contaminated material as waste according to section 13.

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

- · Handling:
- · Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- · Information about protection against explosions and fires: 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.

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· Further information about storage conditions:

See product labelling.

Keep receptacle tightly sealed.

· Specific end use(s) Professional Dental Teeth Whitening Gel

#### 8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see section 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace:

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

-5 Glycerin		
Long-term value: 15* 5** mg/m³		
mist; *total dust **respirable fraction		
TLV withdrawn-insufficient data human occup. exp.		
4-1 Hydrogen Peroxide		
Long-term value: 1.4 mg/m³, 1 ppm		
Long-term value: 1.4 mg/m³, 1 ppm		
Long-term value: 1 ppm		
A3		
1-4 Polyacrylic Acid		
Short-term value: 0.05 mg/m³		
68-3 Polyethylene Glycol		
Long-term value: 10 mg/m³		
(H); MW>200		
1310-73-2 Sodium Hydroxide		
Long-term value: 2 mg/m³		
Ceiling limit value: 2 mg/m³		
Ceiling limit value: 2 mg/m³		

- Additional information: The lists that were valid during the creation 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.

Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· Protection of hands:



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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 is based 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 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	
Color:	Colorless	
· Odor:	Mint	
· Odor threshold:	Not determined.	
· pH-value at 20 °C:	5.6-7.2	
· Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined	
· Flash point:	Not applicable	
· Flammability:	Not applicable.	
· Decomposition temperature:	Not determined.	
· Ignition temperature:	Product is not selfigniting.	
· Danger of explosion:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not determined.	
Density at 20 °C:	$1.27 \text{ g/cm}^3$	
· Relative density	Not determined	
· Vapor density	Not determined.	
· Evaporation rate	Not determined.	
	(0.11	

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· Solubility in / Miscibility with	1	
Water:	Partly soluble	
· Partition coefficient (n-octan	ol/water): Not determined.	
· Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined	
· Other information	No further relevant information available.	

#### 10 Stability and reactivity

LC50 Fish

25322-68-3 Polyethylene Glycol LD50

Oral

Oral

- · 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.

Informati Acute tox	on on toxicological ej icity:	ffects		
	values that are relevant for classification:			
ATE (Acı	ite Toxicity Estimate)			
Oral	LD50	1,569-2,051 mg/kg		
Dermal	LD50	11,602 mg/kg		
Inhalative	LC50/4 h	120 mg/l		
56-81-5 G	lycerin	·		
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-	Hydrogen Peroxide	•		
Oral	LC50 Fish	16.4 mg/l (Fish)		

580 mg/l (Fish)

19,600 mg/kg (guinea pig)

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		17,300 mg/kg (mouse)
		>10,000 mg/kg (rat)
	LC50 Fish	>100 mg/l (Fish)
Dermal	LD50	>20,000 mg/kg (rabbit)
	LC50(Daphnia magna)	>10,000 mg/l (Water Flea) (Toxicity to aquatic invertebrates)
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)
7757-79-	1 Potassium Nitrate	
Oral	LD50	3,015 mg/kg (rat)
		1,901 mg/kg (rabbit)
	LC50 Fish	1,378 mg/l (Fish)
Dermal	LD50	>5,000 mg/kg (rat)
	LC50(Daphnia magna)	490 mg/l (daphnia)
7681-49-	4 Sodium Fluoride	
Oral	LD50	52 mg/kg (mouse)
	LC50 Fish (static)	17 mg/l (Fish)
Dermal	LD50	175 mg/kg (rat)
8006-90-	4 Oils, Peppermint	
Oral	LD50	2,490 mg/kg (mouse)
		2,426 mg/kg (rat)

- · Primary irritant effect:
- · on the skin: Irritant to skin and mucous membranes.
- · on the eye: Irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations: Harmful Irritant

· Carcinogenic categories

· IARC (Inte	· IARC (International Agency for Research on Cancer)		
7722-84-1	Hydrogen Peroxide	3	
9003-01-4	Polyacrylic Acid	3	
7681-49-4	Sodium Fluoride	3	
· NTP (Natio	· NTP (National Toxicology Program)		
None of the	None of the ingredients is listed.		
· OSHA-Ca (Occupational Safety & Health Administration)			
None of the	e ingredients is listed.		

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#### 12 Ecological information

· Toxicity		
· Aquatic toxicity:		
56-81-5 Glycerin		
EC50	>10,000 mg/kg (Bacteria)	
7722-84-1 Hydrogen I	Peroxide Peroxide	
EC50	1.38 mg/l (Algae)	
	2.4 mg/l (daphnia)	
9003-01-4 Polyacrylic Acid		
EC50	174 mg/kg (daphnia)	
1310-73-2 Sodium Hydroxide		
EC50	40.38 mg/kg (Water Flea)	
7681-49-4 Sodium Fli	uoride	
EC50	272 mg/kg (Algae)	
	98 mg/kg (daphnia)	
Algae Toxicity (static)	7 mg/l (Algae)	

- · **Persistence and degradability** No further relevant information available.
- Behavior 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 (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.

#### 13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

Dispose of contents/container in accordance with international, federal, state, and local regulations.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

#### 14 Transport information

	UN-Number
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· DOT, ADN, IMDG, IATA Not Regulated

· UN proper shipping name

· DOT, ADN, IMDG, IATA Not Regulated

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· Transport hazard class(es)		
· DOT, ADN, IMDG, IATA · Class	Not Regulated	
· Packing group · DOT, IMDG, IATA	Not Regulated	
· Environmental hazards:	Not Applicable.	
· Special precautions for user	Not Applicable	
· Transport in bulk according to Annex MARPOL73/78 and the IBC Code	<b>II of</b> Not Applicable.	
· UN "Model Regulation":	Not Regulated	

#### 15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.

· Sara
· Section 355 (extremely hazardous substances):

7722-84-1 Hydrogen Peroxide

Section 313 (Specific toxic chemical listings):

7757-79-1 Potassium Nitrate

· TSCA (Toxic Substances Control Act):		
	Glycerin	ACTIVE
124-43-6	Carbamide Peroxide	ACTIVE
7722-84-1	Hydrogen Peroxide	ACTIVE
9003-01-4	Polyacrylic Acid	ACTIVE
	Polyethylene Glycol	ACTIVE
	Sodium Hydroxide	ACTIVE
7757-79-1	Potassium Nitrate	ACTIVE
7681-49-4	Sodium Fluoride	ACTIVE
8006-90-4	Oils, Peppermint	ACTIVE

#### · Hazardous Air Pollutants

None of the ingredients is listed.

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

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#### · Carcinogonic categories

Carcinogenic Categories		
· EPA (Env	ronmental Protection Agency)	
None of the	e ingredients is listed.	
· ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)		
7722-84-1	Hydrogen Peroxide	A3
7681-49-4	Sodium Fluoride	A4
· NIOSH-Ca (National Institute for Occupational Safety and Health)		

None of the ingredients is listed.

· Chemical safety assessment:

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

#### 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.

- · Department issuing SDS: Environmental, Health, and Safety
- · Contact: Customer Service
- · Date of preparation / last revision 03/19/2025 / -
- · Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Toxicity - Oral 4: Acute toxicity - Category 4

Skin Irritation 2: Skin corrosion/irritation – Category 2

Eye Irritation 2A: Serious eye damage/eye irritation - Category 2A

Sensitization - Skin 1: Skin sensitisation - Category 1

\* Data compared to the previous version altered.