

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/05/2024

Reviewed on 09/05/2024

1 Identification

- **Product identifier**
- **Trade name:** *Opalescence™ Home Advanced Tooth Whitening 10%*
- **Article number:** SDS 499-001.01R01, 1008679, 1012433, 5477, 5821-US, 6005-US, 6007-US
- **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) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS07

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

- **Label elements**
- **GHS label elements** The product is classified according to the Globally Harmonized System (GHS)
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Health Hazard-determining components of labeling:**
Oils, Peppermint
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
P302+P352 If on skin: Wash with plenty of water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
P363 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 = 1
Fire = 0
Reactivity = 0

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· **HMIS-ratings (scale 0 - 4)**

HEALTH	1	Health = 1
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

3 Composition/information on ingredients

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

· **Dangerous components:**

56-81-5	Glycerin	>20-<40%
7722-84-1	Hydrogen Peroxide	9.5-11.6%
	Trade Secret	>1-<20%
1310-58-3	Potassium Hydroxide	>1-<10%
7758-11-4	Dipotassium Phosphate	>1-<10%
8006-90-4	Oils, Peppermint	<1%
7681-49-4	Sodium Fluoride	<1%

· **Additional information:**

The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.

4 First-aid measures

- **Description of first aid measures**
- **After inhalation:**
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:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult 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:** 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:** No special measures required.

6 Accidental release measures

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

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- **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 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**
See product labeling.
Ensure good ventilation/exhaustion at the workplace.
- **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.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

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.

56-81-5 Glycerin

PEL	Long-term value: 15* 5** mg/m ³ mist; *total dust **respirable fraction
TLV	TLV withdrawn-insufficient data human occup. exp.

7722-84-1 Hydrogen Peroxide

PEL	Long-term value: 1.4 mg/m ³ , 1 ppm
REL	Long-term value: 1.4 mg/m ³ , 1 ppm
TLV	Long-term value: 1 ppm A3

Trade Secret

TWA	Short-term value: 0.8 mg/m ³
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1310-58-3 Potassium Hydroxide

REL	Ceiling limit value: 2 mg/m ³
TLV	Ceiling limit value: 2 mg/m ³

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7681-49-4 Sodium Fluoride

PEL	Long-term value: 2.5 mg/m ³ as F
REL	Long-term value: 2.5 mg/m ³ as F
TLV	Long-term value: 2.5 mg/m ³ as F, A4; BEI

· **Ingredients with biological limit values:**

7681-49-4 Sodium Fluoride

BEI	2 mg/L Medium: urine Time: prior to shift Parameter: Fluoride (background, nonspecific)
	3 mg/L Medium: urine Time: end of shift Parameter: Fluoride (background, nonspecific)

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

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

· **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:**



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 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:** Not required.

· **Body protection:** Protective work clothing

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9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form:	Gel
Color:	White Opaque
Odor:	Mint
Odor threshold:	Not determined.

· **pH-value at 20 °C:** 5-7

· **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined

· **Flash point:** Not applicable

· **Flammability:** Not determined.

· **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 applicable.

Density at 20 °C:	1.3 g/cm ³
Relative density	Not determined
Vapor density	Not applicable.
Evaporation rate	Not applicable.

· **Solubility in / Miscibility with**

Water: Not determined.

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

· **Viscosity:**

Dynamic:	Not applicable.
Kinematic:	Not applicable.

· **Other information** No further relevant information available.

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.

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11 Toxicological information

- Information on toxicological effects

- Acute toxicity:

- LD/LC50 values that are relevant for classification:

ATE (Acute Toxicity Estimate)

Oral	LD50	2,705 mg/kg
Dermal	LD50	72,917 mg/kg (rat)
Inhalative	LC50/4 h	>39.7 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)
Inhalative	LC50/4 h	>0.1425 mg/l (rat)

7722-84-1 Hydrogen Peroxide

Oral	LC50 Fish	16.4 mg/l (Fish)
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Trade Secret

Oral	LD50	>15,000 mg/kg (mouse) >3,300 mg/kg (rat)
	LC50 Fish	>10,000 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	0.139 mg/l (rat)

1310-58-3 Potassium Hydroxide

Oral	LD50	214 mg/kg (rat)
	LC50 Fish	80 mg/l (Fish)

7758-11-4 Dipotassium Phosphate

Oral	LD50	4,260-5,700 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.83 mg/l (rat)

8006-90-4 Oils, Peppermint

Oral	LD50	2,490 mg/kg (mouse) 2,426 mg/kg (rat)
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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:

- on the skin: No irritant effect.

- on the eye: No irritating effect.

- Sensitization: Sensitization possible through skin contact.

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· **Additional toxicological information:**

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

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

7722-84-1	Hydrogen Peroxide	3
9003-39-8	Polyvinylpyrrolidone	3
7681-49-4	Sodium Fluoride	3
79-10-7	acrylic acid	3

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

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)
Trade Secret	
EC50	>1,000 mg/kg (daphnia)
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.

· **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 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

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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	
· DOT, IMDG, IATA	Not Regulated
· UN proper shipping name	
· DOT, IMDG, IATA	Not Regulated
· 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 II of MARPOL73/78 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**
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	
79-10-7	acrylic acid	
110-82-7	cyclohexane	
· TSCA (Toxic Substances Control Act):		
56-81-5	Glycerin	ACTIVE
7722-84-1	Hydrogen Peroxide	ACTIVE
1310-58-3	Potassium Hydroxide	ACTIVE
7758-11-4	Dipotassium Phosphate	ACTIVE
8006-90-4	Oils, Peppermint	ACTIVE
7681-49-4	Sodium Fluoride	ACTIVE

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· **Hazardous Air Pollutants**

79-10-7	acrylic acid
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· **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.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

110-82-7	cyclohexane	I
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· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

7722-84-1	Hydrogen Peroxide	A3
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7681-49-4	Sodium Fluoride	A4
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79-10-7	acrylic acid	A4
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· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **Chemical safety assessment:** A chemical safety assessment has not been carried out.

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** 09/05/2024 / -

· **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

BEI: Biological Exposure Limit

Sensitization - Skin 1: Skin sensitisation – Category 1

· *** Data compared to the previous version altered.**