



# Safety Data Sheet

acc. to OSHA HCS

Printing date 03/19/2025

Reviewed on 03/19/2025

## 1 Identification

- **Product identifier**
- **Trade name:** Opal™ by Opalescence™ Prefilled Whitening Trays Gentle
- **Article number:** SDS 367-001.02R01, 1011043, 1011572, 5526
- **Application of the substance / the mixture** Pre-filled Tooth Whitening Treatment
- **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**



- **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** 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**  
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.
- **P272** Contaminated work clothing must not be allowed out of the workplace.
- **P280** Wear protective gloves / eye protection / face protection.
- **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).

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



- **HMIS-ratings (scale 0 - 4)**

HEALTH	2	Health = 2
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	>30-<50%
7722-84-1	Hydrogen Peroxide	>1-<7%
1310-58-3	Potassium Hydroxide	>1-<10%
	Trade Secret	>0.1-<5%
7758-11-4	Dipotassium Phosphate	>0.1-<5%
8006-90-4	Oils, Peppermint	<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**
- **General information:** Immediately remove any clothing soiled by the product.
- **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. If symptoms persist, consult a doctor.
- **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.

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## 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.
- **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:** Keep receptacle tightly sealed.
- **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 <sup>3</sup> mist; *total dust **respirable fraction
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TLV	TLV withdrawn-insufficient data human occup. exp.
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### 7722-84-1 Hydrogen Peroxide

PEL	Long-term value: 1.4 mg/m <sup>3</sup> , 1 ppm
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REL	Long-term value: 1.4 mg/m <sup>3</sup> , 1 ppm
TLV	Long-term value: 1 ppm A3
<b>1310-58-3 Potassium Hydroxide</b>	
REL	Ceiling limit value: 2 mg/m <sup>3</sup>
TLV	Ceiling limit value: 2 mg/m <sup>3</sup>
<b>Trade Secret</b>	
TWA	Short-term value: 0.8 mg/m <sup>3</sup>

· **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:**



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:**



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

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· <b>Color:</b>	White Opaque
· <b>Odor:</b>	Mint
· <b>Odor threshold:</b>	Not determined.
· <b>pH-value at 20 °C:</b>	5-7
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined
· <b>Flash point:</b>	Not applicable
· <b>Flammability:</b>	Not determined.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not applicable.
· <b>Density at 20 °C:</b>	1.3 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined
· <b>Vapor density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with</b>	
<b>Water:</b>	Partly miscible.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Other information</b>	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	4,265 mg/kg
Inhalative	LC50/4 h	>47.4 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)
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)

### 7722-84-1 Hydrogen Peroxide

Oral	LC50 Fish	16.4 mg/l (Fish)
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### 1310-58-3 Potassium Hydroxide

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

### 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

### 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)

- **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:  
Irritant

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· **Carcinogenic categories**

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

7722-84-1	Hydrogen Peroxide	3
9003-39-8	Polyvinylpyrrolidone	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)

· **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.

## 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.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

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## 14 Transport information

<b>· UN-Number</b>	
<b>· DOT, IMDG, IATA</b>	Not Regulated
<b>· UN proper shipping name</b>	
<b>· DOT, ADN, IMDG, IATA</b>	Not Regulated
<b>· Transport hazard class(es)</b>	
<b>· DOT, ADN, IMDG, IATA</b>	
<b>· Class</b>	Not Regulated
<b>· Packing group</b>	
<b>· DOT, IMDG, IATA</b>	Not Regulated
<b>· Environmental hazards:</b>	Not Applicable.
<b>· Special precautions for user</b>	Not Applicable
<b>· Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not Applicable.
<b>· UN "Model Regulation":</b>	Not Regulated

## 15 Regulatory information

<b>· Safety, health and environmental regulations/legislation specific for the substance or mixture</b>		
No further relevant information available.		
<b>· Sara</b>		
<b>· Section 355 (extremely hazardous substances):</b>		
7722-84-1	Hydrogen Peroxide	
<b>· Section 313 (Specific toxic chemical listings):</b>		
79-10-7	acrylic acid	
110-82-7	cyclohexane	
<b>· TSCA (Toxic Substances Control Act):</b>		
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
<b>· Hazardous Air Pollutants</b>		
79-10-7	acrylic acid	
<b>· Proposition 65</b>		
<b>· Chemicals known to cause cancer:</b>		
None of the ingredients is listed.		
<b>· Chemicals known to cause reproductive toxicity for females:</b>		
None of the ingredients is listed.		
<b>· Chemicals known to cause reproductive toxicity for males:</b>		
None of the ingredients is listed.		

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· **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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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** 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

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.**