

Safety Data Sheet
acc. to OSHA HCS

Printing date 06/29/2022

Reviewed on 06/29/2022

1 Identification

- **Product identifier**
- **Trade name:** *Opalescence™ Office-Mixed*
- **Article number:** SDS 351-001.04, 71195, 71194
- **Application of the substance / the mixture** *Professional Dental Bleaching 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) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887*

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS07

Eye Irritation 2A H319 Causes serious eye irritation.

- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *GHS07*
- **Signal word** *Warning*
- **Hazard statements**
H319 Causes serious eye irritation.
- **Precautionary statements**
*P264 Wash thoroughly after handling.
P280 Wear eye protection / face protection.
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention.*
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**
- | | | |
|------------|---|----------------|
| HEALTH | 2 | Health = 2 |
| FIRE | 0 | Fire = 0 |
| REACTIVITY | 0 | Reactivity = 0 |

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3 Composition/information on ingredients

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

· Dangerous components:		
56-81-5	Glycerin	≥10-<60%
7722-84-1	Hydrogen Peroxide	≥1-<5%
	Trade Secret	1-10%
9003-01-4	Polyacrylic Acid	1-10%
1310-73-2	Sodium Hydroxide	<1%
7681-49-4	Sodium Fluoride	<10%

- **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:** This product is a viscous gel, therefore chance of inhalation is very low.
- **After skin contact:** Generally the product does not irritate the skin.
- **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.

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

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7 Handling and storage

- **Handling:**
- **Precautions for safe handling** See product labeling.
- **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:**
See product labelling.
Keep receptacle tightly sealed.
- **Specific end use(s)** Professional Dental Bleaching Gel

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 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 remaining constituent has 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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9003-01-4 Polyacrylic Acid

TWA	Short-term value: 0.05 mg/m ³
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1310-73-2 Sodium Hydroxide

PEL	Long-term value: 2 mg/m ³
REL	Ceiling limit value: 2 mg/m ³
TLV	Ceiling limit value: 2 mg/m ³

- **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.

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Avoid contact with the eyes and skin.

- **Breathing equipment:** Not required.
- **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
Color:	Red-brown
· Odor:	Odorless
· Odor threshold:	Not determined.

- **pH-value at 20 °C:** 6.8-8.2

- **Change in condition**

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

- **Flash point:** Not applicable

- **Flammability (solid, gaseous):** Not applicable.

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

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· Vapor pressure:	Not determined.
· Density at 20 °C:	1.2-1.3 g/cm ³
· Relative density	Not determined
· Vapor 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:	57.5 %
Water:	34.8 %
VOC content:	0.00 %
	0.0 g/l / 0.00 lb/gal
VOC (EC)	0.00 %
Solids content:	≤5.0 %
· 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.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:		
ATE (Acute Toxicity Estimate)		
Oral	LD50	8,171-9,098 mg/kg
Dermal	LD50	69,832 mg/kg (rat)
Inhalative	LC50/4 h	407 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)

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Dermal	LC50 Fish	>5,000 mg/l (Fish)
	LD50	>21,900 mg/kg (rat) 10,000 mg/kg (rabbit)
7722-84-1 Hydrogen Peroxide		
Oral	LC50 Fish	16.4 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	0.139 mg/l (rat)
9003-01-4 Polyacrylic Acid		
Oral	LC50 Fish	580 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)
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:** Irritating effect.

- **Sensitization:** No sensitizing effects known.

- **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
9003-01-4	Polyacrylic Acid	3
9003-39-8	Polyvinylpyrrolidone	3
7681-49-4	Sodium Fluoride	3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

None of the 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 Peroxide	
EC50	1.38 mg/l (Algae) 2.4 mg/l (daphnia)
Trade Secret	
EC50	>1,000 mg/kg (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 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.

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, ADN, IMDG, IATA** Not Regulated

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· **UN proper shipping name**
 · **DOT, ADN, 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 MARPOL 73/78 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
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· **Section 313 (Specific toxic chemical listings):**

7757-79-1	Potassium Nitrate
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· **TSCA (Toxic Substances Control Act):**

56-81-5	Glycerin	ACTIVE
7722-84-1	Hydrogen Peroxide	ACTIVE
9003-01-4	Polyacrylic Acid	ACTIVE
1310-73-2	Sodium Hydroxide	ACTIVE
7681-49-4	Sodium Fluoride	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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· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the 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:**

The product meets 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.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Date of preparation / last revision** 06/29/2022 / -

· **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)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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

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