

Safety Data Sheet
acc. to OSHA HCS

Printing date 10/08/2020

Reviewed on 10/08/2020

1 Identification

- **Product identifier**
- **Trade name:** Opalescence™ Endo
- **Article number:** 35263
- **Index number:** SDS 74-001.10
- **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**



GHS05 Corrosion

Eye Dam. 1 H318 Causes serious eye damage.



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

Acute Tox. 4 H332 Harmful if inhaled.

Skin Irrit. 2 H315 Causes skin irritation.

STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

- **Label elements**
- **GHS label elements**
Medical Devices, Cosmetics, and Drugs are exempt from the labeling requirements of the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS05, GHS07
- **Signal word** Danger
- **Hazard-determining components of labeling:**
Hydrogen Peroxide
- **Hazard statements**
Harmful if swallowed or if inhaled.
Causes skin irritation.
Causes serious eye damage.
May cause respiratory irritation. May cause drowsiness or dizziness.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P264 Wash thoroughly after handling.

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- P270 Do not eat, drink or smoke when using this product.
 P271 Use only outdoors or in a well-ventilated area.
 P280 Wear protective gloves / eye protection / face protection.
 P301+P312 If swallowed: Call a poison center/doctor if you feel unwell.
 P302+P352 If on skin: Wash with plenty of water.
 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.
 P310 Immediately call a poison center/doctor.
 P321 Specific treatment (see on this label).
 P330 Rinse mouth.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P332+P313 If skin irritation occurs: Get medical advice/attention.
 P403+P233 Store in a well-ventilated place. Keep container tightly closed.
 P405 Store locked up.
 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	3	Health = 3
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

· **Other hazards**· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.

3 Composition/information on ingredients

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

7722-84-1	Hydrogen Peroxide Ox. Liq. 1, H271; Skin Corr. 1A, H314; Acute Tox. 4, H302; Acute Tox. 4, H332	<40%
25322-68-3	Polyethylene Glycol	>10-≤25%

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. 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.
If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Do not induce vomiting; immediately call for medical help.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** Eye irritant, Skin irritant
- **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
- **Special hazards arising from the substance or mixture**
In closed unventilated containers, risk of rupture due to the increased pressure from decomposition. Contact with combustible material may cause fire.
- **Advice for firefighters**
Use water spray to cool fire exposed surfaces and protect personnel. Move containers from fire area if there isn't any risk.
- **Protective equipment:**
Wear fully protective suit.
Mouth respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Keep people at a distance and stay on the windward side.
Keep away from ignition sources
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Hydrogen Peroxide may be decomposed by adding sodium metabisulfite or sodium sulfite after diluting to about 5%.
Stop the flow of material, if this is without risk.
Combustible materials exposed to hydrogen peroxide should be immediately submerged in or rinsed with large amounts of water to ensure that all hydrogen peroxide is removed. Residual hydrogen peroxide that is allowed to dry (upon evaporation hydrogen peroxide can concentrate) on organic materials such as paper, fabrics, cotton, leather, wood or other combustibles can cause the material to ignite and result in fire.
Dilute with plenty water.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 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.

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· Protective Action Criteria for Chemicals

· PAC-1:		
7722-84-1	Hydrogen Peroxide	10 ppm
25322-68-3	Polyethylene Glycol	30 mg/m ³
1310-58-3	Potassium Hydroxide	0.18 mg/m ³
· PAC-2:		
7722-84-1	Hydrogen Peroxide	50 ppm
25322-68-3	Polyethylene Glycol	1,300 mg/m ³
1310-58-3	Potassium Hydroxide	2 mg/m ³
· PAC-3:		
7722-84-1	Hydrogen Peroxide	100 ppm
25322-68-3	Polyethylene Glycol	7,700 mg/m ³
1310-58-3	Potassium Hydroxide	54 mg/m ³

7 Handling and storage

· Handling:

· Precautions for safe handling

Keep away from heat and direct sunlight.

Safety glasses should be used by the patient and doctor. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EN).

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· Information about protection against explosions and fires:

Combustible materials exposed to hydrogen peroxide should be immediately submerged in or rinsed with large amounts of water to ensure that all hydrogen peroxide is removed. Residual hydrogen peroxide that is allowed to dry (upon evaporation hydrogen peroxide can concentrate) on organic materials such as paper, fabrics, cotton, leather, wood or other combustibles can cause the material to ignite and result in fire.

Keep respiratory protective device available.

Protect from heat.

· Conditions for safe storage, including any incompatibilities

· Storage:

· Requirements to be met by storerooms and receptacles:

Suitable material for receptacles and pipes: Stainless steel.

Suitable material for receptacles and pipes: glass.

Suitable material for receptacles and pipes: Aluminium.

Store only in the original receptacle.

Provide ventilation for receptacles.

Store in a cool location.

· Information about storage in one common storage facility:

Store away from reducing agents.

Store away from combustible materials.

Store away from metals.

· Further information about storage conditions:

Store receptacle in a well ventilated area.

Store in a cool place.

See product labelling.

Keep receptacle tightly sealed.

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· **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:**

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: 1.4 mg/m ³ , 1 ppm

25322-68-3 Polyethylene Glycol

WEEL	Long-term value: 10 mg/m ³ (H); MW>200
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· **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 skin.

Avoid contact with the eyes and skin.

· **Breathing equipment:** Use suitable respiratory protective device when high concentrations are present.· **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

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· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

Form:	Gel
Color:	Whitish
Odor:	Odorless
Odor threshold:	Not determined.

· **pH-value:** 3-5· **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.

· **Vapor pressure:** Not determined.

Density at 20 °C:	1.23 g/cm ³
Relative density	Not determined
Vapor density	Not determined.
Evaporation rate	Not determined.

· **Solubility in / Miscibility with**

Water:	Partially soluble
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· **Partition coefficient (n-octanol/water):** Not determined.· **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined

· **Solvent content:**

Water:	< 50 %
VOC content:	0.00 %
	0.0 g/l / 0.00 lb/gal
VOC (EC)	0.00 %

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

10 Stability and reactivity

· **Reactivity** Reactive and oxidizing agent

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- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *Decomposes when exposed to heat*
- **Possibility of hazardous reactions**
Contact with metals, metallic ions, alkalis, reducing agents and organic matter (such as alcohols or terpenes) may produce self-accelerated thermal decomposition.
Reacts with various metals.
Reacts with organic substances.
- **Conditions to avoid**
pH Variations
UV rays
Contamination
Metals
Water, Moist Air
Heat
Avoid strong bases, metals, excess heat, exposure to moist air or water
- **Incompatible materials:**
Heavy Metals
Reducing Agents
Combustible Materials
Organic materials
Strong caustics, most metals
- **Hazardous decomposition products:** *Oxygen*

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:**
- | | | |
|---|----------|--------------|
| · LD/LC50 values that are relevant for classification: | | |
| ATE (Acute Toxicity Estimate) | | |
| Oral | LD50 | >1,366 mg/kg |
| Inhalative | LC50/4 h | 1.47 mg/l |
- **Primary irritant effect:**
 - **on the skin:** *Irritant to skin and mucous membranes.*
 - **on the eye:** *Strong irritant with the danger of severe eye injury.*
 - **Additional toxicological information:**

- **Carcinogenic categories**

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

7722-84-1	Hydrogen Peroxide	3
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- **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:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*

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- **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.
Must not reach bodies of water or drainage ditch undiluted or unneutralized.
- **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:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|--|---|
| <ul style="list-style-type: none"> · UN-Number · DOT · IMDG, IATA | <p>UN2922</p> <p>UN1760</p> |
| <ul style="list-style-type: none"> · UN proper shipping name · DOT · IMDG · IATA | <p><i>Corrosive liquids, n.o.s. (Hydrogen peroxide, stabilized)</i></p> <p>CORROSIVE LIQUID, N.O.S. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, STABILIZED)</p> <p>CORROSIVE LIQUID, N.O.S. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, STABILIZED)</p> |
| <ul style="list-style-type: none"> · Transport hazard class(es) · DOT | <p></p> |
| <ul style="list-style-type: none"> · Class · Label | <p>8 Corrosive substances</p> <p>8, 6.1</p> |
| <ul style="list-style-type: none"> · IMDG, IATA | <p></p> |
| <ul style="list-style-type: none"> · Class | <p>8 Corrosive substances</p> |

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· Label	8
· Packing group · DOT, IMDG, IATA	II
· Environmental hazards:	Not applicable.
· Special precautions for user · Hazard identification number (Kemler code): 86 · EMS Number: · Segregation groups · Stowage Category · Stowage Code	Warning: Corrosive substances F-A,S-B Peroxides B SW2 Clear of living quarters.
· Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1760 CORROSIVE LIQUID, N.O.S. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, STABILIZED), 8, II

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- Sara

· **Section 355 (extremely hazardous substances):**

7722-84-1 Hydrogen Peroxide

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All components have the value 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.

- **TLV (Threshold Limit Value established by ACGIH)**

7722-84-1 Hydrogen Peroxide

A3

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

None of the ingredients is listed.

- **GHS label elements**

Medical Devices, Cosmetics, and Drugs are exempt from the labeling requirements of the Globally Harmonized System (GHS).

- **Hazard pictograms** GHS05, GHS07

- **Signal word** Danger

- **Hazard-determining components of labeling:**

Hydrogen Peroxide

- **Hazard statements**

Harmful if swallowed or if inhaled.

Causes skin irritation.

Causes serious eye damage.

May cause respiratory irritation. May cause drowsiness or dizziness.

- **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.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves / eye protection / face protection.

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

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

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.

P310 Immediately call a poison center/doctor.

P321 Specific treatment (see on this label).

P330 Rinse mouth.

P362+P364 Take off contaminated clothing and wash it before reuse.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

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

- **Chemical safety assessment:**

Product contains high levels of hydrogen peroxide, which has a known toxicological profile. Product is only to be used by licensed dental professionals using the specified engineering controls.

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 & Safety

- **Contact:** Customer Service

- **Date of preparation / last revision** 10/08/2020 / -

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Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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
Ox. Liq. 1: Oxidizing liquids – Category 1
Acute Tox. 4: Acute toxicity – Category 4
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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