

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.11.2022

Version number 11 (replaces version 1)

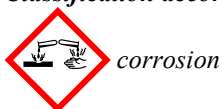
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1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** *Opalescence™ Endo*
- **Article number:** SDS 74-001.11, 35263
- **Relevant identified uses of the substance or mixture and uses advised against** *Professional Dental Bleaching Gel*
- **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*
-
- EC Responsible Person
Ultradent Products GmbH
Am Westhoyer Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Emergency Phone: +49(0)2203-35-92-0*
- **Further information obtainable from:** *Customer Service*
- **Emergency telephone number:**
*CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887*

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



corrosion

Eye Dam. 1 H318 Causes serious eye damage.



Acute Tox. 4 H302 Harmful if swallowed.

Skin Irrit. 2 H315 Causes skin irritation.

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

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *GHS05, GHS07*
- **Signal word** *Danger*
- **Hazard-determining components of labelling:**
Hydrogen Peroxide

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· Hazard statements

- H302 Harmful if swallowed.
 H315 Causes skin irritation.
 H318 Causes serious eye damage.
 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

· Precautionary statements




- P101 If medical advice is needed, have product container or label at hand.
 P102 Keep out of reach of children.
 P103 Read carefully and follow all instructions.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 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.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition/information on ingredients

· Mixtures

· Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

| | | |
|-------------------------------------|--|----------|
| CAS: 7722-84-1 EINECS: 231-765-0 | Hydrogen Peroxide  Ox. Liq. 1, H271;  Skin Corr. 1A, H314;  Acute Tox. 4, H302; Acute Tox. 4, H332 Specific concentration limits: Ox. Liq. 1; H271: C ≥ 70 % Ox. Liq. 2; H272: 50 % ≤ C < 70 % Skin Corr. 1A; H314: C ≥ 70 % Skin Corr. 1B; H314: 50 % ≤ C < 70 % Skin Irrit. 2; H315: 35 % ≤ C < 50 % Eye Dam. 1; H318: C ≥ 8 % Eye Irrit. 2; H319: 5 % ≤ C < 8 % STOT SE 3; C ≥ 35 % | >31-<39% |
|-------------------------------------|--|----------|

· Additional information: For the wording of the listed hazard phrases refer to section 16.

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.

· After inhalation:

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

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- **After swallowing:** Call for a doctor immediately.
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Water spray
Use fire extinguishing methods suitable to surrounding conditions.
- **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.

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).
Use neutralising agent.
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.

7 Handling and storage

- **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.

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Prevent formation of aerosols.

- **Information about fire - and explosion protection:**

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.

- **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.

- **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 container tightly sealed.

- **Specific end use(s)** Professional Dental Bleaching Gel

8 Exposure controls/personal protection

- **Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

7722-84-1 Hydrogen Peroxide

| | |
|-----|---|
| WEL | Short-term value: 2.8 mg/m ³ , 2 ppm |
| | Long-term value: 1.4 mg/m ³ , 1 ppm |

- **Additional information:** The lists valid during the making were used as basis.

- **Exposure controls**

- **Appropriate engineering controls** No further data; see item 7.

- **Individual protection measures, such as 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.

- **Respiratory protection:**

Use suitable respiratory protective device when high concentrations are present.

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Hand protection**



Protective gloves

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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 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/face protection**



Tightly sealed goggles

- **Body protection: Protective work clothing**

9 Physical and chemical properties

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

- **General Information**

| | |
|---|------------------------|
| · Physical state | Fluid |
| · Colour: | Clear to White |
| · Odour: | Odourless |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Undetermined. |
| · Boiling point or initial boiling point and boiling range | Undetermined. |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | Not applicable. |
| · Decomposition temperature: | Not determined. |
| · pH at 20 °C | 3-5 |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · Dynamic: | Not determined. |
| · Solubility | |
| · water: | Partly soluble. |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Vapour pressure: | Not determined. |
| · Density and/or relative density | |
| · Density at 20 °C: | 1.23 g/cm ³ |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |

- **Other information**

- **Appearance:**

- **Form:** Paste

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- **Important information on protection of health and environment, and on safety.**
- **Auto-ignition temperature:** *Product is not selfigniting.*
- **Explosive properties:** *Product does not present an explosion hazard.*
- **Change in condition**
- **Evaporation rate** *Not determined.*

- **Information with regard to physical hazard classes**
- **Explosives** *Void*
- **Flammable gases** *Void*
- **Aerosols** *Void*
- **Oxidising gases** *Void*
- **Gases under pressure** *Void*
- **Flammable liquids** *Void*
- **Flammable solids** *Void*
- **Self-reactive substances and mixtures** *Void*
- **Pyrophoric liquids** *Void*
- **Pyrophoric solids** *Void*
- **Self-heating substances and mixtures** *Void*
- **Substances and mixtures, which emit flammable gases in contact with water** *Void*
- **Oxidising liquids** *Void*
- **Oxidising solids** *Void*
- **Organic peroxides** *Void*
- **Corrosive to metals** *Void*
- **Desensitised explosives** *Void*

10 Stability and reactivity

- **Reactivity** *Reactive and oxidizing agent*
- **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
- **Incompatible materials:**
Heavy Metals
Reducing Agents
Combustible Materials
Organic materials
Strong caustics, most metals

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· **Hazardous decomposition products:** Oxygen

11 Toxicological information

- **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Harmful if swallowed.

· **LD/LC50 values relevant for classification:****ATE (Acute Toxicity Estimates)**

| | | |
|------------|----------|-------------|
| Oral | LD50 | 1,418 mg/kg |
| Inhalative | LC50/4 h | 31.2 mg/l |

7722-84-1 Hydrogen Peroxide

| | | |
|------|-----------|------------------|
| Oral | LC50 Fish | 16.4 mg/l (Fish) |
|------|-----------|------------------|

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye damage.
- **STOT-single exposure** May cause respiratory irritation. May cause drowsiness or dizziness.
- **Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**· **Aquatic toxicity:****7722-84-1 Hydrogen Peroxide**

| | |
|------|--------------------|
| EC50 | 1.38 mg/l (Algae) |
| | 2.4 mg/l (daphnia) |

- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.
- **Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (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 sewage water or drainage ditch undiluted or unneutralised.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**

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

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN number or ID number**· **ADR, IMDG, IATA** UN3265· **UN proper shipping name**· **ADR**3265 CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S.
(HYDROGEN PEROXIDE, AQUEOUS SOLUTION,
STABILIZED)· **IMDG, IATA**CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (HYDROGEN
PEROXIDE, STABILIZED)· **Transport hazard class(es)**· **ADR, IMDG, IATA**· **Class**

8 Corrosive substances.

· **Label**

8

· **Packing group**· **ADR, IMDG, IATA**

II

· **Environmental hazards:**

Not applicable.

· **Special precautions for user**

Warning: Corrosive substances.

· **Hazard identification number (Kemler code):** 80· **EMS Number:**

F-A,S-B

· **Segregation groups**

(SGG1) Acids

· **Stowage Category**

B

· **Stowage Code**

SW2 Clear of living quarters.

· **Segregation Code**

SG36 Stow "separated from" SGG18-alkalis.

SG49 Stow "separated from" SGG6-cyanides

· **Maritime transport in bulk according to IMO instruments**

Not applicable.

· **Transport/Additional information:**· **ADR**· **Limited quantities (LQ)**

1L

· **Excepted quantities (EQ)**

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· **Transport category**

2

· **Tunnel restriction code**

E

· **IMDG**· **Limited quantities (LQ)**

1L

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| | |
|-----------------------------------|---|
| · Excepted quantities (EQ) | Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml |
| · UN "Model Regulation": | UN 3265 CORROSIVE LIQUID, ACIDIC, ORGANIC, 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**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **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.

- **Relevant phrases from Section 3**
H271 May cause fire or explosion; strong oxidiser.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H332 Harmful if inhaled.
- **Department issuing SDS:** Environmental, Health, and Safety
- **Contact:** Customer Service
- **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
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
- *** Data compared to the previous version altered.**