

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

Printing date 09.03.2020

Revision: 04.02.2019

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

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



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**
- **Labelling according to Regulation (EC) No 1272/2008**
The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2020

Revision: 04.02.2019

Trade name: Opalescence™ Endo

(Contd. of page 1)

- **Hazard pictograms** GHS05, GHS07
- **Signal word** *Danger*
- **Hazard-determining components of labelling:**
Hydrogen Peroxide
- **Hazard statements**
H302+H332 *Harmful if swallowed or if inhaled.*
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 label before use.*
P261 *Avoid breathing dust/fume/gas/mist/vapours/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.*
P332+P313 *If skin irritation occurs: Get medical advice/attention.*
P362+P364 *Take off contaminated clothing and wash it before reuse.*
P403+P233 *Store in a well-ventilated place. Keep container tightly closed.*
P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 7722-84-1	Hydrogen Peroxide	<40%
EINECS: 231-765-0	⚠ Ox. Liq. 1, H271; ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332	

- **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.

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2020

Revision: 04.02.2019

Trade name: Opalescence™ Endo

(Contd. of page 2)

- **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; call for medical help immediately.
- **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 Firefighting 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.

(Contd. on page 4)

GB2

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2020

Revision: 04.02.2019

Trade name: **Opalescence™ Endo**

(Contd. of page 3)

See Section 13 for disposal information.

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 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.

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 container tightly sealed.

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

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

- **Control parameters**

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

7722-84-1 Hydrogen Peroxide

<i>WEL (Great Britain)</i>	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.

(Contd. on page 5)

GB2

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2020

Revision: 04.02.2019

Trade name: *Opalescence™ Endo*

(Contd. of page 4)

- **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.
- **Respiratory protection:** 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 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
Colour:	Whitish
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value:** 3-5
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Decomposition temperature:** Not determined.

(Contd. on page 6)

GB2

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

Printing date 09.03.2020

Revision: 04.02.2019

Trade name: Opalescence™ Endo

(Contd. of page 5)

· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density at 20 °C:	1.23 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Partially soluble
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Water:	< 50 %
VOC (EC)	0.00 %
· Other information	No further relevant information available.

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

(Contd. on page 7)

GB2

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2020

Revision: 04.02.2019

Trade name: *Opalescence™ Endo*

(Contd. of page 6)

· **Hazardous decomposition products:** *Oxygen*

11 Toxicological information

· **Information on toxicological effects**· **Acute toxicity***Harmful if swallowed or if inhaled.*· **LD/LC50 values relevant for classification:****ATE (Acute Toxicity Estimates)**

Oral	LD50	1,418 mg/kg
Inhalative	LC50/4 h	1.47 mg/l

· **Primary irritant effect:**· **Skin corrosion/irritation***Causes skin irritation.*· **Serious eye damage/irritation***Causes serious eye damage.*· **Respiratory or skin sensitisation** *Based on available data, the classification criteria are not met.*· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**· **Germ cell mutagenicity** *Based on available data, the classification criteria are not met.*· **Carcinogenicity** *Based on available data, the classification criteria are not met.*· **Reproductive toxicity** *Based on available data, the classification criteria are not met.*· **STOT-single exposure***May cause respiratory irritation. May cause drowsiness or dizziness.*· **STOT-repeated exposure** *Based on available data, the classification criteria are not met.*· **Aspiration hazard** *Based on available data, the classification criteria are not met.*

12 Ecological information

· **Toxicity**· **Aquatic toxicity:** *No further relevant information available.*· **Persistence and degradability** *No further relevant information available.*· **Behaviour 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 (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.*· **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 together with household garbage. Do not allow product to reach sewage system.*

(Contd. on page 8)

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

Printing date 09.03.2020

Revision: 04.02.2019

Trade name: Opalescence™ Endo

(Contd. of page 7)

· **European waste catalogue**

HP 6 Acute Toxicity

HP 8 Corrosive

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.**14 Transport information**· **UN-Number**· **ADR, IMDG, IATA**

UN1760

· **UN proper shipping name**· **ADR**

1760 CORROSIVE LIQUID, N.O.S. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, STABILIZED)

· **IMDG**

CORROSIVE LIQUID, N.O.S. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, STABILIZED)

· **IATA**

CORROSIVE LIQUID, N.O.S. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, 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.

· **Danger code (Kemler):**

86

· **EMS Number:**

F-A,S-B

· **Segregation groups**

Peroxides

· **Stowage Category**

B

· **Stowage Code**

SW2 Clear of living quarters.

· **Transport in bulk according to Annex II of Marpol and the IBC Code**

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

(Contd. on page 9)

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

Printing date 09.03.2020

Revision: 04.02.2019

Trade name: Opalescence™ Endo

(Contd. of page 8)

<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p><i>IL</i></p> <p>Code: E2</p> <p>Maximum net quantity per inner packaging: 30 ml</p> <p>Maximum net quantity per outer packaging: 500 ml</p>
<ul style="list-style-type: none"> · UN "Model Regulation": 	<p><i>UN 1760 CORROSIVE LIQUID, N.O.S. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, STABILIZED), 8, II</i></p>

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **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**
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:** Regulatory Affairs
- **Contact:** Customer Service
- **Abbreviations and acronyms:**
ADR: Accord européen sur le transport 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)
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
Ox. Liq. 1: Oxidizing liquids – Category 1
Acute Tox. 4: Acute toxicity - oral – 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