

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

Printing date 21.11.2018

Revision: 27.09.2018

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

- **Product identifier**
- **Trade name:** Opalescence® Boost (38 and 40%) Mixed
- **Article number:** 34567, 15083, 71087
- **Index number:** SDS 199-001.13
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental In-Office Tooth Bleaching Gel
- **Application of the substance / the mixture** Professional Dental In-Office Tooth 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**



GHS07

Skin Irrit. 2 H315 Causes skin irritation.
 Eye Irrit. 2 H319 Causes serious eye 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.
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Hydrogen Peroxide
Potassium Hydroxide

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Hazard statements

- H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 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.
 P280 Wear protective gloves / eye protection / face protection.
 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.
 P405 Store locked up.
 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 EINECS: 231-765-0	Hydrogen Peroxide ⚠ Ox. Liq. 1, H271; ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332	≤40%
CAS: 56-81-5 EINECS: 200-289-5	Glycerine substance with a Community workplace exposure limit	<12%
CAS: 7757-79-1 EINECS: 231-818-8	Potassium Nitrate ⚠ Ox. Sol. 3, H272	≤3%
CAS: 1310-58-3 EINECS: 215-181-3	Potassium Hydroxide ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302	<3%
CAS: 7681-49-4 EINECS: 231-667-8	Sodium Fluoride ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	1.1%
CAS: 25322-68-3 NLP: 500-038-2	Polyethylene Glycol ⚠ Acute Tox. 2, H330	<1%

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.
- **After inhalation:** Seek medical treatment in case of complaints.
- **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.

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- **After swallowing:** Do not induce vomiting; call for medical help immediately.
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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:**
Dilute with plenty of water.
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).
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

- **Handling:**
- **Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** 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 container tightly sealed.
- **Specific end use(s)** Professional Dental In-Office Tooth Bleaching Gel

8 Exposure controls/personal protection

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

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· **Control parameters**

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

7722-84-1 Hydrogen Peroxide	
WEL (Great Britain)	Short-term value: 2.8 mg/m ³ , 2 ppm Long-term value: 1.4 mg/m ³ , 1 ppm
56-81-5 Glycerine	
WEL (Great Britain)	Long-term value: 10 mg/m ³
Synthetic Amorphous, Pyrogenic Silica	
TWA (Great Britain)	Short-term value: 6 mg/m ³
1310-58-3 Potassium Hydroxide	
WEL (Great Britain)	Short-term value: 2 mg/m ³

· **Additional information:** The lists valid during the making 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.

· **Respiratory protection:**

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.

· **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:**

Use chemical splash goggles and face shield(ANSI Z87.1 or approved equivalent)



Tightly sealed goggles

· **Body protection:** Protective work clothing

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9 Physical and chemical properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Gel
Colour:	Red
· Odour:	Odourless
· Odour threshold:	Not determined.
· pH-value at 20 °C:	6-8.5
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C
· Flash point:	>65 °C
· Flammability (solid, gas):	Not applicable.
· Decomposition temperature:	Not determined.
· 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:	1.2-1.4 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	<30 %
Water:	40.0 %
VOC (EC)	0.00 %
Solids content:	<20.0 %
· 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.

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- **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** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral	LD50	861 mg/kg
Dermal	LD50	15,432 mg/kg
Inhalative	LC50/4 h	>1.28 mg/l

56-81-5 Glycerine

Oral	LD50	7,750 mg/kg (Guinea pig) 4,100 mg/kg (mouse) 5,570 mg/kg (rat) 27,000 mg/kg (rabbit)
Dermal	LD50	>5,000 mg/l (Fish) >21,900 mg/kg (rat) 10,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.1425 mg/l (rat)

7757-79-1 Potassium Nitrate

Oral	LD50	3,015 mg/kg (rat) 1,901 mg/kg (rabbit)
Dermal	LD50	1,378 mg/l (Fish) >5,000 mg/kg (rat)
	LC50(Daphnia magna)	490 mg/l (daphnia)

1310-58-3 Potassium Hydroxide

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

25322-68-3 Polyethylene Glycol

Oral	LD50	19,600 mg/kg (Guinea pig) 17,300 mg/kg (mouse) >10,000 mg/kg (rat)
Dermal	LD50	>100 mg/l (Fish) >20,000 mg/kg (rabbit)
Inhalative	LC50/4 h	1.65 mg/l (rat)
	LC50(Daphnia magna)	>10,000 mg/l (Water Flea) (Toxicity to aquatic invertebrates)

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- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **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:	
56-81-5 Glycerine	
EC50	>10,000 mg/l (Bacteria)
	>10,000 mg/l (daphnia)
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.
- **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.
- **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.

· European waste catalogue	
HP 6	Acute Toxicity
HP 8	Corrosive

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- **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	UN3139
· UN proper shipping name · ADR · IMDG · IATA	3139 OXIDIZING LIQUID, N.O.S. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, STABILIZED) OXIDIZING LIQUID, N.O.S. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, STABILIZED) OXIDIZING LIQUID, N.O.S. (HYDROGEN PEROXIDE AQUEOUS SOLUTION, STABILIZED)
· Transport hazard class(es) · ADR, IATA	
	
· Class · Label	5.1 Oxidising substances. 5.1
· IMDG	
	
· Class · Label	5.1 Oxidising substances. 5.1
· Packing group · ADR, IMDG, IATA	II
· Environmental hazards:	Not applicable.
· Special precautions for user · Danger code (Kemler): · EMS Number: · Stowage Category · Segregation Code	Warning: Oxidising substances. 86 F-A,S-Q B SG38 Stow "separated from" ammonium compounds. SG49 Stow "separated from" cyanides SG60 Stow "separated from" peroxides
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.

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· **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

· **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 3139 OXIDIZING LIQUID, N.O.S. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, STABILIZED), 5.1, II

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.

H272 May intensify fire; oxidiser.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H330 Fatal if inhaled.

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)

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*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**Ox. Sol. 3: Oxidizing solids – Category 3**Acute Tox. 3: Acute toxicity – Category 3**Acute Tox. 4: Acute toxicity – Category 4**Acute Tox. 2: Acute toxicity – Category 2**Skin Corr. 1A: Skin corrosion/irritation – Category 1A**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*

GB2