

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

Printing date 06.08.2019

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 199-001.14
- **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**



GHS05 corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.



GHS07

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** GHS05, GHS07

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- **Signal word** *Danger*

- **Hazard-determining components of labelling:**

Hydrogen Peroxide
Potassium Hydroxide

- **Hazard statements**

H314 Causes severe skin burns and eye damage.
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.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
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).
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 | <i>Hydrogen Peroxide</i> ⚠ 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 | <i>Glycerine</i> <i>substance with a Community workplace exposure limit</i> | <12% |
| CAS: 7757-79-1 EINECS: 231-818-8 | <i>Potassium Nitrate</i> ⚠ Ox. Sol. 2, H272; ⚠ Skin Irrit. 2, H315; STOT SE 3, H335-H336 | ≤3% |
| CAS: 1310-58-3 EINECS: 215-181-3 | <i>Potassium Hydroxide</i> ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302 | <3% |
| CAS: 7681-49-4 EINECS: 231-667-8 | <i>Sodium Fluoride</i> ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319 | 1.1% |

- **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.

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- **After inhalation:**
Seek medical treatment in case of complaints.
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. If symptoms persist, 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** 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:** 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.
During heating or in case of fire poisonous gases are produced.
- **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.
Mount respiratory protective device.
Wear protective equipment. Keep unprotected persons away.
- **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:**
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.

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- **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:**
 - 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.
- **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 In-Office Tooth 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 | |
| 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 |

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1310-58-3 Potassium HydroxideWEL (Great Britain) Short-term value: 2 mg/m³

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

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Do not eat or drink while working.

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.

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

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

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| | |
|--|---|
| · 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** Stable under recommended conditions.
- **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
- **Incompatible materials:**
Heavy Metals

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Reducing Agents
Combustible Materials
Alkalis
Organic materials
· **Hazardous decomposition products:** Oxygen

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 | >1.29 mg/l |

7722-84-1 Hydrogen Peroxide

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

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) |
| | | LC50 Fish |
| Dermal | LD50 | >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) | |
| | | LC50 Fish | 1,378 mg/l (Fish) |
| | | Dermal | LD50 |
| | 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) |

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.

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- **CMR effects (carcinogenity, 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:**

7722-84-1 Hydrogen Peroxide

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

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** May be accumulated in organism
- **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** Do not allow product to reach sewage system.

- **European waste catalogue**

| | |
|-----|----------------|
| HP6 | Acute Toxicity |
| HP8 | Corrosive |

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

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· Recommended cleansing agents: Water, if necessary together with cleansing agents.

14 Transport information

| | |
|--|---|
| · UN-Number · ADR, IMDG, IATA | UN3264 |
| · UN proper shipping name · ADR, IMDG · IATA | CORROSIVE LIQUID, ACIDIC, INORGANIC N.O.S. (HYDROGEN PEROXIDE, STABILIZED) CORROSIVE LIQUID, N.O.S. (HYDROGEN PEROXIDE, STABILIZED) |
| · Transport hazard class(es) · ADR, IATA | |
|  | |
| · Class · Label | 8 Corrosive substances. 8 |
| · IMDG | |
|  | |
| · Class · Label | 8 Corrosive substances. 8 |
| · Packing group · ADR, IMDG, IATA | II |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user · Danger code (Kemler): · EMS Number: · Segregation groups · Stowage Category · Stowage Code · Segregation Code | Warning: Corrosive substances. 80 F-A,S-B Acids B SW2 Clear of living quarters. SG38 Stow "separated from" SGG2-ammonium compounds. SG49 Stow "separated from" SGG6-cyanides SG60 Stow "separated from" SGG16-peroxides |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | |
| · ADR · 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 |

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| | |
|-----------------------------------|---|
| · 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 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC N.O.S. (HYDROGEN PEROXIDE, 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.
- **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.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
- **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

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Ox. Liq. 1: Oxidizing liquids – Category 1
Ox. Sol. 2: Oxidizing solids – Category 2
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

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