

Safety Data Sheet
according to WHS Regulations

Printing date 29.09.2023

Revision: 29.09.2023

1 Identification

- **Product identifier**
- **Trade name:** *Opalescence™ Boost (mixed)*
- **Article number:** *SDS 199-001.18R01, 34567, 71087, 1008067*
- **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*

- Ultradent Australia Pty Ltd.
Level 22/2 Market Street
Sydney NSW 2000
Australia
Email: info.anz@ultradent.com
Toll Free: 1-800-290929*
- **Further information obtainable from:** *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**

*flame over circle**Ox. Liq. 2 H272 May intensify fire; oxidizer.**corrosion**Skin Corr. 1A H314 Causes severe skin burns and eye damage.**Eye Dam. 1 H318 Causes serious eye damage.**Acute Tox. 4 H302 Harmful if swallowed.**Flam. Liq. 4 H227 Combustible liquid.*

(Contd. on page 2)

Safety Data Sheet

according to WHS Regulations

Printing date 29.09.2023

Revision: 29.09.2023

Trade name: **Opalescence™ Boost (mixed)**

(Contd. of page 1)

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** GHS03, GHS05, GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**
Hydrogen Peroxide
Potassium Hydroxide
Sodium Fluoride
- **Hazard statements**
H227 Combustible liquid.
H272 May intensify fire; oxidizer.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
- **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.
P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P303+P361+P353 IF ON SKIN (or hair): Remove/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.

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of 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	>36-<50%
56-81-5	Glycerin ⚠ Serious eye damage/irritation – Category 2A, H319	>5-<20%
	Synthetic Amorphous, Pyrogenic Silica	>1-<10%
7757-79-1	Potassium Nitrate ⚠ Ox. Sol. 2, H272; ⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335-H336	>1-<10%
	Potassium Hydroxide ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302	>1-<10%
7681-49-4	Sodium Fluoride ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319	>0.88-<1.320%

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

AU

(Contd. on page 3)

Safety Data Sheet

according to WHS Regulations

Printing date 29.09.2023

Revision: 29.09.2023

Trade name: **Opalescence™ Boost (mixed)**

(Contd. of page 2)

4 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:**

Seek medical treatment in case of complaints.

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:**

Seek immediate medical advice.

Rinse opened eye for several minutes under running water. Then consult a doctor.

- **After swallowing:**

Call for a doctor immediately.

Drink plenty of water and provide fresh air. Call for a doctor 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 Fire Fighting Measures

- **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

(Contd. on page 4)

Safety Data Sheet according to WHS Regulations

Printing date 29.09.2023

Revision: 29.09.2023

Trade name: Opalescence™ Boost (mixed)

(Contd. of page 3)

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

· **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 ignition sources away - Do not smoke.

Keep respiratory protective device available.

· **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 and personal protection

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

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

7722-84-1 Hydrogen Peroxide

WES Long-term value: 1.4 mg/m³, 1 ppm

(Contd. on page 5)

Safety Data Sheet according to WHS Regulations

Printing date 29.09.2023

Revision: 29.09.2023

Trade name: **Opalescence™ Boost (mixed)**

(Contd. of page 4)

56-81-5 GlycerinTWA Short-term value: 10 mg/m³WES Long-term value: 10 mg/m³
inhalable dust**Synthetic Amorphous, Pyrogenic Silica**TWA Short-term value: 2 mg/m³**Potassium Hydroxide**WES Peak limitation: 2 mg/m³

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

· **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

· **General Information**

· **Appearance:**

· **Form:** Gel

(Contd. on page 6)

Safety Data Sheet according to WHS Regulations

Printing date 29.09.2023

Revision: 29.09.2023

Trade name: **Opalescence™ Boost (mixed)**

(Contd. of page 5)

· 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:	Not determined.
· 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.
· 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
Reducing Agents
Combustible Materials
Alkalis
Organic materials
- **Hazardous decomposition products:** Oxygen

AU

(Contd. on page 7)

Safety Data Sheet

according to WHS Regulations

Printing date 29.09.2023

Revision: 29.09.2023

Trade name: Opalescence™ Boost (mixed)

(Contd. of page 6)

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Harmful if swallowed.

· **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)

Oral	LD50	874 mg/kg
Dermal	LD50	15,432 mg/kg
Inhalative	LC50/4 h	27.5 mg/l

7722-84-1 Hydrogen Peroxide

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

56-81-5 Glycerin

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)

Synthetic Amorphous, Pyrogenic Silica

Oral	LD50	>5,000 mg/kg (rat) (Oral Test Method)
	LC50 Fish	>10,000 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (rabbit) (Dermal test method)
	LC50(Daphnia magna)	>1,000-10,000 mg/l (daphnia) (Toxicity to aquatic invertebrates)

7757-79-1 Potassium Nitrate

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

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)

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

(Contd. on page 8)

Safety Data Sheet according to WHS Regulations

Printing date 29.09.2023

Revision: 29.09.2023

Trade name: **Opalescence™ Boost (mixed)**

(Contd. of page 7)

· **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 Glycerin

EC50	>10,000 mg/kg (Bacteria)
------	--------------------------

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**

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

· **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**· **ADG, IMDG, IATA**

UN3093

· **UN proper shipping name**· **ADG**3093 CORROSIVE LIQUID, OXIDIZING, N.O.S.
(HYDROGEN PEROXIDE, AQUEOUS SOLUTION,
STABILIZED, POTASSIUM HYDROXIDE)

(Contd. on page 9)

-AU-

Safety Data Sheet

according to WHS Regulations

Printing date 29.09.2023

Revision: 29.09.2023

Trade name: *Opalescence™ Boost (mixed)*

(Contd. of page 8)

· **IMDG, IATA**

CORROSIVE LIQUID, OXIDIZING, N.O.S. (HYDROGEN PEROXIDE, STABILIZED, POTASSIUM HYDROXIDE)

· **Transport hazard class(es)**· **ADG**· **Class**

8 Corrosive substances.

· **Label**

8+5.1

· **IMDG**· **Class**

8 Corrosive substances.

· **Label**

8/5.1

· **IATA**· **Class**

8 Corrosive substances.

· **Label**

8 (5.1)

· **Packing group**· **ADG, IMDG, IATA**

II

· **Environmental hazards:**

Not applicable.

· **Special precautions for user**

Warning: Corrosive substances.

· **Hazard identification number (Kemler code):**

85

· **EMS Number:**

F-A,S-Q

· **Stowage Category**

E

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

Not applicable.

· **Transport/Additional information:**· **ADG**· **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

(Contd. on page 10)

Safety Data Sheet

according to WHS Regulations

Printing date 29.09.2023

Revision: 29.09.2023

Trade name: **Opalescence™ Boost (mixed)**

(Contd. of page 9)

· 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 3093 CORROSIVE LIQUID, OXIDIZING, N.O.S. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, STABILIZED, POTASSIUM HYDROXIDE), 8 (5.1), II

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Industrial Chemicals**

7722-84-1	Hydrogen Peroxide
7732-18-5	Water
56-81-5	Glycerin
7757-79-1	Potassium Nitrate
	Potassium Hydroxide
7681-49-4	Sodium Fluoride
25322-68-3	Polyethylene Glycol
7235-40-7	Trans Beta Carotene
9003-01-4	Polyacrylic Acid

· **Standard for the Uniform Scheduling of Medicines and Poisons**

7722-84-1	Hydrogen Peroxide	S5, S6, S10
	Potassium Hydroxide	S5, S6, S10

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category P8** OXIDISING LIQUIDS AND SOLIDS

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t

· **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 oxidizer.

H272 May intensify fire; oxidizer.

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.

(Contd. on page 11)

Safety Data Sheet according to WHS Regulations

Printing date 29.09.2023

Revision: 29.09.2023

Trade name: Opalescence™ Boost (mixed)

(Contd. of page 10)

H319 Causes serious eye irritation.
 H332 Harmful if inhaled.
 H335 May cause respiratory irritation.
 H336 May cause drowsiness or dizziness.

· **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

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

Flam. Liq. 4: Flammable liquids – Category 4

Ox. Liq. 1: Oxidizing liquids – Category 1

Ox. Liq. 2: Oxidizing liquids – Category 2

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 Dam. 1: Serious eye damage/eye irritation – Category 1

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· *** Data compared to the previous version altered.**

AU