

Printing date 09/26/2023 Reviewed on 09/26/2023

1 Identification

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

- · Information department: 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



GHS03 Flame over circle

Oxidizing Liquids 2 H272 May intensify fire; oxidizer.



GHS05 Corrosion

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

Eye Damage 1 H318 Causes serious eye damage.



GHS07

Acute Toxicity - Oral 4 H302 Harmful if swallowed.

Flammable Liquids 4 H227 Combustible liquid.

- · Label elements
- · GHS label elements Void
- · Hazard pictograms GHS03, GHS05, GHS07
- · Signal word Danger
- · Health Hazard-determining components of labeling:

Hydrogen Peroxide Potassium Hydroxide Sodium Fluoride

(Contd. on page 2)

Printing date 09/26/2023 Reviewed on 09/26/2023

Trade name: OpalescenceTM Boost (mixed)

(Contd. of page 1)

· Hazard statements

H227 Combustible liquid.

H272 May intensify fire; oxidizer.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

· Precautionary statements

P210 Keep away from flames and hot surfaces. – No smoking.

P210 Keep away from heat.

P220 Keep/Store away from clothing/combustible materials.
P221 Take any precaution to avoid mixing with combustibles.

P260 Do not breathe dusts or mists. P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P312 If swallowed: Call a poison center/doctor if you feel unwell. P301+P330+P331 If swallowed: Rinse mouth. Do NOT induce vomiting.

P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/

shower.

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.
 P321 Specific treatment (see on this label).
 P363 Wash contaminated clothing before reuse.

P370+P378 In case of fire: Use CO2, powder or water spray to extinguish.

P403+P235 Store in a well-ventilated place. Keep cool.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 3 Fire = 3 Reactivity = 0

The substance possesses oxidizing properties.

· HMIS-ratings (scale 0 - 4)



Health = 3 Fire = 3

REACTIVITY 0 Reactivity = 0

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:		
7722-84-1	Hydrogen Peroxide	>36-<50%
56-81-5	Glycerin	>5-<20%
	Synthetic Amorphous, Pyrogenic Silica	>1-<10%
		(Contd. on page 3)

rage 3)

Printing date 09/26/2023 Reviewed on 09/26/2023

Trade name: OpalescenceTM Boost (mixed)

			(Contd. of page 2)
	7757-79-1	Potassium Nitrate	>1-<10%
Ī		Potassium Hydroxide	>1-<10%
Ī	7681-49-4	Sodium Fluoride	>0.88-<1.320%

· Additional information:

The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.

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:

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:

Immediately call a doctor.

Drink copious amounts of water and provide fresh air. Immediately call a doctor.

- · 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

- · 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.

LIC

Printing date 09/26/2023 Reviewed on 09/26/2023

Trade name: OpalescenceTM Boost (mixed)

(Contd. of page 3)

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).

Use neutralizing 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 protection against explosions and fires:

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.

· 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.

(Contd. on page 5)

Printing date 09/26/2023 Reviewed on 09/26/2023

Trade name: OpalescenceTM Boost (mixed)

(Contd. of page 4)

· 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 receptacle tightly sealed.

· Specific end use(s) Professional dental in-office Tooth Bleaching Gel

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace:

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

7722-8	4-1 Hydrogen Peroxide				
PEL	Long-term value: 1.4 mg/m³, 1 ppm				
REL	Long-term value: 1.4 mg/m³, 1 ppm				
TLV	Long-term value: 1 ppm A3				
56-81-5	Glycerin Glycerin				
PEL	Long-term value: 15* 5** mg/m³ mist; *total dust **respirable fraction				
TLV	TLV withdrawn-insufficient data human occup. exp.				
Synther	tic Amorphous, Pyrogenic Silica				
ACGIH	Short-term value: 10* 3 mg/m³				
Potassi	Potassium Hydroxide				
REL	Ceiling limit value: 2 mg/m³				
TLV	Ceiling limit value: 2 mg/m³				

- · Additional information: The lists that were valid during the creation 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.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

(Contd. on page 6)

(Contd. of page 5)

Safety Data Sheet acc. to OSHA HCS

Printing date 09/26/2023 Reviewed on 09/26/2023

Trade name: OpalescenceTM Boost (mixed)

· 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 is based 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

Information on basic physical and	chemical properties	
General Information		
Appearance:		
Form:	Gel	
Color:	Red	
Odor:	Odorless	
Odor threshold:	Not determined.	
pH-value at 20°C:	6-8.5	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	100 °C	
Flash point:	>65 °C	
Flammability (solid, gaseous):	Not applicable.	
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not selfigniting.	
Danger of explosion:	Not determined.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	

(Contd. on page 7)

Reviewed on 09/26/2023 Printing date 09/26/2023

Trade name: OpalescenceTM Boost (mixed)

		(Contd. of page
Vapor pressure:	Not determined.	
Density at 20 °C:	1.2-1.4 g/cm³	
Relative density	Not determined	
· Vapor density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
Water:	Fully miscible.	
Partition coefficient (n-octanol/v	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

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:

· LD/LC50 values that are relevant for classification:				
ATE (Acute Toxicity Estimate)				
Oral	LD50	874 mg/kg		
Dermal	LD50	874 mg/kg 15,432 mg/kg 27.5 mg/l		
Inhalative	LC50/4 h	27.5 mg/l		
7722-84-1	Hydrogen Peroxi			

LC50 Fish 16.4 mg/l (Fish) Oral

(Contd. on page 8)

Printing date 09/26/2023 Reviewed on 09/26/2023

Trade name: OpalescenceTM Boost (mixed)

# C 01 # C	77 •	(Contd. of pa
56-81-5 C	•	
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	>5,000 mg/l (Fish)
Dermal	LD50	>21,900 mg/kg (rat)
		10,000 mg/kg (rabbit)
Synthetic	Amorphous, Pyrogenic S	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-	l Potassium Nitrate	
Oral	LD50	3,015 mg/kg (rat)
		1,901 mg/kg (rabbit)
	LC50 Fish	1,378 mg/l (Fish)
Dermal	LD50	>5,000 mg/kg (rat)
	LC50(Daphnia magna)	490 mg/l (daphnia)
Potassiun	n Hydroxide	
Oral	LD50	214 mg/kg (rat)
	LC50 Fish	80 mg/l (Fish)
7681-49-4	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:
- · on the skin: Strong caustic effect on skin and mucous membranes.
- · on the eye:

Strong caustic effect.

Strong irritant with the danger of severe eye injury.

- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations: Harmful

Corrosive

Irritant

Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

· Carcinogenic categories

· IARC (Int	· IARC (International Agency for Research on Cancer)			
7722-84-1	Hydrogen Peroxide	3		
7681-49-4	Sodium Fluoride	3		
9003-01-4	Polyacrylic Acid	3		
		Contd on page 9)		

(Contd. on page 9)

Printing date 09/26/2023 Reviewed on 09/26/2023

Trade name: OpalescenceTM Boost (mixed)

(Contd. of page 8)

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

· Toxicity

· Aquatic toxicity:						
7722-84-1 Hydrogen I	7722-84-1 Hydrogen Peroxide					
EC50	1.38 mg/l (Algae)					
	2.4 mg/l (daphnia)					
56-81-5 Glycerin	56-81-5 Glycerin					
EC50	>10,000 mg/kg (Bacteria)					
7681-49-4 Sodium Fli	7681-49-4 Sodium Fluoride					
EC50	272 mg/kg (Algae) 98 mg/kg (daphnia)					
	98 mg/kg (daphnia)					
Algae Toxicity (static)	7 mg/l (Algae)					

- · Persistence and degradability No further relevant information available.
- · Behavior 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 (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 bodies of water or drainage ditch undiluted or unneutralized.

- · 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 packagings:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information

- · UN-Number
- · DOT, IMDG, IATA

UN3093

(Contd. on page 10)

Printing date 09/26/2023 Reviewed on 09/26/2023

 $\textit{Trade name: Opalescence}^{\text{TM}} \textit{ Boost (mixed)}$

	(Contd. of pag
UN proper shipping name DOT IMDG, IATA	Corrosive liquids, oxidizing, n.o.s. CORROSIVE LIQUID, OXIDIZING, N.O.S. (HYDROGI
	PEROXIDE, STABILIZED, POTASSIUM HYDROXIDE)
Transport hazard class(es)	
DOT	
OXIDIZER SORROSIVE	
Class	8 Corrosive substances
Label	8, 5.1
IMDG	
(S)	
Class	8 Corrosive substances
Label	8/5.1
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
Class	8 Corrosive substances
Label	8 (5.1)
Packing group	TI.
DOT, IMDG, IATA	II
Environmental hazards:	Not Applicable.
Special precautions for user	Warning: Corrosive substances
Hazard identification number (Kemler code): EMS Number:	85 F-A,S-Q
Stowage Category	E
Transport in bulk according to Annex II of	
MARPOL73/78 and the IBC Code	Not Applicable.
Transport/Additional information:	
DOT	
Quantity limitations	On passenger aircraft/rail: 1 L
~ • • • • • • • • • • • • • • • • • • •	On cargo aircraft only: 30 L
N.C.	
<i>IMDG</i>	

Printing date 09/26/2023 Reviewed on 09/26/2023

Trade name: OpalescenceTM Boost (mixed)

	(Contd. of page 10)
· 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 LIQUIDS, OXIDIZING, N.O.S. (HYDROGEN PEROXIDE AQUEOUS SOLUTIONS, STABILIZED, POTASSIUM HYDROXIDE), 8 (5.1), II

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
- · Sara

· Section 355 (extremely hazardous substances):	
7722-84-1 Hydrogen Peroxide	

· Section 313 (Specific toxic chemical listings):

7757-79-1 Potassium Nitrate

· TSCA (Toxic Substances Co	ntrol Act):
-----------------------------	-------------

15CA (10)	ac Substances Control Acty.	
7722-84-1	Hydrogen Peroxide	ACTIVE
56-81-5	Glycerin	ACTIVE
7757-79-1	Potassium Nitrate	ACTIVE
	Potassium Hydroxide	ACTIVE
7681-49-4	Sodium Fluoride	ACTIVE

· Hazardous Air Pollutants

None of the ingredients is listed.

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

·FPA	(Environmental	Protection	Agonev)

None of the ingredients is listed.

ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)

7722-84-1 Hydrogen Peroxide	A3
7681-49-4 Sodium Fluoride	A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

(Contd. on page 12)

Printing date 09/26/2023 Reviewed on 09/26/2023

Trade name: OpalescenceTM Boost (mixed)

(Contd. of page 11)

· 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.

- · Department issuing SDS: Environmental, Health, and Safety
- · Contact: Customer Service
- · Date of preparation / last revision 09/26/2023
- · Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flammable Liquids 4: Flammable liquids – Category 4

Oxidizing Liquids 2: Oxidizing liquids – Category 2

Acute Toxicity - Oral 4: Acute toxicity - Category 4

Skin Corrosion 1A: Skin corrosion/irritation – Category 1A

Eye Damage 1: Serious eye damage/eye irritation – Category 1

US

^{* *} Data compared to the previous version altered.