

Printing date 09/30/2019 Reviewed on 02/28/2019

1 Identification

· Product identifier

· Trade name: Opalescence™ Boost 35% Non-PF (Mixed)

· Article number: 1005860, 1005861 · Index number: SDS 390-001.02

· 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

· 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



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.

- · Label elements
- · GHS label elements

Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).

- · Hazard pictograms GHS05, GHS07
- · Signal word Danger
- · Hazard-determining components of labeling:

Hydrogen Peroxide

· Hazard statements

Harmful if swallowed or if inhaled.

Causes serious eye damage.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

Wash thoroughly after handling.

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

Use only outdoors or in a well-ventilated area.

Wear eye protection / face protection.

If on skin: Wash with plenty of water.

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IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a poison center/doctor.

If skin irritation occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

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

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



Health = 3 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = 3 Fire = 0Reactivity = 0

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

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

· Dangerous components:		
56-81-5	Glycerine	>25- ≤ 50%
7722-84-1	Hydrogen Peroxide	>10- ≤ 25%
1310-58-3	Potassium Hydroxide	≤2.5%

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:

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.

· 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 No further relevant information available.

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· 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.

· 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.

· Additional information

Move containers from fire area if there isn't any risk.

Cool endangered receptacles with water spray.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Mount respiratory protective device.

Keep away from ignition sources

Keep people at a distance and stay on the windward side.

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).

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.

· Protective Action Criteria for Chemicals

1 Totective	1000 Chemicus	
· <i>PAC-1</i> :		
56-81-5	Glycerine	45 mg/m³
7722-84-1	Hydrogen Peroxide	10 ppm
1310-58-3	Potassium Hydroxide	0.18 mg/m^3
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<i>PAC-2</i> :		
	Glycerine	180 mg/m
7722-84-1	Hydrogen Peroxide	50 ppm
1310-58-3	Potassium Hydroxide	$2 mg/m^3$
PAC-3:		
56-81-5	Glycerine	1,100 mg/m
7722-84-1	Hydrogen Peroxide	100 ppm
1310-58-3	Potassium Hydroxide	54 mg/m^3

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 respiratory protective device available.

- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles:

 $Provide\ ventilation\ for\ receptacles.$

Suitable material for receptacles and pipes: Stainless steel.

Suitable material for receptacles and pipes: Aluminium.

Suitable material for receptacles and pipes: glass.

Store only in the original receptacle.

· Information about storage in one common storage facility:

Store away from combustible materials.

Store away from reducing agents.

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 Bleaching Gel

8 Exposure controls/personal protection

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

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· Control parameters

· Comp	· Components with limit values that require monitoring at the workplace:		
56-81	56-81-5 Glycerine		
PEL	Long-term value: 15* 5** mg/m³ mist; *total dust **respirable fraction		
TLV	TLV withdrawn-insufficient data human occup. exp.		
TWA	Short-term value: 15 mg/m³		
7722-	7722-84-1 Hydrogen Peroxide		
PEL	PEL Long-term value: 1.4 mg/m³, 1 ppm		
REL	Long-term value: 1.4 mg/m³, 1 ppm		
TLV	Long-term value: 1.4 mg/m³, 1 ppm		
1310-	1310-58-3 Potassium Hydroxide		
REL	Ceiling limit value: 2 mg/m ³		
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.

· 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.

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Safety Data Sheet acc. to OSHA HCS

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· Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

Dhysical and chamical manage	ation
Physical and chemical proper	nes — — — — — — — — — — — — — — — — — — —
Information on basic physical and c	chemical properties
General Information	
Appearance: Form:	Gel
Form: Color:	Gei Light Orange to Pink
Odor:	Odorless
Odor threshold:	Not determined.
pH-value at 20 °C:	6.5-8.5
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined
Flash point:	Not applicable
Flammability (solid, gaseous):	Not applicable.
Decomposition temperature:	Not determined.
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not determined.
Density at 20 °C:	1.24 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/wate	e r): Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined
Solvent content:	
Organic solvents:	<50 %
VOC content:	
Water: VOC content:	<80 % 0.00 % 0.0 g/l / 0.00 lb/gal

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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: 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

Combustible Materials

Reducing Agents

Alkalis

Organic materials

· Hazardous decomposition products: Oxygen

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:

		re relevant for classification:	
AIE (Acu	te Toxicity I	<u> </u>	
Oral	LD50	3,181 mg/kg	
Dermal	LD50	>37,594 mg/kg (rabbit)	
Inhalative	LC50/4 h	>0.498 mg/l	
56-81-5 G	lycerine		
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)	
Inhalative	LC50/4 h	>0.1425 mg/l (rat)	
7722-84-1	Hydrogen I	Peroxide	
Oral	LC50 Fish	16.4 mg/l (Fish)	
1310-58-3	Potassium	Hydroxide	
Oral	LD50	214 mg/kg (rat)	

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LC50 Fish 80 mg/l (Fish)

- Primary irritant effect:
- · on the skin: No irritant effect.
- on the eye: 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 Irritant

· Carcinogenic categories

3
3

12 Ecological information

- · Toxicity
- · Aquatic toxicity:

56-81-5 Glycerine

EC50 >10,000 mg/l (Bacteria)

>10,000 mg/l (daphnia)

7722-84-1 Hydrogen Peroxide

EC50 1.38 mg/l (Algae)

2.4 mg/l (daphnia)

- · Persistence and degradability No further relevant information available.
- · Behavior 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 (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: Do not allow product to reach sewage system.

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

UN-Number	TD100.64
DOT, IMDG, IATA	UN3264
UN proper shipping name	Corrosive liquid, acidic, inorganic, n.o.s (Hydrogen peroxide stabilized)
DOT	Corrosive liquid, acidic, inorganic, n.o.s. (Hydrogen peroxide stabilized)
IMDG	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (HYDROGE. PEROXIDE, STABILIZED)
LATA	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (HYDROGE. PEROXIDE, STABILIZE)
Transport hazard class(es)	
DOT	
OGREGISIVE 8	
Class	8 Corrosive substances
Label	8
IMDG, IATA	
Class	8 Corrosive substances
Label	8
Packing group	
DOT, ĬMDG, IATA	II
Environmental hazards:	Not applicable.
Special precautions for user	Warning: Corrosive substances
Danger code (Kemler):	80
EMS Number:	F- A , S - B
Segregation groups	Acids
Stowage Category	B
Stowage Code	SW2 Clear of living quarters.

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· Transport/Additional information:	
\cdot DOT	
· Quantity limitations	On passenger aircraft/rail: 1 L
	On cargo aircraft only: 30 L
· IMDG	
· Limited quantities (LQ)	IL
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. (HYDROGEN PEROXIDE, AQUEOUS SOLUTION, STABILIZED
	8, II

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Sara
- · Section 355 (extremely hazardous substances):

7722-84-1 Hydrogen Peroxide

Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

All components have the value 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
- · EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

7722-84-1 Hydrogen Peroxide

A3

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

None of the ingredients is listed.

- GHS label elements
- Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).
- · Hazard pictograms GHS05, GHS07

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· Signal word Danger

· Hazard-determining components of labeling:

Hydrogen Peroxide

· Hazard statements

Harmful if swallowed or if inhaled.

Causes serious eye damage.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

Wash thoroughly after handling.

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

Use only outdoors or in a well-ventilated area.

Wear eye protection / face protection.

If on skin: Wash with plenty of water.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a poison center/doctor.

If skin irritation occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

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

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: Regulatory Affairs
- · Contact: Customer Service
- · Date of preparation / last revision 09/30/2019 / -
- · Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Tox. 4: Acute toxicity - Category 4

Eye Dam. 1: Serious eye damage/eye irritation - Category 1