

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/30/2019

Reviewed on 02/28/2019

1 Identification

- **Product identifier**
- **Trade name:** Opalescence™ Boost 35% Non-PF (Activator)
- **Article number:** 1005861
- **Index number:** SDS 389-001.02
- **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

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

Eye Dam. 1 H318 Causes serious eye damage.

- **Label elements**
- **GHS label elements**
Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS05
- **Signal word** Danger

- **Hazard-determining components of labeling:**

Potassium Hydroxide

- **Hazard statements**

Causes severe skin burns and eye damage.

- **Precautionary statements**

Do not breathe dusts or mists.

Wash thoroughly after handling.

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

If swallowed: Rinse mouth. Do NOT induce vomiting.

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

Store locked up.

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

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· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



· **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	>50-≤100%
1310-58-3	Potassium Hydroxide	<5%
9003-01-4	Polyacrylic Acid	≤2.5%

4 First-aid measures

· **Description of first aid measures**

· **General information:** Immediately remove any clothing soiled by the product.

· **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.

· **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 mist

Water fog

Water spray

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Foam, dry chemical, carbon dioxide

Use fire fighting measures that suit the environment.

· **Special hazards arising from the substance or mixture**

During heating or in case of fire poisonous gases are produced.

· **Advice for firefighters**

· **Protective equipment:**

Wear fully protective suit.

Mouth respiratory protective device.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**

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:**

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**

· **PAC-1:**

56-81-5	Glycerine	45 mg/m ³
1310-58-3	Potassium Hydroxide	0.18 mg/m ³

· **PAC-2:**

56-81-5	Glycerine	180 mg/m ³
1310-58-3	Potassium Hydroxide	2 mg/m ³

· **PAC-3:**

56-81-5	Glycerine	1,100 mg/m ³
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:**

Protect from heat.

Keep respiratory protective device available.

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- **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:**
Do not store together with acids.
Store away from flammable substances.
- **Further information about storage conditions:**
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.
- **Control parameters**

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

56-81-5 Glycerine

PEL	Long-term value: 15* 5** mg/m ³ mist; *total dust **respirable fraction
TLV	TLV withdrawn-insufficient data human occup. exp.
TWA	Short-term value: 15 mg/m ³

1310-58-3 Potassium Hydroxide

REL	Ceiling limit value: 2 mg/m ³
TLV	Ceiling limit value: 2 mg/m ³

9003-01-4 Polyacrylic Acid

TWA	Short-term value: 0.05 mg/m ³
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- **Additional information:** The lists that were valid during the creation 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.
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

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· **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:**



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
Color:	Orange to Dark Red
Odor:	Odorless
Odor threshold:	Not determined.

· **pH-value at 20 °C:** >12

· **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:	1.3 g/cm ³
Relative density	Not determined
Vapor 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.

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Kinematic:	Not determined
· Solvent content:	
Organic solvents:	<99 %
VOC content:	0.00 %
	0.0 g/l / 0.00 lb/gal
· 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.
- **Conditions to avoid** Heat
- **Incompatible materials:**
 - Organic materials
 - Acids
 - Metals
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:		
ATE (Acute Toxicity Estimate)		
Oral	LD50	2,692 mg/kg
Inhalative	LC50/4 h	>0.15 mg/l (rat)
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	LC50 Fish	>5,000 mg/l (Fish)
	LD50	>21,900 mg/kg (rat)
Inhalative	LC50/4 h	10,000 mg/kg (rabbit)
		>0.1425 mg/l (rat)
1310-58-3 Potassium Hydroxide		
Oral	LD50	214 mg/kg (rat)
	LC50 Fish	80 mg/l (Fish)
9003-01-4 Polyacrylic Acid		
Oral	LC50 Fish	580 mg/l (Fish)

- **Primary irritant effect:**
 - **on the skin:** Strong caustic effect on skin and mucous membranes.
 - **on the eye:** Strong caustic effect.

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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:

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 (International Agency for Research on Cancer)**

9003-01-4	Polyacrylic Acid	3
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· **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:**

56-81-5 Glycerine

EC50	>10,000 mg/l (Bacteria)
	>10,000 mg/l (daphnia)

9003-01-4 Polyacrylic Acid

EC50	174 mg/kg (daphnia)
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· **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.

Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

· **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.

14 Transport information

<ul style="list-style-type: none"> · UN-Number · DOT, IMDG, IATA 	<p style="text-align: right;">UN1814</p>
<ul style="list-style-type: none"> · UN proper shipping name · DOT · IMDG, IATA 	<p style="text-align: right;">Potassium hydroxide, solution mixture POTASSIUM HYDROXIDE SOLUTION mixture</p>
<ul style="list-style-type: none"> · Transport hazard class(es) · DOT 	<div style="text-align: center;">  <p>CORROSIVE</p> </div> <p style="text-align: right;">8 Corrosive substances</p>
<ul style="list-style-type: none"> · Class · Label 	<p style="text-align: right;">8</p>
<ul style="list-style-type: none"> · IMDG, IATA 	<div style="text-align: center;">  <p>CORROSIVE</p> </div> <p style="text-align: right;">8 Corrosive substances</p>
<ul style="list-style-type: none"> · Class · Label 	<p style="text-align: right;">8</p>
<ul style="list-style-type: none"> · Packing group · DOT, IMDG, IATA 	<p style="text-align: right;">II</p>
<ul style="list-style-type: none"> · Environmental hazards: 	<p style="text-align: right;">Not applicable.</p>
<ul style="list-style-type: none"> · Special precautions for user · Danger code (Kemler): · EMS Number: · Segregation groups · Stowage Category · Segregation Code 	<p style="text-align: right;">Warning: Corrosive substances 80 F-A,S-B Alkalis A SG35 Stow "separated from" SGG1-acids</p>
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code 	<p style="text-align: right;">Not applicable.</p>
<ul style="list-style-type: none"> · Transport/Additional information: · DOT · Quantity limitations 	<p style="text-align: right;">On passenger aircraft/rail: 1 L On cargo aircraft only: 30 L</p>
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p style="text-align: right;">1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml</p>

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· **UN "Model Regulation":** UN 1814 POTASSIUM HYDROXIDE SOLUTION MIXTURE, 8, II

15 Regulatory information

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

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **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)**

None of the ingredients is listed.

· **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**

· **Signal word Danger**

· **Hazard-determining components of labeling:**

Potassium Hydroxide

· **Hazard statements**

Causes severe skin burns and eye damage.

· **Precautionary statements**

Do not breathe dusts or mists.

Wash thoroughly after handling.

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

If swallowed: Rinse mouth. Do NOT induce vomiting.

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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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.
Specific treatment (see on this label).
Wash contaminated clothing before reuse.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.
 · **Chemical safety assessment:** A chemical safety assessment has not been carried out.

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
 Skin Corr. 1A: Skin corrosion/irritation – Category 1A
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1