Safety Data Sheet
according to WHS Regulations

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*

1 Identification

· **Other means of identification**

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

· **Article number:** SDS 389-001.03R01, 1005861, 13651
· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **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

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) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification

· **Classification of the substance or mixture**

corrosion

Skin corrosion/irritation – Category 1A H314 Causes severe skin burns and eye damage.
Eye damage/irritation – Category 1 H318 Causes serious eye damage.

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** GHS05
· **Signal word** Danger

· **Hazard-determining components of labelling:**
Potassium Hydroxide (<5 %)
· **Hazard statements**
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.
P260 Do not breathe dusts or mists.

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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:**

56-81-5	Glycerin Eye damage/irritation – Category 2A, H319	>50-≤100%
1310-58-3	Potassium Hydroxide Skin corrosion/irritation – Category 1A, H314; Acute toxicity - oral – Category 4, H302	<5%

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

4 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.
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:** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing:**
Do not induce vomiting; call for medical help 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 mist
Water fog
Water spray
Foam, dry chemical, carbon dioxide
Use fire extinguishing methods suitable to surrounding conditions.
· **Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.

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· **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 neutralising agent.
Dispose contaminated material as waste according to section 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:** Keep respiratory protective device available.
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Store away from flammable substances.
· **Further information about storage conditions:**
See product labelling.
Keep container tightly sealed.
· **Specific end use(s)** Professional Dental Bleaching Gel

8 Exposure controls and personal protection

· **Appropriate engineering controls** No further data; see section 7.

· **Ingredients with limit values that require monitoring at the workplace:**	
56-81-5 Glycerin	
TWA	Short-term value: 10 mg/m³
WES	Long-term value: 10 mg/m³ inhalable dust
1310-58-3 Potassium Hydroxide	
WES	Peak limitation: 2 mg/m³

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

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· **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.
· **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:**

Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and Chemical Properties

· **General Information**	
· **Appearance:**	
· **Form:**	Gel
· **Colour:**	Orange to Dark Red
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value at 20 °C:**	>12
· **Change in condition**	
· **Melting point/freezing point:**	Undetermined.
· **Initial boiling point and boiling range:**	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product does not present an explosion hazard.

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· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density at 20 °C:**	1.3 g/cm³
· **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**	
· **Particle characteristics**	Not applicable.
· **Physical state**	Fluid

10 Stability and Reactivity

· **Reactivity** No further relevant information available.
· **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** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**		
ATE (Acute Toxicity Estimates)		
Oral	LD50	7,133 mg/kg (rat)

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	>5,000 mg/l (Fish)
Dermal	LD50	>21,900 mg/kg (rat)
		10,000 mg/kg (rabbit)
1310-58-3 Potassium Hydroxide		
Oral	LD50	214 mg/kg (rat)

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	LC50 Fish	80 mg/l (Fish)

· **Primary irritant effect:**
· **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.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological Information

· **Toxicity**

· **Aquatic toxicity:**	
56-81-5 Glycerin	
EC50	>10,000 mg/kg (Bacteria)

· **Persistence and degradability** No further relevant information available.
· **Behaviour 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 (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.
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.
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.

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14 Transport information

· **UN-Number**	
· **ADG, IMDG, IATA**	UN1814
· **UN proper shipping name**	
· **ADG**	1814 POTASSIUM HYDROXIDE SOLUTION
· **IMDG, IATA**	POTASSIUM HYDROXIDE SOLUTION
· **Transport hazard class(es)**	
· **ADG, IMDG, IATA**	

· **Class**	8 Corrosive substances.
· **Label**	8
· **Packing group**	
· **ADG, IMDG, IATA**	II
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Warning: Corrosive substances.
· **Hazard identification number (Kemler code):**	80
· **EMS Number:**	F-A,S-B
· **Segregation groups**	(SGG18) Alkalis
· **Stowage Category**	A
· **Segregation Code**	SG35 Stow "separated from" SGG1-acids
· **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
· **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 1814 POTASSIUM HYDROXIDE SOLUTION, 8, II

15 Regulatory information

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

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

None of the ingredients is listed.

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· **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

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

1310-58-3	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.
· **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.

· **Relevant phrases from Section 3**
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H319 Causes serious eye irritation.

· **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
NIOSH: National Institute for Occupational Safety
Acute toxicity - oral – Category 4: Acute toxicity – Category 4
Skin corrosion/irritation – Category 1A: Skin corrosion/irritation – Category 1A
Eye damage/irritation – Category 1: Serious eye damage/eye irritation – Category 1
Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
· *** Data compared to the previous version altered.**