Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 12.06.2024 Version number 1 Revision: 12.06.2024

*
1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· **Trade name: Opalescence™ Boost Activator Gel**

· **Article number:** SDS 196-001.10R01, 71087, 14094, 14241
· **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Tooth Whitening Activator
· **Application of the substance / the mixture** Professional Dental Tooth Whitening Activator

· **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
EC Responsible Person
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Emergency Phone: +49(0)2203-35-92-0

· **Further information obtainable from:** Customer Service
· **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) :(800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

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2 Hazards identification

· **Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**


flame over circle

Ox. Liq. 2 H272 May intensify fire; oxidiser.


corrosion

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

Acute Tox. 4 H302 Harmful if swallowed.
Acute Tox. 4 H332 Harmful if inhaled.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void

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· **Hazard pictograms** GHS03, GHS05, GHS07
· **Signal word** Danger

· **Hazard-determining components of labelling:**
Potassium Hydroxide
Sodium Fluoride
· **Hazard statements**
H272 May intensify fire; oxidiser.
H302+H332 Harmful if swallowed or if inhaled.
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 carefully and follow all instructions.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or 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.

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3 Composition/information on ingredients

· **Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**		
CAS: 56-81-5 EINECS: 200-289-5	Glycerin substance with a Community workplace exposure limit	>40-<60%
CAS: 7757-79-1 EINECS: 231-818-8	Potassium Nitrate Ox. Sol. 2, H272; Skin Irrit. 2, H315; STOT SE 3, H335-H336	>10-<30%
	Potassium Hydroxide Skin Corr. 1A, H314; Acute Tox. 4, H302 Specific concentration limits: Skin Corr. 1A; H314: C ≥ 5 % Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0.5 % ≤ C < 2 % Eye Irrit. 2; H319: 0.5 % ≤ C < 2 %	>10->20%
CAS: 7681-49-4 EINECS: 231-667-8	Sodium Fluoride Acute Tox. 3, H301; Acute Tox. 2, H310; Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032	>1-<10%
	Dimethicone Repr. 2, H361f; STOT RE 2, H373	<1%

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

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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.
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 a doctor immediately.
Drink plenty of water and provide fresh air. Call for a doctor immediately.
· **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.

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5 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
Water mist
Foam, dry chemical, carbon dioxide
Water fog
Water spray
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.
· **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 neutralising agent.
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.

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· ***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

· ***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.*

· ***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:***
Store away from flammable substances.
Do not store together with acids.
· ***Further information about storage conditions:***
See product labelling.
Keep container tightly sealed.
· ***Specific end use(s)*** *Professional Dental Tooth Whitening Activator*

8 Exposure controls/personal protection

· ***Control parameters***

· ***Ingredients with limit values that require monitoring at the workplace:***	
56-81-5 Glycerin	
WEL	*Long-term value: 10 mg/m³*
Potassium Hydroxide	
WEL	*Short-term value: 2 mg/m³*

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

· ***Exposure controls***
· ***Appropriate engineering controls*** *No further data; see item 7.*
· ***Individual protection measures, such as 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 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.
· ***Hand protection***

Protective gloves

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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/face protection**

Tightly sealed goggles

· **Body protection:** *Protective work clothing*

*
9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	*Fluid*
· **Colour:**	*Orange to Dark Red*
· **Odour:**	*Odourless*
· **Odour threshold:**	*Not determined.*
· **Melting point/freezing point:**	*Undetermined.*
· **Boiling point or initial boiling point and boiling range**	*Undetermined.*
· **Flammability**	*Not applicable.*
· **Lower and upper explosion limit**	
· **Lower:**	*Not determined.*
· **Upper:**	*Not determined.*
· **Flash point:**	*Not applicable.*
· **Decomposition temperature:**	*Not determined.*
· **pH at 20 °C**	*>12*
· **Viscosity:**	
· **Kinematic viscosity**	*Not determined.*
· **Dynamic:**	*Not determined.*
· **Solubility**	
· **water:**	*Fully miscible.*
· **Partition coefficient n-octanol/water (log value)**	*Not determined.*
· **Vapour pressure:**	*Not determined.*
· **Density and/or relative density**	
· **Density at 20 °C:**	*1.37 g/cm³*
· **Relative density**	*Not determined.*
· **Vapour density**	*Not determined.*

· **Other information**	
· **Appearance:**	
· **Form:**	*Gel*

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· **Important information on protection of health and environment, and on safety.**	
· **Auto-ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Change in condition**	
· **Evaporation rate**	Not determined.

· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Void
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	May intensify fire; oxidiser.
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	Void

*
10 Stability and reactivity

· **Reactivity** Stable
· **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
Moisture
· **Incompatible materials:**
Organic materials
Metals
Acids
· **Hazardous decomposition products:** No dangerous decomposition products known.

*
11 Toxicological information

· **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Harmful if swallowed or if inhaled.

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

ATE (Acute Toxicity Estimates)

Oral	LD50	428 mg/kg
Dermal	LD50	2,059 mg/kg (rat)

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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)
7757-79-1 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)*
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.*
· ***Information on other hazards***

· ***Endocrine disrupting properties***
None of the ingredients is listed.

*
12 Ecological information

· ***Toxicity***

· ***Aquatic toxicity:***	
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.*
· ***Bioaccumulative potential*** *No further relevant information available.*
· ***Mobility in soil*** *No further relevant information available.*
· ***Results of PBT and vPvB assessment***
· ***PBT:*** *Not applicable.*
· ***vPvB:*** *Not applicable.*
· ***Endocrine disrupting properties*** *The product does not contain substances with endocrine disrupting properties.*

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· ***Other adverse effects***
· ***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.

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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 or ID number***
· ***ADR, IMDG, IATA*** *UN3093*

· ***UN proper shipping name***
· ***ADR*** *3093 CORROSIVE LIQUID, OXIDIZING, N.O.S. (POTASSIUM HYDROXIDE)*
· ***IMDG, IATA*** *CORROSIVE LIQUID, OXIDIZING, N.O.S. (POTASSIUM HYDROXIDE)*

· ***Transport hazard class(es)***

· ***ADR***

· ***Class*** *8 Corrosive substances.*
· ***Label*** *8+5.1*

· ***IMDG***

· ***Class*** *8 Corrosive substances.*
· ***Label*** *8/5.1*

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· ***IATA***

· ***Class***	*8 Corrosive substances.*
· ***Label***	*8 (5.1)*
· ***Packing group***	
· ***ADR, 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*
· ***Segregation groups***	*(SGG18) Alkalis*
· ***Stowage Category***	*E*
· ***Maritime transport in bulk according to IMO instruments***	*Not applicable.*
· ***Transport/Additional information:***	
· ***ADR***	
· ***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 3093 CORROSIVE LIQUID, OXIDIZING, N.O.S. (POTASSIUM HYDROXIDE), 8 (5.1), 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.

· ***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*

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· ***Chemical safety assessment:***
Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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***
H272 May intensify fire; oxidiser.
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.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H361f Suspected of damaging fertility.
H373 May cause damage to organs through prolonged or repeated exposure.
EUH032 Contact with acids liberates very toxic gas.

· ***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
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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
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 Irrit. 2: Serious eye damage/eye irritation – Category 2
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
· **** Data compared to the previous version altered.***